CHEMICAL SAFETY REPORT

Non-Confidential Version

Legal name of applicants:	*PPG Industries (UK) Ltd.*
Submitted by:	*PPG Industries (UK) Ltd.*
Substance:	*4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated*
Use title:	*Use 1: The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants for use by Airbus and their associated supply chains*
	Use 2: Mixing, by Airbus and their associated supply chains, including the Applicant, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing < 0.1% w/w of OPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a)
Use number:	*1 and 2*

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DECLARATION

The Applicant is aware of the fact that further evidence might be requested by UK Competent Authority to support the information provided in this document.

Also, we request that the information blanked out in the "public version" of the Chemical Safety Report is not disclosed. We hereby declare that, to the best of our knowledge as of today 28th June 2023 the information is not publicly available, and, in accordance with the due measures of protection that we have implemented, a member of the public should not be able to obtain access to this information without our consent or that of the third party whose commercial interests are at stake.

Signature: Date, Place:

Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

The risk management measures are described in the Exposure Scenarios in Section 9 of Part B of this document.

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

We declare that the risk management measures referred to in section 9 are implemented.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

We declare that the risk management measures referred to in Section 9 are communicated to our customers, when they are relevant for their uses.

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

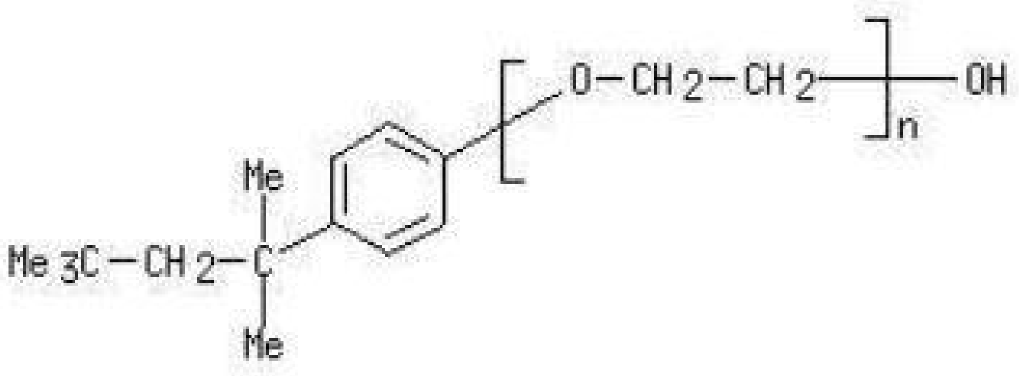
1.1. Name and other identifiers of the substance

Type of substance 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]: multiple substances [organic (origin)]. The characteristics and physical–chemical properties are described below (see the IUCLID dataset for further details).

Table 1. Substance identity

IUPAC name:	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]
Molecular formula:	(C2H4O)n C14H22O

Structural formula:



1.2. Composition of the substance

Table 2. Overall information on composition

Composition	Related composition(s)
4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [per Annex XIV entry) (legal entity composition of the substance)	

Name: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [per Annex XIV entry)

Table 3. Constituents (4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [per Annex XIV entry))

Constituent	Typical concentration	Concentration range	Remarks
4-(1,1,3,3-	100 % (w/w)	ca.100 % (w/w)	

tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues] EC no.:			

Characterisation of polymers

Reactive functional groups

Polymer contains only low concern reactive functional groups

1.3. Physicochemical properties

Table 4. Physicochemical properties

Property	Value used for CSA / Discussion	Description of key information
Appearance	Liquid	
Water solubility	Miscible with water	
Melting point/freezing point	6°C	
Boiling point	>200°C	
Flash point	251°C	
Relative density	1.07	

2. MANUFACTURE AND USES

2.1. Manufacture

No information available on manufacture.

2.2. Identified uses

Table 5. Formulation and Repackaging

	Formulation and Repackaging
F-1	**The formulation of the hardener component containing OPE within Aerospace (A&D) two-part polysulfide sealants to be used by Airbus and their associated supply chains.** Further description of the use: Contributing activity/technique for the environment: **- ERC2: Formulation and Repackaging into mixture** Contributing activity/technique for the workers: Tonnage of substance for that use: tonnes/year Substance supplied to that use: Related assessment:

Table 6. Uses at industrial sites

	Uses at industrial sites
IW-2	**Mixing, by Airbus and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing <0.1% w/w of OPE for aerospace and defence uses that are exempt from authorisation under REACH Art. 56(6)(a).** Further description of the use: Contributing activity/technique for the environment: **- ERC6b: Use of reactive processing aid at industrial site (no inclusion into or onto article)** Contributing activity/technique for the workers: Tonnage of substance for that use: tonnes/year Substance supplied to that use:

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

No relevant information available.

4. ENVIRONMENTAL FATE PROPERTIES

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

No relevant information available.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available.

4.1.1.2.2. Phototransformation in water

No relevant information available.

4.1.1.2.3. Phototransformation in soil

No relevant information available.

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

No relevant information available.

4.1.2.1.2. Simulation tests (water and sediments)

No relevant information available.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

No relevant information available.

4.1.2.2. Biodegradation in soil

No relevant information available.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

No relevant information available.

4.2.2. Volatilisation

No relevant information available.

4.2.3. Distribution modelling

No relevant information available.

4.3. Bioaccumulation

4.3.1. Aquatic bioaccumulation

No relevant information available.

4.3.2. Terrestrial bioaccumulation

No relevant information available.

4.3.3. Summary and discussion of bioaccumulation

No relevant information available.

4.4. Secondary poisoning

The hazard assessment conclusion for secondary poisoning (PNECoral) is 2.36 mg/kg food (see CSR chapter 7.5 “PNEC derivation and other hazard conclusions”).

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

No relevant information available.

5.1.2. Human information

No relevant information available.

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

No relevant information available.

5.2.1.2. Acute toxicity: inhalation

No relevant information available.

5.2.1.3. Acute toxicity: dermal

No relevant information available.

5.2.1.4. Acute toxicity: other routes

No relevant information available.

5.2.2. Human information

No relevant information available.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

No relevant information available.

5.3.1.2. Human information

No relevant information available.

5.3.2. Eye

5.3.2.1. Non-human information

No relevant information available.

5.3.2.2. Human information

No relevant information available.

5.3.3. Respiratory tract

5.3.3.1. Non-human information

No relevant information available

5.3.3.2. Human information

No relevant information available.

5.4. Corrosivity

5.4.1. Non-human information

No relevant information available.

5.4.2. Human information

No relevant information available.

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

No relevant information available.

5.5.1.2. Human information

No relevant information available.

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available.

5.5.2.2. Human information

No relevant information available.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

No relevant information available.

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available.

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available.

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available.

5.6.2. Human information

No relevant information available.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

No relevant information available.

5.7.1.2. In vivo data

No relevant information available.

5.7.2. Human information

No relevant information available.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available.

5.8.1.2. Carcinogenicity: inhalation

No relevant information available.

5.8.1.3. Carcinogenicity: dermal

No relevant information available.

5.8.1.4. Carcinogenicity: other routes

No relevant information available.

5.8.2. Human information

No relevant information available.

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

No relevant information available.

5.9.1.2. Human information

No relevant information available.

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

No relevant information available.

5.9.2.2. Human information

No relevant information available.

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available.

5.10.1.2. Immunotoxicity

No relevant information available.

5.10.1.3. Specific investigations: other studies

No relevant information available.

5.10.1.4. Additional toxicological effects

No relevant information available.

5.10.2. Human information

No relevant information available.

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

No relevant information available.

5.11.2. Selection of the DNEL(s) or other hazard conclusions for critical health effects

No relevant information available.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

No relevant information available.

6.2. Flammability

Flammability

No relevant information available.

Flash Point

No relevant information available.

6.3. Oxidising potential

No relevant information available.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

Additional information:
The read-across justification was provided in a separate report in Section 13 of the CSR within the original AfA. No information provided within the justification document has changed and as per the original AfA the read across justification is summarised below.

Read-Across
A read-across approach was used to meet minimum data requirements (>10 families of aquatic organisms) to calculate predicted no effect concentrations (PNECaquatic) using species sensitivity distribution; a statistical rather than an assessment factor approach. It has been determined according to this information that read-across from nonylphenol to octylphenol for toxicity to aquatic organisms can be used for four reasons; (i) the two substances are considered analogue substances, (ii) the toxicities of the substances are similar, (iii) the information is reliable, and (iv) the substances tested were without impurities.

Structure
A structural analogue is a source chemical whose physico-chemical and toxicological properties are likely to be similar to the target chemical, as a result of structural similarity. The structural similarity and similar properties between octylphenol and nonylphenol support consideration of these substances as structural analogues for the purpose of read-across. Thus, endpoint information is read-across between structural analogues.

The similarity between octyl- and nonylphenol is based on their structural likeness (→similar chain length: eight and nine C-atoms for octylphenol and nonylphenol, respectively) and their common functional group (→phenol group). Octylphenol and nonylphenol display very similar physico-chemical properties that determine environmental distribution and fate (e.g. molecular weight, partition coefficients such as log Kow, water solubility) and ecotoxic effects.

Toxicity
The aquatic toxicity of the two substances is comparable as summarised in the table below:

A comparison of ecotoxicity data for the same aquatic species (where available) exposed to octylphenol and nonylphenol		
Species and Type of Test	**Nonylphenol toxicity range (mg/L)**	**Octylphenol toxicity range (mg/L)**
Ceriodaphnia sp. 48 hr L(E)C50	0.02 to 0.47	0.07 to 0.28
Americamysis bahia 96 hr LC50	0.043 to 0.06	0.048 to 0.113
Oncorhynchus mykiss 96 hr LC50	0.11 to 0.22	>0.1
Fundulus heteroclitus 96 hr LC50	0.26 to 5.44	0.29 to 3.86
Selenastrum capricornutum 96hr EC50	0.41	1.9
Scenedesmus obliquus 120 hr NOEC	2	2
Daphnia magna 21-d NOEC	0.013 to 0.12	0.03
Fish NOEC	>0.0019 to 0.078	0.012 to 0.035
Microcystis aeruginosa 973 14 d NOEC	0.2	0.45

Oocystis parva 14 d NOEC	0.6	1.25
Microcystis aeruginosa 972 14 d NOEC	0.2	0.5

The data for both short- and long-term toxicity for each type of organism in the table above are within the same orders of magnitude with comparable ranges of toxicity when a like-for-like comparison is made. The short-term toxicity of these alkylphenols for other aquatic freshwater and saltwater invertebrates and fish species (used in the CSR but not presented in the table above) are also in agreement with each other when similar toxicity endpoints are compared. For example, exposure to nonylphenol resulted in similar LC50 concentrations of 0.31 and 1.72 mg/L for the fish species *Cyprinodon variegates* and *Puntius conchonius*. Fish data relating to octylphenol exposure resulted in toxicities of >0.1 and 0.26 mg/L for *Oncorhynchus mykiss* and *Leuciscus idus melanotus*, respectively. Long-term data for different species and similar endpoints are also in agreement. Based on this evidence, it can be stated that octylphenol and nonylphenol have similar degrees of toxicity to the aquatic organisms for which there are reliable data. Therefore, the reliable nonylphenol (source chemical) aquatic toxicity data can be used to fill the data gaps for octylphenol (target chemical) aquatic toxicity in accordance with ECHA guidance set out in Read-Across Assessment Framework (ECHA, 2017).

Reliability, Adequacy and Accuracy of the Source Studies
All of the ecotoxicity studies used in the CSR were carried out in accordance with OECD or similar guidelines and scored a Klimisch 1 or 2. In particular, the studies represented in the table above showed consistent results indicating that octylphenol is ecotoxic to aquatic organisms. These studies are considered to be reliable for use in read-across between nonylphenol and octylphenol.

Evaluation of the purity and impurity profiles of the Test Substance
The purity of octylphenol used in the key studies for ecotoxicological endpoints ranged from 98.97 to 100%. The purity of nonylphenol used in key studies was 85 to 100%, with all but one study being ≥90% purity. Impurities were not reported in these ecotoxicity studies evaluated for the CSR. Because of the high purity of the test substance, impurities probably do have a negligible or no impact on the ecotoxicity of PTOP.

In summary, octylphenol and nonylphenol are similar in structural composition and both exert similar short- and long-term toxic effects to aquatic organisms. The studies used to make these comparisons are highly reliable (Klimisch 1 or 2) and the octylphenol and nonylphenol test substance in toxicity studies were of high purity. Therefore, it is considered scientifically valid for toxicity data relating to nonylphenol studies to be read-across to octylphenol endpoints and used in PNECaquatic derivation.

Discussion
A review of the toxicity test results for exposure of aquatic organisms resulted in reliable data from studies that included freshwater species and saltwater species, representing fish, invertebrates, algae, and a snail. Short-term (acute) exposures of octylphenol to freshwater and marine invertebrates ranged from 0.013 to 0.28 mg octylphenol/L and suggested the freshwater test organism (*Gammarus pulex*) may be more sensitive to effects on immobility and survival than the marine organism tested (*Mysidopsis bahia*). Long-term octylphenol exposure tests indicated a NOEC on inhibition of reproduction on the preferred invertebrate test species, *Daphnia magna*, to be 0.03 mg octylphenol/L. Fish species were generally found to be less sensitive to short-term octylphenol exposure than invertebrate organisms. Short-term survival LC50 values were >0.1 mg octylphenol/L for both fresh and saltwater test species. However, effects on reproduction and survival from long-term octylphenol exposure to freshwater were at equivalent concentration to that reported for invertebrates. Other organisms tested included short-term and long-term octylphenol exposure to algae (*Pseudokirchneriella subcapitata* and *M. aeruginosa 973*), short-term exposure to a mixed culture of microorganisms from activated sludge and long-term exposure to other aquatic vertebrates (*Xenopus leavis*), which were markedly less sensitive to toxic effects of octylphenol than all other species tested.

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

The results are summarised in the following table:

Table 7. Short-term effects on fish

Method	**Results**	**Remarks**
Leuciscus idus melanotus freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96h): 0.26 mg/L test mat. based on: mortality LC0 (96h): 0.21 mg/L test mat. based on: mortality LC100 (96h): 0.39 mg/L test mat. based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** 1,1,3,3-Tetramethylbutylphenol; 2-(1,1,3,3-tetramethylbutyl)phenol / 27193-28-8 / 248-310-7, (full information in **Annex II**). **Reference** **Scholz N 1993**
Pimephales promelas freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96h): ca.0.25 mg/L test mat. (meas. (arithm. mean)) based on: mortality (95 % confidence interval) NOEC (96h): ca.0.077 mg/L test mat. (meas. (arithm. mean)) based on: mortality (95 % confidence interval)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2, Form: solid: particulate/powder - migrated information: powder (full information in **Annex II**). **Reference** **Forbis, A. 1984**
Fundulus heteroclitus saltwater short-term toxicity to fish no guideline followed	LC50 (48h): 2.16 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.29) LC50 (96h): 1.42 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.20)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-tert-octylphenol, (full information in **Annex II**). **Reference** **Kelly SA & Di Giulio RT 2000**
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater	LC50 (96h): >0.1 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study

short-term toxicity to fish equivalent or similar to OECD Guideline 203 (Fish, Acute Toxicity Test)		experimental study **Test material** 4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2, (full information in **Annex II**). **Reference** **I. G. Sewell 1991**
Pimephales promelas freshwater short-term toxicity to fish according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians not applicable	LC50 (96h): 128 µg/L test mat. (meas. (not specified)) based on: mortality EC50 (96h): 96 µg/L test mat. (meas. (not specified)) based on: % organisms exhibiting loss of equilibrium + % organisms immobilized + % organisms killed	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Pimephales promelas freshwater short-term toxicity to fish	LC50 (96h): 128 µg/L test mat. (meas. (not specified)) based on: mortality EC50 (96h): 96 µg/L test mat. (meas. (not specified)) based on: % organisms exhibiting loss of equilibrium + % organisms immobilized + % organisms killed	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: see read-across justification in original AfA		
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater short-term toxicity to fish according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and	LC50 (96h): 221 µg/L test mat. (meas. (not specified)) based on: mortality EC50 (96h): 109 µg/L test mat. (meas. (not specified)) based on: % organisms exhibiting loss of equilibrium + % organisms immobilized + % organisms killed	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical

Amphibians not applicable		mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater short-term toxicity to fish	LC50 (96h): 221 µg/L test mat. (meas. (not specified)) based on: mortality EC50 (96h): 109 µg/L test mat. (meas. (not specified)) based on: % organisms exhibiting loss of equilibrium + % organisms immobilized + % organisms killed	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Justification for type of information: See read-across justification in original AfA		
Danio rerio (previous name: *Brachydanio rerio*) freshwater short-term toxicity to fish according to OECD Test No. 212: Fish, Short-term Toxicity Test on Embryo and Sac-Fry Stages not applicable	LC50 (4d): 0.81 mg/L test mat. (nominal) based on: mortality (C.L. 0.77 < * < 0.85) LC50 (8d): 0.29 mg/L test mat. (nominal) based on: mortality (C.L. 0.27 < * < 0.30)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Yoshifumi Horie, Takahiro Yamagishi, Hiroko Takahashi, Youko Shintaku, Taisen Iguchi, Norihisa Tatarazako 2017**
Justification for type of information: not applicable		
Danio rerio (previous name: *Brachydanio rerio*) freshwater	LC50 (4d): 0.81 mg/L test mat. (nominal) based on: mortality (C.L. 0.77 < * < 0.85) LC50 (8d): 0.29 mg/L test mat. (nominal)	2 (reliable with restrictions) supporting study

short-term toxicity to fish	based on: mortality (C.L. 0.27 < * < 0.30)	read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Danio rerio (previous name: *Brachydanio rerio*) freshwater fish embryo acute toxicity (FET) according to OECD Guideline 236 (Fish embryo acute toxicity (FET) test)	LC50 (96h): 1.505 mg/L test mat. (nominal) based on: mortality EC50 (96h): 0.276 mg/L test mat. (nominal) based on: as specified on test system (± 0.09) EC10 (96h): 0.144 mg/L test mat. (nominal) based on: as specified in test system section (± 0.06)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Daniel Stengel, Florian Zindler, Thomas Braunbeck 2017**
Danio rerio (previous name: *Brachydanio rerio*) freshwater fish embryo acute toxicity (FET)	LC50 (96h): 1.505 mg/L test mat. (nominal) based on: mortality EC50 (96h): 0.276 mg/L test mat. (nominal) based on: as specified on test system (± 0.09) EC10 (96h): 0.144 mg/L test mat. (nominal) based on: as specified in test system section (± 0.06)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Lepomis macrochirus freshwater short-term toxicity to fish according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with	LC50 (96h): 209 µg/L test mat. (meas. (not specified)) based on: mortality EC50 (96h): 203 µg/L test mat. (meas. (not specified)) based on: % organisms exhibiting loss of equilibrium + % organisms immobilized + % organisms	1 (reliable without restriction) supporting study experimental study **Test material**

Fishes, Macroinvertebrates, and Amphibians not applicable	killed	Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Lepomis macrochirus freshwater short-term toxicity to fish	LC50 (96h): 209 µg/L test mat. (meas. (not specified)) based on: mortality EC50 (96h): 203 µg/L test mat. (meas. (not specified)) based on: % organisms exhibiting loss of equilibrium + % organisms immobilized + % organisms killed	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		

Discussion

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

The Sasol (1993) study was selected as key study because it was well documented and provided standard survival endpoints for the freshwater test species. In a 96-hr acute toxicity study, Golden Orfe (*Leusiscus idus*) were exposed to octylphenol at measured concentrations of 0 (control, solvent control), 0.3, 0.4, 0.54, 0.83, and 1.42 mg/L under static-renewal conditions. There was a 48% decrease in concentration in test vessels after 24 h, therefore, concentrations used in endpoint calculation were re-calculated to 0.21, 0.29, 0.39, 0.6, and 1.02 mg/L octylphenol. The 96-hr LC50 was > 0.26 mg/L (Sasol, 1993).

Value used for CSA:
LC50 for freshwater fish: 0.26mg/L
LC50 for marine water fish: 0.285mg/L

Additional information:
The study by Forbis (1989) exposed the fathead minnow, *Pimephales promelas*, to octylphenol for 96 hr determining a more sensitive LC50 of 0.25 mg/l. However, Forbis (1989) did not analytically measure octylphenol concentrations during the test and the Sasol (1993) study is considered to be more reliable than Forbis (1989).

A review of toxicity test results with short-term octylphenol exposure to fish resulted in three reliable 96 hr studies that included two freshwater and one saltwater species. Test endpoints were based on survival of exposure and test results were reported as LC50 concentrations. Freshwater fish results included a LC50 of 0.26 mg octylphenol/L for *Leusiscus idus* (Sasol, 1993) and LC50 of >0.1 for *Onchorhynchus mykiss* (Safepharm, 1991). The supporting Safepharm (1991) study provides similar documentation, however it is only a screening study, therefore is not selected as a key study.

Another supporting study, Kelly et al (2000), exposed four different early life stages (embryo, newly hatched, 2-week-old larvae, and 4-week-old larvae) of *Fundulus heteroclitus* to octylphenol and reported a range of LC50 concentrations from 0.28 mg octylphenol/L (2-week-old larvae) to 3.86 mg octylphenol/L (embryo). Kelly et al (2000) results show decreasing sensitivity of life stages for *F. heteroclitus* to be 2-week-old larvae > newly hatches larvae > 4-week-old larvae > embryo. The Kelly et al (2000) study results provide a range of LC50 concentrations for the more sensitive life stages of *F. heteroclitus* in agreement with the findings of the key study by Sasol (1993).

Five additional short-term studies were available using a read-across approach from the structural analogue, nonylphenol, to octylphenol. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR). LC50 (96h) for mortality ranged from 0.12 mg nonylphenol/L for *Pimephales promelas* (Spehar et al, 2010) to 1.5 mg nonylphenol/L for *Danio rerio* (Stengel et al, 2017).

7.1.1.2. Long-term toxicity to fish

The results are summarised in the following table:

Table 8. Long-term effects on fish

Method	Results	Remarks
Oryzias latipes freshwater long-term toxicity to fish, other according to OECD guideline 240 (Medaka extended one generation reproduction test (MEOGRT))	NOEC (16wk): >=1.27 µg/L test mat. (meas. (arithm. mean)) based on: fertilised egg (weeks post fertilisation) NOEC (16wk): >=9.81 µg/L test mat. (meas. (arithm. mean)) based on: length (weeks post fertilisation) NOEC (16wk): >=27.8 µg/L test mat. (meas. (arithm. mean)) based on: weight (weeks post fertilisation) NOEC (16wk): >=2.95 µg/L test mat. (meas. (arithm. mean)) based on: adult mortality (weeks post fertilisation) NOEC (16wk): >=2.95 µg/L test mat. (meas. (arithm. mean)) based on: number of eggs/spawn (weeks post fertilisation)	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Watanabe h, Yoshifumi H, Hitomi T, Masaaki K, Taisen I and Norihisa T 2017**
Oryzias latipes freshwater long-term toxicity to fish, other according to OECD guideline 240 (Medaka extended one generation reproduction test (MEOGRT))	NOEC (16wk): >=1.27 µg/L test mat. (meas. (arithm. mean)) based on: fertilised egg (weeks post fertilisation) NOEC (16wk): >=9.81 µg/L test mat. (meas. (arithm. mean)) based on: length (weeks post fertilisation) NOEC (16wk): >=27.8 µg/L test mat. (meas. (arithm. mean)) based on: weight (weeks post fertilisation) NOEC (16wk): >=2.95 µg/L test mat. (meas. (arithm. mean)) based on: adult mortality (weeks post fertilisation) NOEC (16wk): >=2.95 µg/L test mat. (meas. (arithm. mean)) based on: number of eggs/spawn (weeks post fertilisation)	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Watanabe h, Yoshifumi H, Hitomi T, Masaaki K, Taisen I and Norihisa T 2017**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Danio rerio (previous name: *Brachydanio*	NOEC (42d): >50 µg/L (nominal) based on:	2 (reliable with

rerio) freshwater fish early-life stage toxicity no guideline followed - Principle of test: the aim of this study was to determine the estrogenicity of different alkylphenol isomers *in vitro*, and to analyse possible effects on zebrafish *in vivo* - Short description of test conditions: newly fertilised zebrafish eggs were collected and immediately transferred to Petri dishes (50 eggs per dish) containing embryo water. 1 dpf embryos (250 per experimental group) were moved to an aerated closed circuit 38 L glass tank system and exposed to 50 µg/L of 33-OP and to DMSO at 0.01% (v/v). 25% of water containing the tested compounds was changed every 24 h. In both experiments, the time of hatching was determined by direct observation of each tank. - Parameters analysed / observed: Survival, hatching and histological analysis	mortality (highest concentration tested)	restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **E. Puy-Azurmendi, A. Olivares, A. Vallejo, M. Ortiz-Zarragoitia, B. Piña, O. Zuloaga, M.P. Cajaraville 2014**
Danio rerio (previous name: *Brachydanio rerio*) freshwater fish life cycle toxicity according to OECD Guideline 210 (Fish, Early-Life Stage Toxicity Test)	NOEC (151d): 0.012 mg/L test mat. (meas. (arithm. mean)) based on: reproduction NOEC (78d): 0.012 mg/L test mat. (meas. (arithm. mean)) based on: growth rate - F1 generation NOEC (38d): >0.035 mg/L test mat. (meas. (arithm. mean)) based on: mortality - F1 generation	1 (reliable without restriction) supporting study experimental study **Test material** 4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2; p-tert-octylphenol, (full information in **Annex II**). **Reference** **Wenzel, A., Schäfers, C., Vollmer, G., Michna, H. and Diel, P. 2001**
Zoarces viviparus saltwater fish early-life stage toxicity no guideline available - Principle of test: Study investigated if maternal exposure to 4-tert-octylphenol induces malformations in eelpout fry and if the malformations occur only by exposure during a temporally narrow, sensitive window. The goal was to clarify if waterborne exposure to 4-tert-octylphenol could lead to abnormal	NOEC (45d): 14.3 µg/L test mat. (meas. (not specified)) based on: mortality and malformations	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**).

embryo development - Short description of test conditions: 24 polyethylene tanks were set up in a flow-through system with a water exchange of 200 L per day and each tank was provided with two air stones and two circulation pumps. The seawater was pumped directly from a natural source and, to provide hiding opportunities and shade during light hours, pieces of drainpipe were put in the tanks and the tanks were partly covered by black plastic. Water samples were collected regularly from the exposure tanks and frozen at -20 C for subsequent chemical analysis. Temperature, salinity and oxygen saturation were measured regularly in the header tanks but only weekly in each individual exposure tank because the fish are very sensitive to movement and sound disturbance. - Parameters analysed / observed: total number of live, dead and deformed larvae, abnormal development (early death, reduced growth, spinal cord and cranial malformations, eye defects, Siamese twins or multiple malformations)		**Reference** **Jane E. Morthorst, Bodil Korsgaard, Poul Bjerregaard 2016**
Salmo salar freshwater fish, juvenile growth test equivalent or similar to OECD Guideline 215 (Fish, Juvenile Growth Test) Generally followed fish juvenile test except purpose of test was to determine effects on gill ATPase activity, plasma vitellogenin levels and hypoosmoregulatory performance. However, mortality was also measured.	NOEC (30d): >0.02 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across based on grouping of substances (category approach) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Moore, A., Scott, A.P., Lower, N., Katsiadiki, I., Greenwood, L. 2003**
Salmo salar freshwater fish, juvenile growth test	NOEC (30d): >0.02 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-

		40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oryzias latipes freshwater fish life cycle toxicity equivalent or similar to EPA OPPTS 850.1500 (Fish Life Cycle Toxicity) Test was performed in three phases, exposure to juvenile fish for 28 days, growout phase and reproduction phase until Day 83. Fish not exposed to toxicant in growout or reproduction phases.	NOEC (28d): >0.002 mg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (28d): >0.002 mg/L test mat. (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) supporting study read-across based on grouping of substances (category approach) **Test material** 4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference** **Nimrod, A.C, and Benson, W. H. 1998**
Oryzias latipes freshwater fish life cycle toxicity	NOEC (28d): >0.002 mg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (28d): >0.002 mg/L test mat. (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Gobiocypris rarus freshwater long-term toxicity to fish [deactivated phrase] equivalent or similar to OECD 229	NOEC (21d): >0.02 mg/L test mat. (meas. (arithm. mean)) based on: adult mortality NOEC (21d): >0.02 mg/L test mat. (meas. (arithm. mean)) based on: fertility NOEC (21d): >0.02 mg/L test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study read-across based on grouping of substances (category approach) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4,

		(full information in **Annex II**). **Reference** **Zha, J., Sun, L., Spear, P., Wang, Z. 2008**
Gobiocypris rarus freshwater long-term toxicity to fish [deactivated phrase]	NOEC (21d): >0.02 mg/L test mat. (meas. (arithm. mean)) based on: adult mortality NOEC (21d): >0.02 mg/L test mat. (meas. (arithm. mean)) based on: fertility NOEC (21d): >0.02 mg/L test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish life cycle toxicity equivalent or similar to EPA OPP 72-5 (Fish Life Cycle Toxicity) Study author refers to OECD Guideline 204 for analytical requirements. However, this test was a full life cycle test on rainbow trout, starting with eyed-eggs through one year of life. Experiment tested only two different nonylphenol concentrations.	NOEC (365d): >10 µg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (365d): >10 µg/L test mat. (meas. (arithm. mean)) based on: growth rate NOEC (365d): >10 µg/L test mat. (meas. (arithm. mean)) based on: number hatched	2 (reliable with restrictions) supporting study read-across based on grouping of substances (category approach) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Ackermann,G.E., Schwaiger, J., Negele, R.D, Fent, K. 2002**
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish life cycle toxicity	NOEC (365d): >10 µg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (365d): >10 µg/L test mat. (meas. (arithm. mean)) based on: growth rate NOEC (365d): >10 µg/L test mat. (meas. (arithm. mean)) based on: number hatched	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in

		Annex II). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish early-life stage toxicity according to ASTM	NOEC (91d): 0.006 mg/L test mat. (meas. (arithm. mean)) based on: growth rate LOEC (91d): 0.01 mg/L test mat. (meas. (arithm. mean)) based on: growth rate	1 (reliable without restriction) supporting study read-across based on grouping of substances (category approach) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish early-life stage toxicity	NOEC (91d): 0.006 mg/L test mat. (meas. (arithm. mean)) based on: growth rate LOEC (91d): 0.01 mg/L test mat. (meas. (arithm. mean)) based on: growth rate	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Pimephales promelas freshwater fish, juvenile growth test according to ASTM 1993 Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. E1022-84; according to USEPA; equivalent or similar to OECD Guideline 215 (Fish, Juvenile Growth Test)	NOEC (28d): 0.038 mg/L test mat. (meas. (arithm. mean)) based on: growth rate - wet weight NOEC (28d): 0.077 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (28d): 0.077 mg/L test mat. (meas. (arithm. mean)) based on: growth rate LOEC (28d): 0.193 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in

		Annex II). **Reference** **Brooke, L.T. 1993**
Pimephales promelas freshwater fish, juvenile growth test	NOEC (28d): 0.038 mg/L test mat. (meas. (arithm. mean)) based on: growth rate - wet weight NOEC (28d): 0.077 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (28d): 0.077 mg/L test mat. (meas. (arithm. mean)) based on: growth rate LOEC (28d): 0.193 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study read-across based on grouping of substances (category approach) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Lepomis macrochirus freshwater fish, juvenile growth test according to ASTM 1993 Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs. E1022-84; according to USEPA; equivalent or similar to OECD Guideline 215 (Fish, Juvenile Growth Test)	NOEC (28d): 0.059 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (28d): 0.126 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Lepomis macrochirus freshwater fish, juvenile growth test	NOEC (28d): 0.059 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (28d): 0.126 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in

		Annex II). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oncorhynchus tschawytscha freshwater fish short-term toxicity test on embryo and sac-fry stages equivalent or similar to OECD Guideline 212 (Fish, Short-term Toxicity Test on Embryo and Sac-Fry Stages) Study authors state no specific guidelines were followed. Salmon alevins (sac-fry) were exposed for 29 days post hatch in static-renewal test to different test concentrations. Mortality as well as genetic sex was determined using Y-chromosomal DNA markers at 103 and 179 days post hatch.	NOEC (29d): >0.01 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Afonso, L. , Smith, J., Ikonomou, M., Devlin, R. 2002**
Oncorhynchus tschawytscha freshwater fish short-term toxicity test on embryo and sac-fry stages	NOEC (29d): >0.01 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oryzias latipes freshwater long-term toxicity to fish [deactivated phrase] equivalent or similar to OECD 229	NOEC (21d): 0.051 mg/L test mat. (meas. (arithm. mean)) based on: fertility - and fecundity LOEC (21d): 0.101 mg/L test mat. (meas. (arithm. mean)) based on: fertility - and fecundity	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in

		Annex II). **Reference** **Kang, I.J. , Yokota, H., Oshima, Y., Tsurday, Y., Hano, T., Maeda, M., Imada, N., Tadokoro, H., Honjo, T. 2003**
Oryzias latipes freshwater long-term toxicity to fish [deactivated phrase]	NOEC (21d): 0.051 mg/L test mat. (meas. (arithm. mean)) based on: fertility - and fecundity LOEC (21d): 0.101 mg/L test mat. (meas. (arithm. mean)) based on: fertility - and fecundity	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oryzias latipes freshwater fish life cycle toxicity equivalent or similar to EPA OPPTS 850.1500 (Fish Life Cycle Toxicity) Generally follows fish life cycle test procedures, but extends length of test to cover two generations. Embryological development, hatching success, post-hatch survival, growth, sexual differentiation, and reproduction of the first generation and progeny are assessed.	NOEC (104d): 0.008 mg/L test mat. (meas. (geom. mean)) based on: F0 generation post swim-up mortality LOEC (104d): 0.018 mg/L test mat. (meas. (geom. mean)) based on: F0 generation post swim-up mortality	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Yokota, H., Seki, M., Maeda, M., Oshima, Y., Tadokoro, H., Honjo, T., Kobayashi, K. 2001**
Oryzias latipes freshwater fish life cycle toxicity	NOEC (104d): 0.008 mg/L test mat. (meas. (geom. mean)) based on: F0 generation post swim-up mortality	2 (reliable with restrictions) supporting study

	LOEC (104d): 0.018 mg/L test mat. (meas. (geom. mean)) based on: F0 generation post swim-up mortality	read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Salmo trutta freshwater fish, juvenile growth test according to - Principle of test: In the present study, plasma levels of thyroid-related hormones (TSH, T3 and T4) and GH as vital hormones contributing to key physiological processes were used as endocrine biomarkers. In addition, gill and intestine histopathology, as suitable non-endocrine toxicant biomarkers, and plasma total calcium, as a surrogate measure for plasma vitellogenin, were also evaluated in Caspian brown trout following exposure to both environmentally relevant and higher levels of nonylphenol. - Short description of test conditions: three nominal concentrations of nonylphenol [1 (~0.5% of LC50), 10 (~5% of LC50) and 100 (~50% of LC50) µg/l] were used for the subacute semi-static *in vivo* exposure conditions in the current study. Fishes were randomly allocated to five treatments in duplicate (Lammer et al., 2009; Modesto and Martinez, 2010) (ten 300-l tanks containing 100 l water) in which each replicate contained ten fish. In addition to the nonylphenol treatments (1, 10 and 100 µg/l), two control treatments [water control and solvent control (0.01% (v/v) ethanol)] were also used. - Parameters analysed / observed: weight, length	NOEC (21d): 100 µg/L test mat. (nominal) based on: weight (highest concentration tested) NOEC (21d): 100 µg/L test mat. (nominal) based on: length (highest concentration tested)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Iman Shirdel, Mohammad Reza Kalbassi 2016**
Salmo trutta freshwater fish, juvenile growth test	NOEC (21d): 100 µg/L test mat. (nominal) based on: weight (highest concentration tested) NOEC (21d): 100 µg/L test mat. (nominal) based on: length (highest concentration tested)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material**

		Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Danio rerio (previous name: *Brachydanio rerio*) freshwater fish early-life stage toxicity no guideline followed - Principle of test: the aim of this study was to determine the estrogenicity of different alkylphenol isomers *in vitro*, and to analyse possible effects on zebrafish *in vivo* - Short description of test conditions: newly fertilised zebrafish eggs were collected and immediately transferred to Petri dishes (50 eggs per dish) containing embryo water. 1 dpf embryos (250 per experimental group) were moved to an aerated closed circuit 38 L glass tank system and exposed to 50, 250, 500 µg/L of cNP and to DMSO at 0.01% (v/v). 25% of water containing the tested compounds was changed every 24 h. In both experiments, the time of hatching was determined by direct observation of each tank. - Parameters analysed / observed: Survival, hatching and histological analysis	NOEC (42d): 50 µg/L (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **E. Puy-Azurmendi, A. Olivares, A. Vallejo, M. Ortiz-Zarragoitia, B. Piña, O. Zuloaga, M.P. Cajaraville 2014**
Danio rerio (previous name: *Brachydanio rerio*) freshwater fish early-life stage toxicity	NOEC (42d): 50 µg/L (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish early-life stage toxicity	NOEC (91d): 6 µg/L test mat. (meas. (not specified)) based on: egg hatchability, survival, and growth EC20 (91d): 8.4 µg/L test mat. (meas. (not	1 (reliable without restriction) supporting study experimental study

according to ASTM E1241 - 05(2013) Standard Guide for Conducting Early Life-Stage Toxicity Tests with Fishes	specified)) based on: calculated from the concentration response curve for biomass (percentage survival x weight) LOEC (91d): 10.3 µg/L test mat. (meas. (not specified)) based on: egg hatchability, survival, and growth Chronic value - Geometric mean of the NOEC and LOEC (91d): 7.9 µg/L test mat. (meas. (not specified)) based on: egg hatchability, survival, and growth	**Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish early-life stage toxicity	NOEC (91d): 6 µg/L test mat. (meas. (not specified)) based on: egg hatchability, survival, and growth EC20 (91d): 8.4 µg/L test mat. (meas. (not specified)) based on: calculated from the concentration response curve for biomass (percentage survival x weight) LOEC (91d): 10.3 µg/L test mat. (meas. (not specified)) based on: egg hatchability, survival, and growth Chronic value - Geometric mean of the NOEC and LOEC (91d): 7.9 µg/L test mat. (meas. (not specified)) based on: egg hatchability, survival, and growth	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		

Discussion

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

A read-across approach from the structural analogue nonylphenol to octylphenol is used to determine the key study for the long-term toxicity to fish. The read-across justification is provided in a separate report in in the original AfA (Section 13 of the CSR).

The selected key study, Watanabe et al (2017), exposed Japanese medaka, *Oryzias latipes*, to nonylphenol for 16 weeks in a flow-through system. The key value is a NOEC for fertilised eggs, F0 and F1 generations, of 0.000127 mg/l or 1.27 ug/l. Although long-term fish studies are available for octylphenol, the study by Watanabe et al (2017) provides NOEC values that are an order of magnitude lower than the most sensitive octylphenol NOEC data and is a high quality, reliable study.

Value used for CSA:
EC10/LC10 or NOEC for freshwater fish: 0mg/L
EC10/LC10 or NOEC for marine water fish:

Additional information:
Three reliable long-term exposure of octylphenol to fish were available, two investigating the toxicity of octylphenol on the mortality and reproduction of the freshwater fish, *Danio rerio,* (Wenzel et al, 2001 and Puy-Azurmendi et al, 2014) and one using eelpout fry, *Zoarces viviparus*, (Morthorst et al, 2016). Wenzel et al (2001) exposed the zebrafish, *Danio rerio*, for 151 days to octylphenol following the OECD 212 Guideline determining a NOEC of 0.012 mg/L octylphenol based on growth and fecundity. Wenzel et al (2001) also provided two endpoint NOEC values in a 78-day exposure that included 0.012 mg octylphenol/L for inhibition of reproduction and >0.035 mg octylphenol/L for survival of *D. rerio*. In contrast, Puy-Azurmendi et al (2014)

did not find any mortality to juveniles of *D. rerio* after 42 days exposure at the maximum concentration tested of 0.050 mg/l, determining a NOEC >0.050 mg/l. Morthorst et al (2016) exposed *Z. viviparus* fry for 45 days determining a NOEC of 0.0143 mg/l for mortality and development malformations.

Thirteen additional long-term studies were available using a read-across approach from the structural analogue, nonylphenol, to octylphenol. The read-across justification is provided in the original AfA (Section 13 of the CSR). NOEC for mortality ranged from 0.002 mg nonylphenol/L for O. latipes (Nimrod and Benson, 1998) to 0.08 mg nonylphenol/L for *Pimephales promelas* (Brooke et al, 1993) and 0.1 mg nonylphenol/L for changes in weight and length for *Salmo trutta* (Shirdel et al, 2016).

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 9. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Gammarus pulex freshwater semi-static equivalent or similar to EPA OPPTS 850.1020 (Gammarid Acute Toxicity Test)	EC50 (96h): 13.3 µg/L test mat. (meas. (not specified)) based on: mobility (12.3-14.8) LC50 (96h): 19.6 µg/L test mat. (meas. (not specified)) based on: mortality (16.8-23.4)	1 (reliable without restriction) key study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Sims, I.; Whitehouse, P. 1998**
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater static according to EPA OTS 797.1930 (Mysid Acute Toxicity Test)	LC50 (96h): >0.048 - <0.113 mg/L test mat. (meas. (not specified)) based on: mortality (95% CL 0.0361-0.1437)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(tert-octyl)phenol, (full information in **Annex II**). **Reference** **Cripe GM, Ingley-Guezou A, Goodman LR, & Forester J 1989**
Ceriodaphnia dubia not specified static according to US EPA. Methods for measuring the acute toxicity of effluents	EC50 (48h): 0.07 mg/L not specified (nominal) based on: mobility (95% CL 0.06-0.11 mg/l)	2 (reliable with restrictions) supporting study experimental study

and receiving waters to freshwater and marine organisms, 4th Ed. EPA 600-4-90-027F. Washing ton DC, US EPA 1993.		**Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Isidori M, Lavorgna M, Nardelli A & Parrella A 2006**
other aquatic mollusc: *Physella virgata* freshwater flow-through according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians not applicable	EC50 (96h): 378 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization LC50 (96h): 774 µg/L test mat. (meas. (not specified)) based on: mortality	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Justification for type of information: not applicable		
other aquatic mollusc: *Physella virgata* freshwater flow-through	EC50 (96h): 378 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization LC50 (96h): 774 µg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater semi-static according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and	EC50 (48h): 104 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol,

Amphibians not applicable		branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Daphnia magna freshwater semi-static	EC50 (48h): 104 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
other aquatic arthropod: *Ophiogomphus sp.* freshwater flow-through according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians not applicable	EC50 (96h): 596 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Justification for type of information: not applicable		
other aquatic arthropod: *Ophiogomphus sp.* freshwater flow-through	EC50 (96h): 596 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material**

		Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
other aquatic worm: *Lumbriculus variegatus* freshwater flow-through according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians no data	EC50 (96h): 268 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization LC50 (96h): 342 µg/L test mat. (meas. (not specified)) based on: mortality	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Justification for type of information: not applicable		
other aquatic worm: *Lumbriculus variegatus* freshwater flow-through	EC50 (96h): 268 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization LC50 (96h): 342 µg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
other aquatic worm: *Ficopomatus enigmaticus* saltwater static according to EPA/600/4-91/003 (Arbaciapunctulata, Fertilization Test Method 1008.0) not applicable	EC50 (24h): 1.38 µg/L test mat. (not specified) based on: sperm toxicity - 30 ppt EC50 (24h): 6.8 µg/L test mat. (not specified) based on: larval development - 30 ppt EC50 (24h): 1.43 µg/L test mat. (not specified) based on: sperm toxicity - 35 ppt EC50 (24h): 1.3 µg/L test mat. (not specified) based on: sperm toxicity - 15 ppt EC50 (24h): 1.37 µg/L test mat. (not specified) based on: sperm toxicity - 10 ppt	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**).

	EC50 (24h): 6.86 µg/L test mat. (not specified) based on: larval development - 35 ppt EC50 (24h): 6.03 µg/L test mat. (not specified) based on: larval development - 15 ppt EC50 (24h): 6.18 µg/L test mat. (not specified) based on: larval development - 10 ppt	**Reference** **Matteo Oliva, Elvira Mennillo, Martina Barbaglia, Gianfranca Monni, Federica Tardelli, Valentina Casu, Carlo Pretti 2018**
other aquatic worm: *Ficopomatus enigmaticus* saltwater static	EC50 (24h): 1.38 µg/L test mat. (not specified) based on: sperm toxicity - 30 ppt EC50 (24h): 6.8 µg/L test mat. (not specified) based on: larval development - 30 ppt EC50 (24h): 1.43 µg/L test mat. (not specified) based on: sperm toxicity - 35 ppt EC50 (24h): 1.3 µg/L test mat. (not specified) based on: sperm toxicity - 15 ppt EC50 (24h): 1.37 µg/L test mat. (not specified) based on: sperm toxicity - 10 ppt EC50 (24h): 6.86 µg/L test mat. (not specified) based on: larval development - 35 ppt EC50 (24h): 6.03 µg/L test mat. (not specified) based on: larval development - 15 ppt EC50 (24h): 6.18 µg/L test mat. (not specified) based on: larval development - 10 ppt	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
other aquatic crustacea: *Hyalella azteca* freshwater flow-through according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fishes, Macroinvertebrates, and Amphibians not applicable	EC50 (96h): 21 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization LC50 (96h): 21 µg/L test mat. (meas. (not specified)) based on: mortality	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Justification for type of information: not applicable		
other aquatic crustacea: *Hyalella azteca* freshwater flow-through	EC50 (96h): 21 µg/L test mat. (meas. (not specified)) based on: percentage of mortality + loss equilibrium + immobilization LC50 (96h): 21 µg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue

		or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

The Sims and Whitehouse (1998) study was selected as the key study because the study was well documented and provided endpoints that distinguished between immobility and survival, exposing freshwater shrimp, *Gammarus pulex*, to octylphenol for 96h. The L(E)C50 key value for immobility was 0.013 mg octylphenol/L (Sims and Whitehouse 1998).

Value used for CSA:
EC50/LC50 for freshwater invertebrates: 0.013mg/L
EC50/LC50 for marine invertebrates: 0.048mg/L

Additional information:
Oliva et al (2018) reported a more sensitive EC50 of 0.0014 mg/l for sperm toxicity when exposing the saltwater worm, *Ficopomatus enigmaticus*, to nonylphenol. However, the choice of key study was driven by the selection of test substance - octylphenol - the use of a standard test organism, the use of a freshwater organism and the testing of adults.

Reliable toxicity data for aquatic invertebrate exposure to octylphenol from 48 to 96 hours included three studies with data for two freshwater and one marine species, with immobility or survival test endpoints expressed as L(E)C50 concentrations. The range of L(E)C50 values for immobility was 0.13 mg octylphenol/L for *Gammarus pulex* (Sims and Whitehouse, 1998) to 0.28 mg/L for *Ceriodaphnia dubia* (Isidori et al, 2006). Two reliable supporting studies, Cripe et al (1989) and Isidori et al (2006), were available. Cripe et al (1989) reported an LC50 range of 0.048 to 0.113 mg/L for survival of the marine species, *Mysidopsis bahia*, at 96 hr exposure to octylphenol. Isidori et al (2006) exposed the freshwater *Ceriodaphnia dubia* to 4-octylphenol and 4-tert-octylphenol for 48 hours. The EC50 values for immobilisation were 0.07 mg/L and 0.28 mg/L, respectively, for 4-octylphenol and 4-tert-octylphenol. Endpoint L(E)C50 concentrations reported by the supporting studies of Isidori et al (2006) and Cripe et al (1989) were similar to the findings of the key study.

Six additional short-term studies were available using a read-across approach from the structural analogue, nonylphenol, to octylphenol. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR). L(E)50 (96h) values ranged for mortality from 0.02 mg nonylphenol/L for *Hyalella azteca* (Spehar et al, 2010) to 0.38 mg nonylphenol/L for *Physella virgata* (Spehar et al, 2010) and 0.77 mg nonylphenol/L for percentage of mortality + loss equilibrium + immobilization for *Physella virgata* (Spehar et al, 2010).

7.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 10. Long-term effects on aquatic invertebrates

Method	Results	Remarks

Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to OECD 202, part II, 1984	NOEC (21d): 0.03 mg/L test mat. (nominal) based on: reproduction LOEC (21d): 0.1 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) key study experimental study **Test material** 1,1,3,3-Tetramethylbutylphenol; 2-(1,1,3,3-tetramethylbutyl)phenol / 27193-28-8 / 248-310-7, (full information in **Annex II**). **Reference** **Scholz N 1991**
other aquatic crustacea: *Tigriopus japonicus* saltwater long-term toxicity to aquatic invertebrates no guideline available	NOEC (21d): >0.01 mg/L test mat. (nominal) based on: mortality - parent generation NOEC (21d): >0.01 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** p-t-octylphenol, (full information in **Annex II**). **Reference** **Marcial, H. , Hagiwara, A., Snell, T.W. 2003**
Potamopyrgus antipodarium freshwater long-term toxicity to aquatic invertebrates no guideline available Snails exposed to octylphenol for 9 weeks in semi-static renewal system. Growth and embryo production were assessed.	NOEC (9wk): >0.1 mg/L test mat. (nominal) based on: mortality NOEC (9wk): >0.1 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 2-octylphenol / 67554-50-1 / 266-717-8, (full information in **Annex II**). **Reference** **Jobling, S., Casey, D., Rodgers-Gary, T., Oehlmann, J., Schulte-Oehlmann, U., Pawlowski, S., Baunbeck, T., Turner, A.P., Tyler, C.R. 2003**
Tisbe batagliai saltwater long-term toxicity to aquatic invertebrates	NOEC (53d): 0.02 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study

no guideline available		experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Bechmann, R. 2005**
Tisbe batagliai saltwater long-term toxicity to aquatic invertebrates	NOEC (53d): 0.02 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study migrated information: read-across from supporting substance (structural analogue or surrogate) [deactivated phrase] **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
other aquatic worm: *Caenorhabditis elegans* freshwater long-term toxicity to aquatic invertebrates according to ISO10872:2010 Study references Traunspurger et al. 1997 as method followed. The method presented by Traunspurger et al. 1997 has since been approved as a standard test method ISO 10872:2010 which is a 96h test. This study performed test for 72h, but was considered by the authors to be a full life-cycle. Although was performed as water only exposure to a sediment dwelling organism, USEPA has accepted water-only studies on sediment organisms (*Hylella azeteca*).	NOEC (72h): >0.235 mg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (72h): >0.235 mg/L test mat. (meas. (arithm. mean)) based on: growth NOEC (72h): >0.235 mg/L test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Hoss, Sebastian, Juttner, I., Traunspurger, W., Pfister, G., Schramm, K.W., Steinberg, C. 2002**
other aquatic worm: *Caenorhabditis elegans* freshwater long-term toxicity to aquatic invertebrates	NOEC (72h): >0.235 mg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (72h): >0.235 mg/L test mat. (meas. (arithm. mean)) based on: growth NOEC (72h): >0.235 mg/L test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate)

		Test material Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Ceriodaphnia dubia freshwater long-term toxicity to aquatic invertebrates according to ISO/CD 20665 procedure (2001)	NOEC (7d): 0.001 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Isidori, M., Lavorgna, M., Nardelli, A., Parrella, A. 2006**
Ceriodaphnia dubia freshwater long-term toxicity to aquatic invertebrates	NOEC (7d): 0.001 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Ceriodaphnia dubia freshwater long-term toxicity to aquatic invertebrates according to USEPA 600/4-89/001; according to Standard Methods 1980 15th ed; according to USEPA 660/3-75-009 1975	NOEC (7d): 0.1 mg/L test mat. (nominal) based on: reproduction LOEC (7d): 0.3 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference** **D.E. England 1995**

Ceriodaphnia dubia freshwater long-term toxicity to aquatic invertebrates	NOEC (7d): 0.1 mg/L test mat. (nominal) based on: reproduction LOEC (7d): 0.3 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates equivalent or similar to ASTM 1988. Standard Guide for Conducting Renewal Life-Cycle Toxicity Tests with *Daphnia magna*	NOEC (21d): >0.1 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.05 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; Nonylphenol, (full information in **Annex II**). **Reference** **Baldwin, W., Graham, S., Shea, D., LeBlanc, G. 1997**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): >0.1 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.05 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Americamysis bahia (previous name:	NOEC (28d): 0.009 mg/L test mat. (meas.	1 (reliable without

Mysidopsis bahia) saltwater long-term toxicity to aquatic invertebrates according to ASTM 1990. Standard Guide for Conducting Life-cycle Toxicity Tests with Saltwater Mysids. E1191-90	(arithm. mean)) based on: reproduction NOEC (28d): 0.028 mg/L test mat. (meas. (arithm. mean)) based on: mortality	restriction) supporting study experimental study **Test material** 4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5; Nonylphenol, (full information in **Annex II**). **Reference** **Kuhn, A., Munns Jr.,W.R., Champlin, D., McKinney, R., Tagliabue, M., Serbst, J., Gleason, T. 2001**
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater long-term toxicity to aquatic invertebrates	NOEC (28d): 0.009 mg/L test mat. (meas. (arithm. mean)) based on: reproduction NOEC (28d): 0.028 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5; Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to ASTM 1991. Standard Guide for Conducting Renewal Life-Cycle Toxicity Tests with *Daphnia magna*	NOEC (21d): 0.116 mg/L test mat. (meas. (arithm. mean)) based on: reproduction NOEC (21d): 0.116 mg/L test mat. (meas. (arithm. mean)) based on: growth NOEC (21d): 0.215 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (21d): 0.215 mg/L test mat. (meas. (arithm. mean)) based on: reproduction	1 (reliable without restriction) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **L.T. Brooke 1993**

Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): 0.116 mg/L test mat. (meas. (arithm. mean)) based on: reproduction NOEC (21d): 0.116 mg/L test mat. (meas. (arithm. mean)) based on: growth NOEC (21d): 0.215 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (21d): 0.215 mg/L test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to OECD 202	NOEC (21d): 0.024 mg/L test mat. (meas. (arithm. mean)) based on: reproduction NOEC (21d): 0.039 mg/L test mat. (meas. (arithm. mean)) based on: growth - mean length of parent NOEC (21d): 0.13 mg/L test mat. (meas. (arithm. mean)) based on: mortality	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Comber, M.H. I., Williams, T.D., and Stewart, K.M. 1993**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): 0.024 mg/L test mat. (meas. (arithm. mean)) based on: reproduction NOEC (21d): 0.039 mg/L test mat. (meas. (arithm. mean)) based on: growth - mean length of parent NOEC (21d): 0.13 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates equivalent or similar to OECD Guideline 211 (*Daphnia magna* Reproduction Test)	NOEC (21d): 0.025 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.013 mg/L test mat. (nominal) based on: reproduction LOEC (21d): 0.05 mg/L test mat. (nominal) based on: mortality - of parent animals LOEC (21d): 0.025 mg/L test mat.	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in

	(nominal) based on: reproduction	**Annex II**). **Reference** **Sun, H. and Gu, X. 2005**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): 0.025 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.013 mg/L test mat. (nominal) based on: reproduction LOEC (21d): 0.05 mg/L test mat. (nominal) based on: mortality - of parent animals LOEC (21d): 0.025 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates equivalent or similar to ISO 2000 Water Quality-Determination of Long Term Toxicity of Substances to *Daphnia Magna* Straus (Cladocera, Crustacea)	NOEC (21d): 0.04 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.06 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brennan, S., Brougham, C., Roche, J., Fogarty, A. 2006**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): 0.04 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.06 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Chironomus tentans	NOEC (20d): 0.042 mg/L test mat. (meas.	2 (reliable with

freshwater long-term toxicity to aquatic invertebrates equivalent or similar to OECD 219 Method followed cited as Benoit et al. (1997). *Chironomus tentans* life cycle test: Design and evaluation for use in assessing toxicity of contaminated sediments. Environ. Toxicol. Chem Vol 16 pp1165-1176. Water only exposure	(arithm. mean)) based on: mortality LOEC (20d): 0.091 mg/L test mat. (meas. (arithm. mean)) based on: mortality	restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Kahl, Michael, Makynen, E., Kosian, P., Ankley, G. 1997**
Chironomus tentans freshwater long-term toxicity to aquatic invertebrates Water only exposure	NOEC (20d): 0.042 mg/L test mat. (meas. (arithm. mean)) based on: mortality LOEC (20d): 0.091 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
other aquatic crustacea: *Tigriopus japonicus* saltwater long-term toxicity to aquatic invertebrates no guideline available	NOEC (21d): >0.01 mg/L test mat. (nominal) based on: mortality - parent generation NOEC (21d): >0.01 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Marcial, H. , Hagiwara, A., Snell, T.W. 2003**
other aquatic crustacea: *Tigriopus japonicus* saltwater long-term toxicity to aquatic invertebrates	NOEC (21d): >0.01 mg/L test mat. (nominal) based on: mortality - parent generation NOEC (21d): >0.01 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-

		40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia galeata freshwater long-term toxicity to aquatic invertebrates equivalent or similar to OECD Guideline 211 (*Daphnia magna* Reproduction Test)	NOEC (21d): 0.05 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.05 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Tanaka, Y., Nakanishi, J. 2002**
Daphnia galeata freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): 0.05 mg/L test mat. (nominal) based on: mortality - of parent animals NOEC (21d): 0.05 mg/L test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to OECD 202, part II, 1984	NOEC (21d): >=100 µg/L test mat. (nominal) based on: reproduction NOEC (21d): >=100 µg/L test mat. (nominal) based on: mortality - of parent animals LOEC (21d): >100 µg/L test mat. (nominal) based on: reproduction LOEC (21d): >100 µg/L test mat. (nominal) based on: mortality - of parent animals	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Scholz N 1992**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): >=100 µg/L test mat. (nominal) based on: reproduction NOEC (21d): >=100 µg/L test mat. (nominal) based on: mortality - of parent animals	2 (reliable with restrictions) supporting study read-across from supporting substance

	LOEC (21d): >100 µg/L test mat. (nominal) based on: reproduction LOEC (21d): >100 µg/L test mat. (nominal) based on: mortality - of parent animals	(structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates according to ASTM E1193 - 97(2012) Standard Guide for Conducting *Daphnia magna* Life-Cycle Toxicity Tests not applicable	NOEC (21d): 116 µg/L test mat. (meas. (not specified)) based on: growth and reproduction EC20 (21d): 170 µg/L test mat. (meas. (not specified)) based on: reproduction LOEC (21d): 215 µg/L test mat. (meas. (not specified)) based on: growth and reproduction Chronic value: Geometric mean of the NOEC and LOEC (21d): 158 µg/L test mat. (meas. (not specified)) based on: growth and reproduction	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Justification for type of information: not applicable		
Daphnia magna freshwater long-term toxicity to aquatic invertebrates	NOEC (21d): 116 µg/L test mat. (meas. (not specified)) based on: growth and reproduction EC20 (21d): 170 µg/L test mat. (meas. (not specified)) based on: reproduction LOEC (21d): 215 µg/L test mat. (meas. (not specified)) based on: growth and reproduction Chronic value: Geometric mean of the NOEC and LOEC (21d): 158 µg/L test mat. (meas. (not specified)) based on: growth and reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Gammarus sp. Natural drilled groundwater long-term toxicity to aquatic invertebrates no guideline available - Principle of test: the test was developed in order to propose an accurate reproductive toxicity test for this species. - Summary of test conditions: *Gammarus fossarum* were collected using a net (by	NOEC (21d): 5 µg/L test mat. (nominal) based on: mortality (highest concentration tested) NOEC (21d): 5 µg/L test mat. (nominal) based on: feeding rate (highest concentration tested)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full

kick sampling) from La Tour du Pin, upstream of the Bourbre River (eastern central France). Adult organisms recovered using 2- and 2.5-mm sieves were selected for each sampling date. Immediately after sampling, specimens were stored in plastic bottles containing ambient fresh water, and quickly transferred to the laboratory. Before all experiments, the organisms were kept during an acclimatization period of 30 to 35 d, in 30-L tanks continuously supplied with drilled groundwater adjusted to the sampling site conductivity (i.e., 600 mS/cm) and under constant aeration. A 16:8 h light:dark photoperiod was maintained and the temperature was kept at 12+/- 1C. Organisms were fed *ad libitum* with alder leaves (*Alnus glutinosa*). The leaves were conditioned for at least 61 d in water. Freeze-dried *Tubifex* worms (Europrix) were provided as a dietary supplement twice a week.		information in **Annex II**). **Reference** **Olivier Geffard, Benoit Xuereb, Arnaud Chaumot, Alain Geffard, Sylvie Biagianti, Claire Noel, Khedidja Abbaci, Jeanne Garric, Guy Charmantier, Mireille Charmantier-Daures 2010**
Gammarus sp. Natural drilled groundwater long-term toxicity to aquatic invertebrates	NOEC (21d): 5 µg/L test mat. (nominal) based on: mortality (highest concentration tested) NOEC (21d): 5 µg/L test mat. (nominal) based on: feeding rate (highest concentration tested)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater - artificial sea salt (SEALIFE, Marine tech Co., Ltd., Japan) long-term toxicity to aquatic invertebrates no guideline followed - Principle of test: During the 14 d exposure, number of exuviae and survival rate in each treatment group were measured daily, and total number of molts was calculated. After completion of the14 d exposure, the tested mysids were sacrificed (whole body). - Short description of test conditions: juvenile mysids (7d old) were exposed to nominal concentrations of 1, 3, 10 and 30 µg/l of	NOEC (14d): 1 µg/L test mat. (nominal) based on: molting ratio NOEC (14d): >30 µg/L test mat. (nominal) based on: mortality (highest concentration tested) LOEC (14d): 3 µg/L test mat. (nominal) based on: molting ratio	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Masaya Uchida, Masashi Hirano, Hiroshi Ishibashi,**

NP (with 0.01 ml/l of DMSO as a solvent) in 250 ml of the culture medium in glass beakers for 14 days at 24+/-1 °C, pH 8.0,and 16h light: 8h dark cycle, with twice a day feeding schedule - Parameters analysed / observed: survival, molting rate		**Jun Kobayashi, Yoshihiro Kagami, Akiko Koyanagi, Teruhiko Kusano, Minoru Koga, Koji Arizono 2016**
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater - artificial sea salt (SEALIFE, Marine tech Co., Ltd., Japan) long-term toxicity to aquatic invertebrates	NOEC (14d): 1 µg/L test mat. (nominal) based on: molting ratio LOEC (14d): 3 µg/L test mat. (nominal) based on: molting ratio	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater long-term toxicity to aquatic invertebrates according to EPA/600/4-91/003 (Chronic toxicity of effluents and receiving waters to marine and estuarine organisms) not applicable	NOEC (14d): >30 µg/L test mat. (nominal) based on: mortality NOEC (14d): 0.3 µg/L test mat. (nominal) based on: body length NOEC (14d): 3 µg/L test mat. (nominal) based on: carapace length LOEC (14d): 1 µg/L test mat. (nominal) based on: body length LOEC (14d): 10 µg/L test mat. (nominal) based on: carapace length	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Masashi Hirano, Hiroshi Ishibashi, Joon-Woo Kim, Naomi Matsumura, Koji Arizono 2009**
Justification for type of information: not applicable		
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater long-term toxicity to aquatic invertebrates	NOEC (14d): >30 µg/L test mat. (nominal) based on: mortality NOEC (14d): 0.3 µg/L test mat. (nominal) based on: body length NOEC (14d): 3 µg/L test mat. (nominal) based on: carapace length LOEC (14d): 1 µg/L test mat. (nominal) based on: body length LOEC (14d): 10 µg/L test mat. (nominal) based on: carapace length	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**).

		Reference
Justification for type of information: read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC

The Scholz (1991) study was selected as key study as it followed OECD standard guidelines, exposing the freshwater preferred test species, *Daphnia magna*, to octylphenol for the duration of 21 days. The key NOEC value was 0.03 mg octylphenol/L for reproduction inhibition.

Value used for CSA:
EC10/LC10 or NOEC for freshwater invertebrates: 0.03mg/L
EC10/LC10 or NOEC for marine invertebrates: 0.01mg/L

Additional information:
Marcial et al (2003) reported a more sensitive NOEC for survival of >0.01 mg octylphenol/L, exposing for 21 days the marine copepod, *Tigriopus japonicus*. However, since the study did not use standard guidelines or standard species and due to the use of a saltwater organism, the study was not chosen as the key study.

Another reliable toxicity study for long-term exposure of octylphenol to aquatic invertebrates was available. Jobling et al (2003) exposed for 9 weeks the snail, *Potamopyrgus antipodarum*, to octylphenol, resulting in a NOEC for survival and reproduction of 0.1 mg octylphenol/L.

Fifteen additional long-term studies for freshwater species and 3 for saltwater invertebrates were available using a read-across approach from the structural analogue, nonylphenol, to octylphenol. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR). NOECs ranged for mortality from 0.001 mg nonylphenol/L for *Ceriodaphnia dubia* (Isidori et al, 2006) to 0.21 mg nonylphenol/L for *Daphnia magna* (Brooke, 1993). A NOEC value of 0.03 mg nonylphenol/L was available for the saltwater invertebrate mysid, *Americamysis bahia* (Kuhn et al, 2001; Uchina et al, 2016 and Hirano et al, 2009).

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 11. Effects on algae and aquatic plants

Method	Results	Remarks
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata, Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ASTM E47.01 1983. Proposed Standard Practice for Conducting Short-term Toxicity Tests with Fresh Water and Salt Water Algae	EC50 (96h): 1.9 mg/L test mat. (nominal) based on: cell number (1.0-2.7) NOEC (96h): <1 mg/L test mat. (nominal) based on: cell number	1 (reliable without restriction) key study experimental study **Test material** 2-octylphenol / 67554-50-1 / 266-717-8, (full information in **Annex II**). **Reference** **Analytical Bio-Chemistry Laboratories, Inc. 1984**

Microcystis aeruginosa (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 1.6 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.15) NOEC (14d): 0.45 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.04) EC90 (14d): 2.5 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.28)	2 (reliable with restrictions) key study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Scenedesmus obliquus (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline available The objective of this study was to investigate the removal mechanisms of *Scenedesmus obliquus* for alkylphenol OP in aqueous systems. The algal responses to OP were also evaluated by measuring algal growth, algal ultrastructure and photosynthetic parameters, such as photosynthetic pigment and chlorophyll a fluorescence.	NOEC (5d): 2 mg/L test mat. (nominal) based on: growth rate LOEC (5d): 4 mg/L test mat. (nominal) based on: growth rate LOEC (10h): 0.5 mg/L test mat. (nominal) based on: chlorophyll fluorescence (Fv/Fm values) (see attached figure)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Guang-Jie Zhou, Fu-Qiang Peng, Bin Yang, Guang-Guo Ying 2013**
Skeletonema costatum (algae) saltwater - water collected at 60 m depth from the Outer Oslofjord supplemented with ISO10253 stock solution toxicity to aquatic algae and cyanobacteria according to ISO 10253 (Water quality - Marine Algal Growth Inhibition Test with *Skeletonema costatum* and *Phaeodactylum tricornutum*)	EC50 (72h): 0 mol/L test mat. (nominal) based on: growth rate (- 95% C.L. (0.0000052-0.0000061) mol/L)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Karina Petersen, Harald Hasle Heiaas, Knut Erik Tollefsen 2014**
Oocystis parva (algae)	EC50 (14d): 3.45 mg/L test mat. (nominal)	2 (reliable with

BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	based on: growth rate (S.D. ± 0.33) NOEC (14d): 1.25 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.18) EC90 (14d): 4.1 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.73)	restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Microcystis aeruginosa (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 1.5 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.23) NOEC (14d): 0.5 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.04) EC90 (14d): 1.9 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.21)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Oscillatoria agardhii Gom (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a	EC50 (14d): 1.65 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.18) NOEC (14d): 0.65 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07) EC90 (14d): 1.95 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.20)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N.**

volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth		**G. Medvedeva, V. N. Mamontova 2015**
Aphanizomenon flos-aquae (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 1.5 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.20) NOEC (14d): 0.8 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.09) EC90 (14d): 1.95 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.21)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Scenedesmus quadricauda (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 3.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.38) NOEC (14d): 1.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.17) EC90 (14d): 4.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.86)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Anabaena variabilis (algae) BG11 medium	EC50 (14d): 1.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.18)	2 (reliable with restrictions)

toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	NOEC (14d): 0.9 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.08) EC90 (14d): 2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.20)	supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Nodularia spumigena (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of octylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 1.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.16) NOEC (14d): 0.8 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.11) EC90 (14d): 2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.20)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Desmodesmus subspicatus (previous name: *Scenedesmus subspicatus*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to Algal growth inhibition test according to UBA (Feb. 1984)	EC50 (72h): 1.3 mg/L test mat. (nominal) based on: biomass EC10 (72h): 0.5 mg/L test mat. (nominal) based on: biomass	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Scholz N 1989**
Desmodesmus subspicatus (previous	EC50 (72h): 1.3 mg/L test mat. (nominal)	2 (reliable with

name: *Scenedesmus subspicatus*) (algae) freshwater toxicity to aquatic algae and cyanobacteria	based on: biomass EC10 (72h): 0.5 mg/L test mat. (nominal) based on: biomass	restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in section 13.		
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to Stephan et al (1985) Guidelines for deriving numerical national water quality criteria for the protection of aquatic organisms and their uses. EPA PB 85-2270; according to ASTM (1991b) Standard guide for conducting static 96-hr toxicity tests with algae. ASTM Annual Book of Standards 11.04:1218-90	NOEC (96h): 0.694 mg/L test mat. (meas. (arithm. mean)) based on: biomass LOEC (96h): 1.48 mg/L test mat. (meas. (arithm. mean)) based on: biomass	1 (reliable without restriction) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0; Nonylphenol, (full information in **Annex II**). **Reference** **Brooke LT 1993**
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria	NOEC (96h): 0.694 mg/L test mat. (meas. (arithm. mean)) based on: biomass LOEC (96h): 1.48 mg/L test mat. (meas. (arithm. mean)) based on: biomass	1 (reliable without restriction) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0; Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Chlorella vulgaris (algae) Bristol medium (BM) toxicity to aquatic algae and cyanobacteria no guideline followed	NOEC (96h): 4 mg/L test mat. (nominal) based on: concentration and dry weight of Chlorophyll a	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full

		information in **Annex II**). **Reference** **Q.T. Gao, N.F.Y. Tam 2011**
Chlorella vulgaris (algae) Bristol medium (BM) toxicity to aquatic algae and cyanobacteria	NOEC (96h): 4 mg/L test mat. (nominal) based on: concentration and dry weight of Chlorophyll a	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Scenedesmus capricornutum (algae) Soil extract (SE) medium toxicity to aquatic algae and cyanobacteria no guideline followed	EC50 (96h): 1.05 mg/L test mat. (nominal) based on: concentration Chlorophyll a - ± 0.14 NOEC (96h): 0.25 mg/L test mat. (nominal) based on: Concentration and dry weight of Chlorophyll a NOEC (96): 0.5 mg/L test mat. (nominal) based on: Chlorophyll fluorescence	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Q.T. Gao, N.F.Y. Tam 2011**
Scenedesmus capricornutum (algae) Soil extract (SE) medium toxicity to aquatic algae and cyanobacteria	EC50 (96h): 1.05 mg/L test mat. (nominal) based on: concentration Chlorophyll a - ± 0.14 NOEC (96h): 0.25 mg/L test mat. (nominal) based on: Concentration and dry weight of Chlorophyll a NOEC (96): 0.5 mg/L test mat. (nominal) based on: Chlorophyll fluorescence	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**

Justification for type of information: See read-across justification in original AfA		
Scenedesmus obliquus (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline available The objective of this study was to investigate the removal mechanisms of *Scenedesmus obliquus* for alkylphenol NP in aqueous systems. The algal responses to NP were also evaluated by measuring algal growth, algal ultrastructure and photosynthetic parameters such as photosynthetic pigment and chlorophyll a fluorescence.	NOEC (5d): 2 mg/L test mat. (nominal) based on: growth rate LOEC (5d): 4 mg/L test mat. (nominal) based on: growth rate LOEC (10h): 0.25 mg/L test mat. (nominal) based on: chlorophyll fluorescence (Fv/Fm values) (see attached figure)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Guang-Jie Zhou, Fu-Qiang Peng, Bin Yang, Guang-Guo Ying 2013**
Scenedesmus obliquus (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	NOEC (5d): 2 mg/L test mat. (nominal) based on: growth rate LOEC (5d): 4 mg/L test mat. (nominal) based on: growth rate LOEC (10h): 0.25 mg/L test mat. (nominal) based on: chlorophyll fluorescence (Fv/Fm values) (see attached figure)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ASTM E1218 - 04(2012) Standard Guide for Conducting Static Toxicity Tests with Microalgae no data	NOEC (96h): 694 µg/L test mat. (nominal) based on: cell number and growth rate EC20 (96h): 829 µg/L test mat. (nominal) based on: cell number and growth rate LOEC (96h): 1480 µg/L test mat. (nominal) based on: cell number and growth rate Chronic value (96h): 1013 µg/L test mat. (nominal) based on: cell number and growth rate (Geometric mean of the NOEC and LOEC)	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Pseudokirchneriella subcapitata (previous	NOEC (96h): 694 µg/L test mat. (nominal)	2 (reliable with

names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria	based on: cell number and growth rate EC20 (96h): 829 µg/L test mat. (nominal) based on: cell number and growth rate LOEC (96h): 1480 µg/L test mat. (nominal) based on: cell number and growth rate Chronic value (96h): 1013 µg/L test mat. (nominal) based on: cell number and growth rate (Geometric mean of the NOEC and LOEC)	restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Planktothrix agardhii (Gom.) Anagnostidis et Komárek (= *Oscillatoria agardhii Gom*. CALU 1113) (algae) BG11 medium toxicity to aquatic algae and cyanobacteria equivalent or similar to OECD Guideline 201 (Freshwater Alga and Cyanobacteria, Growth Inhibition Test) - Principle of test: The objective of the present study was to investigate the cellular responses of bloom-forming cyanobacterium *Planktothrix agardhii* 1113 to stress caused by NP and to assess the ability of *P. agardhii* to biodegrade NP. - Short description of test conditions: Cyanobacterial cells at the exponential growth phase were added aseptically into the BG11 medium with different concentrations of NP, and the initial concentration of biomass was 0.015 g L−1. Culturing was performed in 250-mL Erlenmeyer flasks filled with 100 mL of medium at 25±2 °C and 1000 lx light intensity, with a 12h:12 h (light:dark) regime. The cyanobacterium was grown under static conditions and was shaken manually daily. The duration of the experiments varied up to 14 days. - Parameters analysed / observed: Growth parameters: Lag-phase, days; Specific growth rate µ, day−1; Biomass	NOEC (14d): 0.4 mg/L test mat. (nominal) based on: growth rate	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Nadezda Medvedeva, Tatyana Zaytseva, Irina Kuzikova 2017**

yield, mg L−1 (4 days)		
Planktothrix agardhii (Gom.) Anagnostidis et Komárek (= *Oscillatoria agardhii Gom*. CALU 1113) (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	NOEC (14d): 0.4 mg/L test mat. (nominal) based on: growth rate	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Scenedesmus quadricauda (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom-forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 2.45 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.28) NOEC (14d): 0.65 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.11) EC90 (14d): 3.5 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.34)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Scenedesmus quadricauda (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 2.45 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.28) NOEC (14d): 0.65 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.11) EC90 (14d): 3.5 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.34)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**).

		Reference
Justification for type of information: See read-across justification in original AfA		
Anabaena variabilis (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 0.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.06) NOEC (14d): 0.3 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.02) EC90 (14d): 0.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Anabaena variabilis (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 0.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.06) NOEC (14d): 0.3 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.02) EC90 (14d): 0.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Microcystis aeruginosa (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of	EC50 (14d): 0.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07) NOEC (14d): 0.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.06) EC90 (14d): 1.4 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.13)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**).

25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth		**Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Microcystis aeruginosa (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 0.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07) NOEC (14d): 0.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.06) EC90 (14d): 1.4 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.13)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oscillatoria agardhii Gom (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 1 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.09) NOEC (14d): 0.4 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.04) EC90 (14d): 1.4 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.15)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Oscillatoria agardhii Gom (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 1 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.09) NOEC (14d): 0.4 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.04) EC90 (14d): 1.4 mg/L test mat. (nominal)	2 (reliable with restrictions) supporting study read-across from supporting substance

	based on: growth rate (S.D. ± 0.15)	(structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Oocystis parva (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 2.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.22) NOEC (14d): 0.6 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.09) EC90 (14d): 3.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.35)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Oocystis parva (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 2.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.22) NOEC (14d): 0.6 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.09) EC90 (14d): 3.2 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.35)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		

Nodularia spumigena (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	EC50 (14d): 0.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.06) NOEC (14d): 0.14 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.03) EC90 (14d): 0.7 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
Nodularia spumigena (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 0.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.06) NOEC (14d): 0.14 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.03) EC90 (14d): 0.7 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Aphanizomenon flos-aquae (algae) BG11 medium toxicity to aquatic algae and cyanobacteria no guideline followed - Principle of test: The objective of this work is to study the effect of nonylphenols on the growth and photosynthetic activity and synthesis of secondary metabolites by bloom forming microalgae. - Short description of test conditions: Microalgae were cultivated in the BG11 medium under static conditions at a temperature of 25 ± 2°C in Erlenmeyer bottles with a volume of 250 mL; the volume of the medium was 100 mL and the light/darkness conditions were 12 h : 12 h. The inoculum of the logarithmic phase of	EC50 (14d): 0.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07) NOEC (14d): 0.25 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.03) EC90 (14d): 0.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.08)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**

growth was introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per liter. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth		
Aphanizomenon flos-aquae (algae) BG11 medium toxicity to aquatic algae and cyanobacteria	EC50 (14d): 0.55 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.07) NOEC (14d): 0.25 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.03) EC90 (14d): 0.75 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.08)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to TSCA Test Standards 40 CFR 792.1050	EC50 (96h): 0.41 mg/L test mat. (meas. (not specified)) based on: cell number (0.36-0.48) EC10 (96h): 0.12 mg/L test mat. (meas. (not specified)) based on: cell number (0.09-0.15) EC50 (24h): 0.53 mg/L test mat. (meas. (not specified)) based on: cell number (0.42-0.76) EC50 (48h): 0.44 mg/L test mat. (meas. (not specified)) based on: cell number (0.28-0.55) EC50 (72h): 0.33 mg/L test mat. (meas. (not specified)) based on: cell number (0.16-0.72) EC10 (24h): 0.7 mg/L test mat. (meas. (not specified)) based on: cell number (<0.044-0.12) EC10 (48h): 0.08 mg/L test mat. (meas. (not specified)) based on: cell number (<0.044-0.17) EC90 (24h): >0.72 mg/L test mat. (meas. (not specified)) based on: cell number EC90 (48h): >0.72 mg/L test mat. (meas. (not specified)) based on: cell number EC90 (96h): >0.72 mg/L test mat. (meas. (not specified)) based on: cell number	1 (reliable without restriction) supporting study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference** **Ward, T.J. and R.L. Boeri 1990**
Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and	EC50 (96h): 0.41 mg/L test mat. (meas. (not specified)) based on: cell number (0.36-0.48) EC10 (96h): 0.12 mg/L test mat. (meas. (not specified)) based on: cell number (0.09-	2 (reliable with restrictions) supporting study read-across from supporting substance

cyanobacteria	0.15) EC50 (24h): 0.53 mg/L test mat. (meas. (not specified)) based on: cell number (0.42-0.76) EC50 (48h): 0.44 mg/L test mat. (meas. (not specified)) based on: cell number (0.28-0.55) EC50 (72h): 0.33 mg/L test mat. (meas. (not specified)) based on: cell number (0.16-0.72) EC10 (24h): 0.7 mg/L test mat. (meas. (not specified)) based on: cell number (<0.044-0.12) EC10 (48h): 0.08 mg/L test mat. (meas. (not specified)) based on: cell number (<0.044-0.17) EC90 (24h): >0.72 mg/L test mat. (meas. (not specified)) based on: cell number EC90 (48h): >0.72 mg/L test mat. (meas. (not specified)) based on: cell number EC90 (96h): >0.72 mg/L test mat. (meas. (not specified)) based on: cell number	(structural analogue or surrogate) **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference**
Skeletonema costatum (algae) saltwater toxicity to aquatic algae and cyanobacteria equivalent or similar to EPA OTS 797.1050 (Algal Toxicity, Tiers I and II) ; according to Test Standard 40 CFR 797.1930	EC50 (96h): 0.027 mg/L test mat. (meas. (not specified)) based on: cell number (0.024-0.030 mg/L)	1 (reliable without restriction) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0; 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference** **Ward TJ & Boeri RL 1990**
Skeletonema costatum (algae) saltwater toxicity to aquatic algae and cyanobacteria	EC50 (96h): 0.027 mg/L test mat. (meas. (not specified)) based on: cell number (0.024-0.030 mg/L)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0; 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**).

		Reference
Lemna minor (aquatic plants) freshwater flow-through according to ASTM E1415 - 91(2012) Standard Guide for Conducting Static Toxicity Tests with *Lemna gibba* G3 no data	NOEC (96h): 901 µg/L test mat. (nominal) based on: frond number LOEC (96h): 2080 µg/L test mat. (nominal) based on: frond number EC20 (96h): >2080 µg/L test mat. (nominal) based on: frond number Chronic value (96h): 1369 µg/L test mat. (nominal) based on: frond number (Geometric mean of the NOEC and LOEC)	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
Lemna minor (aquatic plants) freshwater flow-through	NOEC (96h): 901 µg/L test mat. (nominal) based on: frond number LOEC (96h): 2080 µg/L test mat. (nominal) based on: frond number EC20 (96h): >2080 µg/L test mat. (nominal) based on: frond number Chronic value (96h): 1369 µg/L test mat. (nominal) based on: frond number (Geometric mean of the NOEC and LOEC)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Lemna minor (aquatic plants) freshwater flow-through according to ASTM 1991. E1415-91 Standard Guide for Conducting Static Toxicity Tests with *Lemna gibba*.	NOEC (96h): 0.901 mg/L test mat. (meas. (not specified)) based on: frond number LOEC (96h): 2.08 mg/L test mat. (meas. (not specified)) based on: frond number	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0; Nonylphenol, (full information in **Annex II**). **Reference** **Brooke LT 1993**
Lemna minor (aquatic plants) freshwater flow-through	NOEC (96h): 0.901 mg/L test mat. (meas. (not specified)) based on: frond number LOEC (96h): 2.08 mg/L test mat. (meas. (not specified)) based on: frond number	2 (reliable with restrictions) supporting study read-across from

		supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0; Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

Effects on algae / cyanobacteria

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

Two studies were found to be reliable and selected as key studies for this endpoint: ABC Labs (1984) for short-term exposure and Zaytseva et al (2015) for long-term exposure. ABC Labs (1984) studied the effects of a 96-hr exposure of octylphenol to the freshwater algae, *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*). Results showed an EC50 for growth inhibition of 1.9 mg octylphenol/L. Zaytseva et al (2015) exposed several freshwater microalgae to octylphenol for 14 days. The more sensitive chronic value was selected for *M. aeruginosa 973*, with a NOEC for growth rate of 0.45 mg/l.

Value used for CSA:
EC50 for freshwater algae: 1.9mg/L
EC50 for marine water algae:
EC10/LC10 or NOEC for freshwater algae: 0.45mg/L
EC10/LC10 or NOEC for marine water algae:

Additional information:
Two other reliable short-term studies were available for the green microalgae, *Scenedesmus obliquus*, and the diatom, *Skeletonema pseudocostatum* (Zhou et al, 2013 and Petersen et al, 2014). Zhou et al (2013) exposed *S. obliquus* to octylphenol for 5 days and determined a NOEC for growth rate of 2 mg/L. Petersen et al (2014) exposed *S. pseudocostatum* to octylphenol for 72 hours. The EC50 for the diatom based on the growth rate was 0.0000056 mol/L (equivalent to 1.15 mg/l).

A reliable long-term study, Zaytseva et al (2015), was available for a 14-day exposure to octylphenol of several freshwater microalgae: *Oocystis parva*, *Microcystis aeruginosa 973* and *972*, *Oscillatoria agardhii*, *Aphanizomenon flos-aquae*, *Scenedesmus quadricauda*, *Anabaena variabilis* and *Nodularia spumigena*. Results revealed NOECs for growth rate ranging from 0.45 mg/l for *M. aeruginosa 973,* to 1.25 mg/l for *O. parva* and EC50s for growth inhibition ranging from 1.5 mg/l for *M. aeruginosa 972* and *A. flos-aquae,* to 3.75 mg/l for *S. quadricauda*.

No saltwater short or long-term studies with algae are available.

Additional long-term studies were available using a read-across approach from the structural analogue, nonylphenol, to octylphenol. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR). Nonylphenol exposure studies with algae ranged from 72-96 hr and 14 days duration, and reliable data included nine studies representing a wide range of freshwater algae and one study with the marine diatom taxon, *S. costatum* (Bacillariophyta) (Ward and Boeri, 1990).

Long-term (14 days) test results were reported as NOECs and EC50s based on growth rate and ranged, respectively, from 0.14 mg nonylphenol/L for *Nodularia spumigena*, to 0.65 mg nonylphenol/L for *Scenedesmus quadricauda*, and from 0.45 mg nonylphenol/L for *Microcystis aeruginosa* (972), to 2.45 mg nonylphenol/L for *S. quadricauda* (Zaytseva et al, 2015; Medvedeva et al, 2017).

Short-term (72 to 96 and 120 hr) test results were reported as EC50 values based on cell growth or growth rate and ranged from 0.4 mg nonylphenol/L for *P. subcaptata* at 96 hr (Ward and Boeri, 1990) to 1.3 mg nonylphenol/L at 72 hr for *D. subspicatus* (Scholz, 1989). An EC50 concentration of 0.027 mg nonylphenol/L was reported by Ward and Boeri (1990) for cell growth of the marine diatom *S. costatum*.

Discussion

Effects on aquatic plants other than algae

The following information is taken into account for effects on aquatic plants other than algae for the derivation of PNEC:

The NOECs for two reliable studies using *Lemna minor* and exposure to nonylphenol were 0.901 mg/l (Brooke, 1993 and Spehar et al, 2010).

Value used for CSA:
EC50 for freshwater algae:
EC50 for marine water algae:
EC10/LC10 or NOEC for freshwater algae: 0.901mg/L
EC10/LC10 or NOEC for marine water algae:

Additional information:
A read- across approach from nonylphenol to octylphenol is used to determine the toxicity to aquatic plants other than algae. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR). Two reliable studies on exposure of the monocot, *Lemna minor* (*Araceae*), to nonylphenol were reported by Brooke (1993) and Spehar et al (2010), with 96 hr test results based on frond production. The NOEC for *L. minor* frond production was the same in both studies at 0.901 mg nonylphenol/L.

Determination of the NOEC was dependent upon the exposure treatment dilution series in the test.

7.1.4. Sediment organisms

The results are summarised in the following table:

Table 12. Effects on sediment organisms

Method	Results	Remarks
Chironomus riparius freshwater sediment toxicity: long-term (laboratory study) semi-static Sediment: natural sediment according to OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment) Study used the 1998 version of the Guideline	EC10 (28d): 258.9 µg/g dw test mat. (not specified) based on: emergence rate (217.8-285.6) EC10 (28d): 203 µg/g dw test mat. (not specified) based on: emergence rate (59.1-235.2)	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Bettinetti, R. and Provini, A. 2002**
Chironomus riparius freshwater sediment toxicity: long-term (laboratory study) semi-static Sediment: natural sediment	EC10 (28d): 258.9 µg/g dw test mat. (not specified) based on: emergence rate (217.8-285.6) EC10 (28d): 203 µg/g dw test mat. (not specified) based on: emergence rate (59.1-235.2)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue

equivalent or similar to OECD Guideline 218 (Sediment-Water Chironomid Toxicity Test Using Spiked Sediment)		or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Bettinetti, R. and Provini, A. 2002**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Tubifex freshwater sediment toxicity: long-term (laboratory study) semi-static Sediment: natural sediment equivalent or similar to OECD 225 or EPA OPPTS 850.6200 Study references the following as test guidance. Test procedures described in the paper are similar to OECD 225 or EPA OPPTS 850.6200 Reynoldson, T.B., Thompson, S.P., and Bamsey, J.L. (1991). A sediment bioassay using the tubificid oligochaete work *Tubifex tubifex*. Environ. Toxicol. Chem. 10, 1061-1072.	EC10 (28d): 336.7 ug/g dw test mat. (not specified) based on: reproduction - cocoon production (295-384.4) EC10 (28d): 382.7 ug/g dw test mat. (not specified) based on: reproduction - cocoon production (363.7-403.7) EC10 (28d): 335 ug/g test mat. (not specified) based on: reproduction - number of young worms (311.6-360.3) EC10 (28d): 382.8 ug/g test mat. (not specified) based on: reproduction - number of young worms (366-400.4)	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Bettinetti, R. and Provini, A. 2002**
Tubifex tubifex freshwater sediment toxicity: long-term (laboratory study) semi-static Sediment: natural sediment equivalent or similar to OECD 225 or EPA OPPTS 850.6200	EC10 (28d): 336.7 ug/g dw test mat. (not specified) based on: reproduction - cocoon production (295-384.4) EC10 (28d): 382.7 ug/g dw test mat. (not specified) based on: reproduction - cocoon production (363.7-403.7) EC10 (28d): 335 ug/g test mat. (not specified) based on: reproduction - number of young worms (311.6-360.3) EC10 (28d): 382.8 ug/g test mat. (not specified) based on: reproduction - number of young worms (366-400.4)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Bettinetti, R. and Provini, A. 2002**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Leptocheirus plumulosus saltwater sediment toxicity: long-term (laboratory study) static Sediment: natural sediment equivalent or similar to Emery et al. 1997 Study references Emery et al. (1997) as	NOEC (28d): >61.5 mg/kg sediment dw test mat. (meas. (arithm. mean)) based on: mortality NOEC (28d): >61.5 mg/kg sediment dw test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in

the method adapted for use in this study. However, procedures were modified by using a smaller 250 ml test chamber with 50 g wet sediment and 200 ml overlying seawater.		**Annex II**). **Reference** **Zulkosky, A.M., Ferguson, P.L. , McElroy, A.E. 2002**
Leptocheirus plumulosus saltwater sediment toxicity: long-term (laboratory study) static Sediment: natural sediment	NOEC (28d): >61.5 mg/kg sediment dw test mat. (meas. (arithm. mean)) based on: mortality NOEC (28d): >61.5 mg/kg sediment dw test mat. (meas. (arithm. mean)) based on: reproduction	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for sediment toxicity for the derivation of PNEC:

A read-across approach from supporting substance (structural analogue or surrogate) from nonylphenol to octylphenol is used to evaluate the OP sediment toxicity. The read-across justification is provided in a separate report in the original CSR (Section 13) of the CSR. The selected key study was Bettinetti and Provini (2002), which provided a 28-day EC10 of 231 mg nonylphenol/kg dw, based on inhibition of *Chironomus riparius* emergence. This value is the mean of two test results, 203 and 259 mg/kg dw.

Value used for CSA:
EC50 or LC50 for freshwater sediment:
EC50 or LC50 for marine water sediment:
EC10, LC10 or NOEC for freshwater sediment: 231mg/kg sediment dw
EC10, LC10 or NOEC for marine water sediment: 61.5mg/kg sediment dw

Additional information:
A review of reports for nonylphenol exposure to sediment organisms resulted in selection of two reliable studies that included two freshwater organisms and one marine organism. The study of nonylphenol exposure to *Chironomus riparius* and *Tubifex tubifex* in spiked sediment tests by Bettinetti and Provini (2002) was selected as the key study because it provided calculated EC10 concentrations for endpoints derived from duplicate tests for more than one sediment organism. The EC10 concentration is accepted as an equivalent substitute for the NOEC value, and has the added benefit of being a calculated response-based concentration, rather than an estimate derived from the treatment dilution series. The average EC10 concentration reported in the key study for inhibition of *C. riparius* emergence was 231 mg nonylphenol/Kg dw, which was comparable to an average EC10 concentration of 360 and 359 mg nonylphenol/Kg dw for production of cocoons and production of young worms, respectively, for *T. tubifex* (Bettinetti and Provini 2002).

Another supporting study by Zulkosky et al (2002) was available presenting a 28 -day NOEC for *Leptocheirus plumulosus*, a marine benthic crustacean. Survival and reproduction from exposure to nonylphenol was reported to be > 61.5 mg nonylphenol/Kg dw for both endpoints.

7.1.5. Other aquatic organisms

The results are summarised in the following table:

Table 13. Effects on other aquatic organisms

Method	Results	Remarks
Xenopus laevis freshwater - Lake Superior Water (LSW) initially filtered through sand, UV sterilized and filtered again to 5 µm before entering the in-house culture or exposure aquaria flow-through according to OECD Test No. 241: The Larval Amphibian Growth and Development Assay (LAGDA)	NOEC (10wk): 50 µg/L test mat. (nominal) based on: survival and growth	1 (reliable without restriction) key study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Jonathan T. Haselman, Patricia A. Kosian, Joseph J. Korte, Allen W. Olmstead, Taisen Iguchi, Rodney D. Johnson and Sigmund J. Degitz 2016**
Dreissena polymorpha freshwater semi-static no guideline available	NOEC (50d): 0.1 mg/L test mat. (nominal) based on: all parameters measured (NOEC is inferred) LC10 (50d): 0.68 mg/L not specified (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Quinn, B., Gagne, F., Blaise, C., Costello, M., Wilson, J.G., Mothersill, C. 2006**
Dreissena polymorpha freshwater semi-static	NOEC (50d): 0.1 mg/L test mat. (nominal) based on: all parameters measured (NOEC is inferred) LC10 (50d): 0.68 mg/L not specified (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material**

		4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Bombina orientalis freshwater semi-static equivalent or similar to Test No. 241: The Larval Amphibian Growth and Development Assay (LAGDA) - Principle of test: elucidate the mechanisms of endocrine disruption by alkylphenols in this amphibian species, we examined the effects of NP on the survival and early development resorption during T3-induced metamorphosis in *B. orientalis*	NOEC (240h): 0.1 µmol/L test mat. (nominal) based on: mortality - embryos NOEC (7d): 0.1 µmol/L test mat. (nominal) based on: changes in tail length tadpoles LOEC (240h): 1 µmol/L test mat. (nominal) based on: mortality LOEC (216h): 0.1 µmol/L test mat. (nominal) based on: body length (lower concentration tested)	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Chan Jin Park, Han Seung Kang, Myung Chan Gye 2010**
Bombina orientalis freshwater semi-static	NOEC (240h): 0.1 µmol/L test mat. (nominal) based on: mortality - embryos NOEC (7d): 0.1 µmol/L test mat. (nominal) based on: changes in tail length tadpoles LOEC (240h): 1 µmol/L test mat. (nominal) based on: mortality LOEC (216h): 0.1 µmol/L test mat. (nominal) based on: body length (lower concentration tested)	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for any hazard / risk assessment:
A study was performed to assess the effect of the test material on the survival and growth rate of the African frog, *Xenopus laevis*, over a 10 -weeks period. The study followed the OECD Guideline Test No. 241: The Larval Amphibian Growth and Development Assay (LAGDA) and so is reliable without restrictions (Klimisch 1). Analytical measurement data of test material were performed and revealed recoveries of spiked samples around 90% for all the treatments. Exposure of the frogs to octylphenol did not affect their survival or growth rate, resulting in a NOEC > 0.050 mg/l.

7.2. Terrestrial compartment

Additional information:

Read Across
Reliable studies regarding toxicity of nonylphenol to terrestrial organisms were used according to a read-across approach to fill data requirements for octylphenol for these endpoints. Argumentations based on the structure of the substances, purity and reliability of studies were the same as for aquatic organisms and are presented in more detail in the Read-Across Report in the original AfA (Section 13 of the CSR). It is reasonable to assume that the trends in toxicity between nonylphenol and octylphenol seen in aquatic organisms will be reflected in the toxicities between nonylphenol and octylphenol in terrestrial organisms. The approach is considered scientifically justified and appropriately conservative.

Structure
A structural analogue is a source chemical whose physico-chemical and toxicological properties are likely to be similar to the target chemical as a result of structural similarity. The structural similarity and similar properties between nonylphenol and octylphenol support consideration of these substances as structural analogues for the purpose of read-across. Thus, endpoint information is read-across between structural analogues.

The similarity between nonylphenol and octylphenol is based on their structural likeness (→similar chain length: eight and nine C-atoms for octylphenol and nonylphenol, respectively) and their common functional group (→phenol group). Octylphenol and nonylphenol display very similar physico-chemical properties that determine environmental distribution and fate (e.g. molecular weight, partition coefficients such as log Kow, water solubility) and ecotoxic effects.

Toxicity
In the absence of reliable toxicity data for sediment and soil organisms, the aquatic toxicity of the two substances was compared (data are summarised in the Aquatic Toxicity endpoint. The data for both short- and long-term toxicity are within the same orders of magnitude with comparable ranges of toxicity. It would be reasonable to assume that comparable ranges of toxicity between octylphenol and nonylphenol would also be exhibited by sediment and soil organisms. Accordingly, reliable nonylphenol sediment and soil toxicity data are used to fill the data gap for octylphenol sediment and soil toxicity. Reliable data for nonylphenol toxicity to aquatic organisms is also used in the calculation of the PNECsediment and PNECsoil for octylphenol.

A comparison of ecotoxicity data for the same aquatic species (where available) exposed to octylphenol and nonylphenol		
Species and Type of Test	**Nonylphenol toxicity range (mg/L)**	**Octylphenol toxicity range (mg/L)**
Ceriodaphnia sp. 48 hr L(E)C50	0.02 to 0.47	0.07 to 0.28
Americamysis bahia 96 hr LC50	0.043 to 0.06	0.048 to 0.113
Oncorhynchus mykiss 96 hr LC50	0.11 to 0.22	>0.1
Fundulus heteroclitus 96 hr LC50	0.26 to 5.44	0.29 to 3.86
Selenastrum capricornutum 96hr EC50	0.41	1.9
Scenedesmus obliquus 120 hr NOEC	2	2
Daphnia magna 21-d NOEC	0.013 to 0.12	0.03
Fish NOEC	>0.0019 to 0.078	0.012 to 0.035
Microcystis aeruginosa 973 14 d NOEC	0.2	0.45
Oocystis parva 14 d NOEC	0.6	1.25

Microcystis aeruginosa 972 14 d NOEC	0.2	0.5

Reliability, Adequacy and Accuracy of the Source Studies
All of the ecotoxicity studies used in the CSR were carried out in accordance with OECD or similar guidelines and scored a Klimisch 1 or 2. In particular, the aquatic studies were consistent indicating that octylphenol is ecotoxic to aquatic organisms. These studies are considered to be reliable for use in read-across between nonylphenol and octylphenol.

Evaluation of the purity and impurity profiles of the Test Substance
The purity of octylphenol used in the key studies for ecotoxicological endpoints ranged from 98.97 to 100%. The purity of nonylphenol used in key studies was 85 to 100%, with all but one study being ≥90% purity. Impurities were not reported in these ecotoxicity studies evaluated for the CSR. Because of the high purity of the test substance, impurities probably have a negligible or no impact on the ecotoxicity of octylphenol.
In summary, nonylphenol and octylphenol are similar in structural composition and both exert similar short- and long-term toxic effects to aquatic organisms. The studies used to make these comparisons are highly reliable (Klimisch 1 or 2) and the nonylphenol and octylphenol test substance in toxicity studies were of high purity. Therefore, it is considered scientifically appropriate for terrestrial toxicity data relating to NP studies to be read-across to octylphenol endpoints and used in PNECsoil derivation.

Terrestrial Toxicity Data
The review of nonylphenol exposure to terrestrial organisms resulted in reliable toxicity test studies on terrestrial species of soil invertebrates, plants and soil micro-organisms. From the limited reliable data available, soil invertebrates were more sensitive to the toxic effects of nonylphenol than terrestrial plants and micro-organisms for acute, short-term exposures, and the relative sensitivity between soil invertebrates and plants was an order of magnitude different (L(E)C50 for earthworm survival and plant growth were 88.6 and 559 mg nonylphenol/L, respectively).

Toxicity data for long-term exposure to nonylphenol indicated the lowest Key Study NOEC or EC10 value of 23 mg nonylphenol/kg soil for reproduction in the Collembolan (*Folsomia fimetaria*) by Scott-Fordsmand et al (2004). The lowest Key Study NOEC or EC10 for plants based on fresh weight was field mustard (*Brassica rapa*) of 574.8 mg nonylphenol/kg using artificial soils (Domene et al, 2009). As in short-term toxicity studies, soil invertebrates were more sensitive than plants to long-term nonylphenol exposures.

A single study was available for avian toxicity, where the test substance was octylphenol. No effects were seen in zebra finches (*Taeniopygia guttata*) for a number of reproductive endpoints at 100 nmol/g body mass per day (Millamet al, 2001).

7.2.1. Toxicity to soil macro-organisms

The results are summarised in the following table:

Table 14. Effects on soil macro-organisms

Method	Results	Remarks
Enchytraeus crypticus (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to ISO Guideline 16387 Soil Quality - effects of pollutants on Enchytraeidae (*Enchytraeus sp.*) - determination of effects on survival and reproduction. Guideline No. 16387. International Organisation for Standardisation, Geneva, pp 1-22 (ISO	EC10 (4wk): 24 mg/kg soil dw test mat. (nominal) based on: reproduction ((5.2, 110.7))	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**).

2003)		**Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008**
Enchytraeus crypticus (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to ISO Guideline 16387 Soil Quality - effects of pollutants on Enchytraeidae (*Enchytraeus sp.*) - determination of effects on survival and reproduction. Guideline No. 16387. International Organisation for Standardisation, Geneva, pp 1-22 (ISO 2003)	EC10 (4wk): 24 mg/kg soil dw test mat. (nominal) based on: reproduction ((5.2, 110.7))	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Eisenia sp. [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to ISO 11268-2 (Effects of Pollutants on Earthworms. 2. Determination of Effects on Reproduction)	NOEC (8wk): 100 mg/kg soil dw test mat. (nominal) based on: Mean number of live juvenile earthworms (offspring)	2 (reliable with restrictions) key study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Johnson I., Weeks J.M. & Kille P. 2005**
Eisenia sp. [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to ISO 11268-1 (Effects of Pollutants on Earthworms. 1. Determination of Acute Toxicity Using Artificial Soil Substrate)	NOEC (8wk): 100 mg/kg soil dw test mat. (nominal) based on: Mean number of live juvenile earthworms (offspring)	2 (reliable with restrictions) key study experimental study **Test material** Nonylphenol, (full information in **Annex II**).

		Reference **Johnson I., Weeks J.M. & Kille P. 2005**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Eisenia sp. [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: short-term (laboratory study) Substrate: artificial soil according to ISO 11268-1 (Effects of Pollutants on Earthworms. 1. Determination of Acute Toxicity Using Artificial Soil Substrate)	LC50 (14d): 88.6 mg/kg soil dw test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Johnson I., Weeks J.M. & Kille P. 2005**
Eisenia sp. [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: short-term (laboratory study) Substrate: artificial soil	LC50 (14d): 88.6 mg/kg soil dw test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Eisenia sp. [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to ISO 11268-2 (Effects of Pollutants on Earthworms. 2. Determination of Effects on Reproduction)	EC10 (8wk): 55.8 mg/kg soil dw test mat. (nominal) based on: reproduction	1 (reliable without restriction) supporting study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008**
Eisenia sp. [Annelida] (annelids) toxicity to soil macroorganisms except	EC10 (8wk): 55.8 mg/kg soil dw test mat. (nominal) based on: reproduction	2 (reliable with restrictions)

arthropods: long-term (laboratory study) Substrate: artificial soil		supporting study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Eisenia andrei [Annelida] (Clitellata) toxicity to soil macroorganisms except arthropods: short-term (laboratory study) Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt) according to OECD Guideline 207 (Earthworm, Acute Toxicity Tests)	NOEC (7d): 1700 mg/kg soil dw test mat. (nominal) based on: normalcy (survival, mucous secretion, bleeding, swelling, thinning, and fragmentation) EC50 (7d): 1828 mg/kg soil dw test mat. (nominal) based on: normalcy (survival, mucous secretion, bleeding, swelling, thinning, and fragmentation) (95% C.I. (1779-1878))	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Eisenia andrei [Annelida] (Clitellata) toxicity to soil macroorganisms except arthropods: short-term (laboratory study) Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt)	NOEC (7d): 1700 mg/kg soil dw test mat. (nominal) based on: normalcy (survival, mucous secretion, bleeding, swelling, thinning, and fragmentation) EC50 (7d): 1828 mg/kg soil dw test mat. (nominal) based on: normalcy (survival, mucous secretion, bleeding, swelling, thinning, and fragmentation) (95% C.I. (1779-1878))	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Dendrabaena octaedra (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: natural soil no guideline followed - Principle of test: The aim of the study was to investigate the sensitivity of *D. octaedra* to NP applied alone and in combination with stressfully high or low temperatures. The effects were quantified in terms of mortality as well as sublethal	EC50 (14d): 53 mg/kg soil dw test mat. (estimated) based on: reproduction LC50 - at 25 C (28d): 308 mg/kg soil dw test mat. (estimated) based on: mortality LC50 - at 31 C (28d): 190 mg/kg soil ww test mat. (estimated) based on: mortality LC50 - at 33C 40 mg/kg soil dw test mat. (estimated) based on: mortality LC50 - at 1.4 C (28d): 535 mg/kg soil ww test mat. (estimated) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**).

endpoints including body weight and reproduction. - Short description of test conditions: worms were placed in containers with dry soil and exposed to NP for 28 days at 1.4 °C, followed by exposure to either 1.4 °C or sub-zero temperatures. Worms were kept frozen for 8 days, then thawed for 24 hours, and survival was assessed. Both fresh weight and number of cocoons were assessed every 14 days. - Parameters analysed / observed: Survival, reproduction		**Reference** **Dorthe Jensen, Mark Bayley, Martin Holmstrup 2009**
Dendrabaena octadra (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: natural soil	EC50 (14d): 53 mg/kg soil dw test mat. (estimated) based on: reproduction LC50 - at 25 C (28d): 308 mg/kg soil dw test mat. (estimated) based on: mortality LC50 - at 31 C (28d): 190 mg/kg soil ww test mat. (estimated) based on: mortality LC50 - at 33C 40 mg/kg soil dw test mat. (estimated) based on: mortality LC50 - at 1.4 C (28d): 535 mg/kg soil ww test mat. (estimated) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Caenorhabditis elegans [Nematoda] (nematods) toxicity to soil macroorganisms except arthropods: short-term (laboratory study) Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt) according to ASTM International. 2001. Standard guide for conducting laboratory soil toxicity tests with the nematode *Caenorhabditis elegans*. E2172-01. West Conshohocken, PA, USA. DOI: 10.1520/E2172-01R08; according to International Organization for Standardization. 2010. Water quality—Determination of the toxic effect of sediment and soil samples on growth, fertility and reproduction of *Caenorhabditis elegans* (Nematoda). ISO 10872:2010. Geneva, Switzerland	NOEC (24h): 10 mg/kg soil dw test mat. (nominal) based on: reproduction EC50 (24h): 140 mg/kg soil dw test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Caenorhabditis elegans [Nematoda] (nematods) toxicity to soil macroorganisms except arthropods: short-term (laboratory study) Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt)	NOEC (24h): 10 mg/kg soil dw test mat. (nominal) based on: reproduction EC50 (24h): 140 mg/kg soil dw test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical

		mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Eisenia fetida [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil according to BBA Guideline VI, 2-2 ISO/DIS 1126-2 not applicable	NOEC (28d): >56 mg/kg soil dw test mat. (nominal) based on: mortality NOEC (28d): >56 mg/kg soil dw test mat. (nominal) based on: growth NOEC (28d): >56 mg/kg soil dw test mat. (nominal) based on: reproduction	1 (reliable without restriction) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Debra Teixeira 2002**
Eisenia fetida [Annelida] (annelids) toxicity to soil macroorganisms except arthropods: long-term (laboratory study) Substrate: artificial soil	NOEC (28d): >56 mg/kg soil dw test mat. (nominal) based on: mortality NOEC (28d): >56 mg/kg soil dw test mat. (nominal) based on: growth NOEC (28d): >56 mg/kg soil dw test mat. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods, other - short and long term studies (laboratory study) according to OECD Guideline 232 (Collembolan Reproduction Test in Soil); according to - Principle of test: In the *F. candida* assay, chronic effects of nonylphenol were evaluated at 21 days, respectively. A total of 10 juvenile *F. candida* (aged 9–10 days) were exposed, and adult survival was recorded after 14 days. Subsequently, the number of *F. candida* offspring was	NOEC (28d): 100 mg/kg soil dw test mat. (nominal) based on: reproduction EC10 (28d): 88 mg/kg soil dw test mat. (nominal) based on: reproduction (95% C.I. (1.2–125)) EC50 (14d): 123 mg/kg soil dw test mat. (nominal) based on: mortality (95% C.I. (115–132))	2 (reliable with restrictions) key study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**

observed after 28 days. Test vials were maintained in an incubator at 20 °C under dark conditions. - Parameters analysed / observed: number of offspring		
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods, other - short and long term studies (laboratory study) according to OECD Guideline 232 (Collembolan Reproduction Test in Soil) ; according to - Principle of test: In the *F. candida* assay, chronic effects of nonylphenol were evaluated at 21 days, respectively. A total of 10 juvenile *F. candida* (aged 9-10 days) were exposed, and adult survival was recorded after 14 days. Subsequently, the number of *F. candida* offspring was observed after 28 days. Test vials were maintained in an incubator at 20 °C under dark conditions. - Parameters analysed / observed: number of offspring	NOEC (28d): 100 mg/kg soil dw test mat. (nominal) based on: reproduction EC10 (28d): 88 mg/kg soil dw test mat. (nominal) based on: reproduction (95% C.I. (1.2-125)) EC50 (14d): 123 mg/kg soil dw test mat. (nominal) based on: mortality (95% C.I. (115-132))	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Folsomia sp. [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) equivalent or similar to ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants) Although the author does not explicitly reference an OECD or ISO Guideline, the author does state that the aim of the study is to evaluate the lethal and sublethal toxicity of NP to the springtail as performed in standard tests used in risk assessment. The test is described in similar terms to a standard Collembolan test, although the duration is one week shorter than the standard duration of 28 days.	EC10 (21d): 23 mg/kg soil dw test mat. (nominal) based on: reproduction	2 (reliable with restrictions) key study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Scott-Fordsmand J.J., Henning Krogh P. 2004**
Folsomia sp. [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) equivalent or similar to ISO 11267	EC10 (21d): 23 mg/kg soil dw test mat. (nominal) based on: reproduction	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate)

(Inhibition of Reproduction of Collembola by Soil Pollutants)		**Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Scott-Fordsmand J.J., Henning Krogh P. 2004**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) according to ISO 11267 (Inhibition of Reproduction of Collembola by Soil Pollutants)	EC10 (28d): 63.2 mg/kg soil dw test mat. (nominal) based on: reproduction ((47.3, 84.5))	1 (reliable without restriction) supporting study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X, Ramirez W, Sola L, Alcaniz J & Andres P. 2008**
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study)	EC10 (28d): 63.2 mg/kg soil dw test mat. (nominal) based on: reproduction ((47.3, 84.5))	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) equivalent or similar to ISO 11267	NOEC (64d): 32 mg/kg soil dw test mat. (nominal) based on: Survival	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full

(Inhibition of Reproduction of Collembola by Soil Pollutants)		information in **Annex II**). **Reference** **Widarto T.H., Krogh P.H., Forbes V.E. 2007**
Folsomia candida [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: toxicity to terrestrial arthropods: long-term (laboratory study)	NOEC (64d): 32 mg/kg soil dw test mat. (nominal) based on: Survival	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Folsomia sp. [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: Artificial Soil (LUFA) toxicity to terrestrial arthropods: long-term (laboratory study) no guideline available No Data	EC10 (21d): 24 mg/kg soil ww test mat. (not specified) based on: reproduction	4 (not assignable) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Hansen B.G., Munn S.J., De Bruijn J., Pakalin S., Luotamo M., Berthault F., Vegro S., Heidorn C.J.A., Pellegrini K., Vormann K., Allanou R., & Scheer S. 2002**
Folsomia sp. [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: toxicity to terrestrial arthropods: long-term (laboratory study)	EC10 (21d): 24 mg/kg soil ww test mat. (not specified) based on: reproduction	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-

		672-0, (full information in **Annex II**). **Reference**
Folsomia sp. [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: long-term (laboratory study) no guideline available No Data	EC10 (21d): 27 mg/kg soil ww test mat. (not specified) based on: reproduction	4 (not assignable) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Hansen B.G., Munn S.J., De Bruijn J., Pakalin S., Luotamo M., Berthault F., Vegro S., Heidorn C.J.A., Pellegrini K., Vormann K., Allanou R., & Scheer S. 2002**
Folsomia sp. [Collembola (soil-dwelling springtail)] (Collembola (soil-dwelling springtail)) Application method: toxicity to terrestrial arthropods: long-term (laboratory study)	EC10 (21d): 27 mg/kg soil ww test mat. (not specified) based on: reproduction	4 (not assignable) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference**
Lobella sokamensis (Collembola (soil-dwelling springtail)) Application method: soil toxicity to terrestrial arthropods: short-term (laboratory study) according to OECD Guideline 232 (Collembolan Reproduction Test in Soil)	EC50 (5d): >250 mg/kg soil dw test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**

		Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017
Lobella sokamensis (Collembola (soil-dwelling springtail)) Application method: toxicity to terrestrial arthropods: short-term (laboratory study)	EC50 (5d): >250 mg/kg soil dw test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion of effects on soil macro-organisms except arthropods

The following information is taken into account for effects on soil macro-organisms except arthropods for the derivation of PNEC:

A read-across approach from the structural analogue, nonylphenol, to octylphenol is used to evaluate the octylphenol toxicity to soil macro-organisms. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR).

The Johnson et al (2005) short-term LC50 of 88.6 mg nonylphenol/kg for *Eisenia andrei* survival meets reliability ownership and adequacy requirements for REACH. The study uses the preferred test species and the preferred test medium, artificial soil. The long-term study of Domene et al (2009) followed international OECD and ISO protocols, uses standard test species and achieves the highest Klimisch rating. Long-term exposure of *Enchytraeus crypticus* reported an EC10 of 24 mg nonylphenol/kg.

Value used for CSA:
Short-term EC50 or LC50 for soil macro-organisms: 88.6mg/kg soil dw
Long-term EC10/LC10 or NOEC for soil macro-organisms: 24mg/kg soil dw

Additional information:
Three reliable studies were available for short-term exposure to soil macro-organisms except arthropods, resulting in a wide range of L(E)50s from 88.6 to 1828 mg nonylphenol/kg. Kwak et al (2017) exposed the preferred earthworm species, *Eisenia andrei*, to nonylphenol for 7 days with a reported EC50 for survival, mucous secretion, bleeding, swelling, thinning, and fragmentation of 1828 mg/kg dw soil and a NOEC of 1700 mg/kg dw soil. Johnson et al (2005) exposed the earthworm, *Eisenia andrei*, to nonylphenol for 7 days with a reported EC50 for survival, mucous secretion, bleeding, swelling, thinning, and fragmentation of 1828 mg/kg dw soil and a NOEC of 1700 mg/kg dw soil. Johnson et al. (2005) exposed the earthworm for 14 days to NP, and estimated a NOEC and LOEC, based on survival, of 32 and 100 mg/kg, respectively. Ramboll UK Ltd calculated an LC50 of 88.6 mg nonylphenol/kg for the survival data using Probit statistical analysis. The derivation of an LC50 means the macroinvertebrate data are more easily comparable with the other short-term study for plants (see Hulzebos et al, 1993), where macroinvertebrates appeared to be more sensitive than plants.

Four studies representing five endpoints were reported for long-term macroinvertebrate exposures to nonylphenol, resulting in NOEC or EC10 values ranging from 24 to 100 mg nonylphenol/kg and of the annelids, *Dendrabaena octadra,*, an EC50 for reproduction (14 days) and mortality (28 days) of 53 and 308 mg nonylphenol/kg, respectively. Teixeira (2002) exposed the annelids, *Eisenia fetida*, for 56 days to nonylphenol and did not record any detrimental effects, estimating a NOEC for reproduction, growth and mortality > 56 mg nonylphenol/kg (the highest concentration tested). Johnson et al (2005) and Domene et al (2009) carried out 8-week earthworm (*Eisenia andreii*) reproduction studies using nonylphenol spiked artificial soil exposures. In addition, the Johnson et al (2005) study did not record any effects on reproduction at the highest concentration tested (NOEC = 100 mg/kg) but the Domene et al (2009) study statistically derived a more robust EC10 of 55.8 mg/kg. Domene et al (2009) also studied reproduction in *Enchytraeus crypticus* and statistically derived an EC10 of 24 mg nonylphenol/kg. The *E. crypticus* duration was 4 weeks and slightly shorter in duration than the standard 6-week duration of the standard ISO Guideline, but this is still considered to be acceptable, as this smaller enchytraeid species' breeding cycle was completed.

In addition, Domene et al (2009) compared the standard toxicity tests between OECD artificial soils and two natural soils. In the earthworm tests, where reproduction in the OECD artificial soil was affected at the 10% level, leading to an EC10 of 55.8 mg/kg, the loamy sand soil from dry grassland affected reproduction at 43.1 mg/kg (more sensitive), but the agricultural loamy soil was less sensitive with an EC10 of 63.6 mg/kg. However, when the enchytraeid study was compared, both natural soils reported far less sensitive values than the OECD soil; 455.8 and 197.2 mg/kg, compared to the EC10 of 24 mg/kg in the OECD soil. The inconsistency in trends between natural and artificial soils means that the artificial soils are preferred for use in this REACH dossier to ensure studies are comparable where possible.

The long-term study of Domene et al (2009) for *E. crypticus*, with an EC10 of 24 mg nonylphenol/kg, is the key study for this endpoint and is supported by the less sensitive long-term and short-term earthworm studies.

Discussion of effects on soil dwelling arthropods

The following information is taken into account for effects on soil dwelling arthropods for the derivation of PNEC:

A read-across approach from the structural analogue nonylphenol to octylphenol to evaluate the octylphenol toxicity to terrestrial arthropods. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR).

Kwak et al (2017) was selected as key study for short-term exposure to terrestrial arthropods. The selected key value was the EC50 for mortality of 123 mg nonylphenol/kg for exposure of *Folsomia candida* to NP for 14 days. The key study by Scott-Fordsmand et al (2004) reported an EC10 based on *Folsomia fimetaria* reproduction of 23 mg nonylphenol/kg. This study is reliable with restriction, using the *Folsomia* genus, an oven-dried soil, and is equivalent to an international ISO protocol. Importantly, this is the lowest EC10 in the reliable dataset.

Value used for CSA:
Short-term EC50 or LC50 for soil dwelling arthropods: 123mg/kg soil dw
Long-term EC10/LC10 or NOEC for soil dwelling arthropods: 23mg/kg soil dw

Additional information:
The reliable Kwak et al (2017) study reported also short-term exposure results to the collembola, *Lobella sokamensis*. Exposure of *L. sokamensis* to nonylphenol for 5 days resulted in an EC50 of >250 mg nonylphenol/kg, with no mortality at the highest concentration tested.

There were six reliable studies relating to the long-term exposure of arthropods to nonylphenol. Two studies met the strict adequacy requirements of the IUCLID Robust Study Summary; these were the Scott-Fordsmand et al (2004) and the Domene et al (2009) studies. The long-term data for Collembola species ranged from 23 to 63.2 mg nonylphenol/kg, with test durations ranging from 21 to 64 days.

Four studies provided comparable data for *Folsomia sp.* exposure to nonylphenol for 21 or 28 days, with EC10 values of 23, 24, 27 and 88 mg nonylphenol/kg, relating to the studies by Scott-Fordsmand and Krogh (2004), Krogh (1996), Holm (undated, but reported in the nonylphenol EU Risk Assessment Report, 2002) and Kwak et al. 2017. Ramboll UK has not been able to review the Krogh (1996) and Holm studies directly, but the data from these studies is taken directly from the EURAR (2002) and is offered as supporting information here. The study by Widarto et al (2007) presented a 64-day NOEC value, based on survival on *F. candida*, of 32 mg nonylphenol/kg. These four studies correspond closely to each other and provide strong evidence that no-effect or EC10 levels for Collembola are between 23 and 32 mg/kg.

Three studies [Widarto et al (2007), Krogh (1996) and Holm (undated)], whilst considered acceptable for REACH purposes, were classified as ‘reliable with restrictions’ (Klimisch 2), as the studies were all shorter than the standard duration (28 days) and lacked crucial information, such as the purity of the chemical. The studies considered to provide adequate information for a Robust Study Summary, whilst being reliable, were those by Scott-Fordsmand et al (2004), Domene et al (2009) and Kwak et al (2017). The Kwak et al (2017) study reported a long-term toxicity (28 days) EC10 and a NOEC of 88 and 100 mg nonylphenol/kg, respectively. The Scott-Fordsmand et al (2004) study reported a *F. fimetaria* long-term toxicity EC10 of 23 mg/kg. The Domene et al (2009) study reported *F. candida*, the preferred test species, was exposed to nonylphenol in artificial soil for the recommended duration of 28 days. The resulting EC10 was 63.2 mg nonylphenol/kg. However, the Scott-Fordsmand et al. (2004) study is recommended as the key study as this represents the most sensitive toxicity data and is supported by the evidence of similar or slightly higher toxicity-based NOEC/EC10 values. The study meets the reliability and adequacy requirements of REACH.

7.2.2. Toxicity to terrestrial plants

The results are summarised in the following table:

Table 15. Effects on terrestrial plants

Method	Results	Remarks
Lactuca sativa (Dicotyledonae (dicots)) toxicity to terrestrial plants: short-term (laboratory study) early seedling growth toxicity test Substrate: natural soil according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]	*Lactuca sativa* EC50 (7d): 559 mg/kg soil dw test mat. (nominal) based on: growth	2 (reliable with restrictions) key study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Hulzebos E.M., Adema D.M.M., Dirven-Van Breemen., Henzen L., Van Dis W.A., Herbold H.A., Hoekstra J.A., Baerselman R. & Van Gestel C.A.M 1993**
Lactuca sativa (Dicotyledonae (dicots)) toxicity to terrestrial plants: short-term (laboratory study) early seedling growth toxicity test Substrate: natural soil according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]	*Lactuca sativa* EC50 (7d): 559 mg/kg soil dw test mat. (nominal) based on: growth	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference**

		Hulzebos E.M., Adema D.M.M., Dirven-Van Breemen., Henzen L., Van Dis W.A., Herbold H.A., Hoekstra J.A., Baerselman R., & Van Gestel C.A.M. 1993
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Brassica rapa (Dicotyledonae (dicots)) toxicity to terrestrial plants: long-term (laboratory study) seedling emergence toxicity / vegetative vigour test Substrate: artificial soil according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006] Not relevant	*Brassica rapa* EC10 (15d): 574.8 mg/kg soil dw test mat. (nominal) based on: Fresh weight of seedling ((279.9, 1180.4))	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008**
Brassica rapa (Dicotyledonae (dicots)) toxicity to terrestrial plants: long-term (laboratory study) seedling emergence toxicity / vegetative vigour test Substrate: artificial soil according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]	*Brassica rapa* EC10 (15d): 574.8 mg/kg soil dw test mat. (nominal) based on: Fresh weight of seedling ((279.9, 1180.4))	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X, Ramirez W, Sola L, Alcaniz J & Andres P. 2008**

Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Lolium perenne (Monocotyledonae (monocots)) toxicity to terrestrial plants: long-term (laboratory study) seedling emergence toxicity / vegetative vigour test Substrate: artificial soil according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006] Not relevant	*Lolium perenne* EC10 (15d): 738.9 mg/kg soil dw test mat. (nominal) based on: Fresh weight of seedling ((49.6, 11011.2))	1 (reliable without restriction) supporting study experimental study **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009** **Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008**
Lolium perenne (Monocotyledonae (monocots)) toxicity to terrestrial plants: long-term (laboratory study) seedling emergence toxicity / vegetative vigour test Substrate: artificial soil	*Lolium perenne* EC10 (15d): 738.9 mg/kg soil dw test mat. (nominal) based on: Fresh weight of seedling ((49.6, 11011.2))	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-nonylphenol (technical grade), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Lactuca sativa (Dicotyledonae (dicots)) toxicity to terrestrial plants: long-term (laboratory study) early seedling growth toxicity test Substrate: natural soil	*Lactuca sativa* EC50 (14d): 625 mg/kg soil dw test mat. (nominal) based on: growth	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Lactuca sativa (Dicotyledonae (dicots)) toxicity to terrestrial plants: long-term (laboratory study) early seedling growth toxicity test Substrate: natural soil	*Lactuca sativa* EC50 (14d): 625 mg/kg soil dw test mat. (nominal) based on: growth	2 (reliable with restrictions) supporting study read-across from supporting substance

according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]		(structural analogue or surrogate) **Test material** Nonylphenol, (full information in **Annex II**). **Reference** **Hulzebos E.M., Adema D.M.M., Dirven-Van Breemen., Henzen L., Van Dis W.A., Herbold H.A., Hoekstra J.A., Baerselman R. & Van Gestel C.A.M. 1993**
Oryza sativa (Poaceae) toxicity to terrestrial plants, other - short and long-term studies (laboratory study) seedling emergence and seedling growth test Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt) according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]	*Oryza sativa* EC50 (14d): 1793 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition *Oryza sativa* EC10 (21d): 1433 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition (95% C.I. (1315-1515)) *Oryza sativa* NOEC (21d): 1500 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Oryza sativa (Poaceae) toxicity to terrestrial plants, other - short and long-term studies (laboratory study) seedling emergence and seedling growth test Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt)	*Oryza sativa* EC50 (14d): 1793 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition *Oryza sativa* EC10 (21d): 1433 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition (95% C.I. (1315-1515)) *Oryza sativa* NOEC (21d): 1500 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Vigna radiata (Magnoliopsida) toxicity to terrestrial plants, other - short and long-term studies (laboratory study) seedling emergence and seedling growth test Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt) according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]	*Vigna radiata* EC50 (14d): >2000 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition *Vigna radiata* EC10 (21d): 1822 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition *Vigna radiata* NOEC (21d): >2000 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Vigna radiata (Magnoliopsida) toxicity to terrestrial plants, other - short and long-term studies (laboratory study) seedling emergence and seedling growth test Substrate: natural soil - LUFA 2.2 (Landwirtschaftliche Untersuchungs and Forschungsanstalt)	*Vigna radiata* EC50 (14d): >2000 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition *Vigna radiata* EC10 (21d): 1822 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition *Vigna radiata* NOEC (21d): >2000 mg/kg soil dw test mat. (nominal) based on: shoot growth inhibition	2 (reliable with restrictions) supporting study read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for toxicity on terrestrial plants for the derivation of PNEC:

A read-across approach from the structural analogue, nonylphenol, to octylphenol is used to evaluate the octylphenol toxicity to terrestrial plants. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR).

A 7-day short-term toxicity test using *Lactuca sativa* reported an EC50 for growth of 559 mg nonylphenol/kg (Hulzebos et al, 1993). The key information for long-term effects to plant relates to the Domene et al (2009) study, where the most sensitive endpoint was a test on *Brassica rapa,* with an EC10, based on fresh weight of seedling, of 574.8 mg nonylphenol/kg.

Value used for CSA:
Short-term EC50 or LC50 for terrestrial plants: 559mg/kg soil dw
Long-term EC10/LC10 or NOEC for terrestrial plants: 574.8mg/kg soil dw

Additional information:
The Key Study is provided by Domene et al (2009), as this study was highly reliable (Klimisch 1) and fulfilled the information requirements for a Robust Study Summary. The 50% effect concentrations in the Hulzebos et al (1993) study are similar to the EC10 results reported by Domene et al (2009). Effects on fresh weight in

Brassica rapa and *Lolium perenne* over a 15-day period resulted in calculated EC10s of 574.8 and 738.9 mg nonylphenol/kg, respectively. This suggests that dicotyledonous plants are more sensitive than monocotyledons to nonylphenol toxicity. A number of factors differ between the long-term exposures in the Hulzebos and Kwak and Domene studies, including (i) the species, (ii) the effect levels and (iii) the soil type. In particular, Domene et al (2009) used artificial soils (the preferred test medium for REACH testing); whereas Hulzebos et al (1993) and Kwak et al (2017) employed natural soil, with the potential to introduce further uncertainty due to the variation in natural soil properties. It is difficult to make direct comparisons between the two studies due to these variations, but the results do suggest that plants are likely to be affected by nonylphenol in soils where concentrations exceed 559 mg nonylphenol/kg. Domene et al (2009) also reports EC50 values for seed germination in *B. rapa* and *L. perenne* of 8159.2 and 7500.7 mg/kg, respectively.

There were four reliable toxicity studies relating to six different species of terrestrial plants. Two reliable short-term studies were available, evaluating the toxicity of NP on three different species: *Lactuca sativa* (Hulzebos et al, 1993), *Oryza sativa* and *Vigna radiata* (Kwak et al, 2017). EC50s for shoot grow inhibition and growth ranged from 559 mg nonylphenol/kg for *L. sativa* (7-day) to >2000 mg nonylphenol/kg for *V. radiata* (14 days). Kwak et al (2017) also reported long-term data for the same species, where NOEC and EC10 values for 21 days of exposure were 1500 and 1433 mg nonylphenol/kg for *O. sativa* and >2000 and 1822 mg/kg for *V. radiata*, respectively. Long-term exposure (14 days) of L. sativa determined, instead, an EC50 of 625 mg/kg (Hulzebos et al, 1993).

In summary, the reliable data present an inconsistent trend of the toxicity of nonylphenol to terrestrial plants, although the NOEC is expected to be around the 0.5 g/kg level or more. Based on the arguments of data reliability, adequacy, and sensitivity of test species, the key value used for long-term plant exposure to nonylphenol and further hazard assessment is the *L. perenne* EC10 of 574.8 mg/kg. These results indicate that nonylphenol is slightly toxic to some plants at the EC10 protection level, but not toxic at the EC50 level. More generally, plants are less sensitive to nonylphenol than soil invertebrates. These data are suitable for use in the nonylphenol assessment.

7.2.3. Toxicity to soil micro-organisms

The results are summarised in the following table:

Table 16. Effects on soil micro-organisms

Method	Results	Remarks
Species/Inoculum: *Chlorococcum infusionum* according to - Principle of test: Effect of NP were evaluated as inhibition of production of chlorophyll-a, measured using a fluorescence microplate reader - Short description of test conditions: Test well plates were maintained in the incubator at 24 °C, 100 rpm, 16 h:8 h light:dark cycle, and 4400−8900 lx. The change in chlorophyll-a, which indicates changes in soil algal growth, was measured after 6 days	NOEC (6d): 100 mg/kg soil dw test mat. (nominal) based on: growth inhibition EC50 (6d): 108 mg/kg soil dw test mat. (nominal) based on: growth inhibition (95% C.I. - (86−136))	2 (reliable with restrictions) weight of evidence experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Species/Inoculum: *Chlorococcum infusionum* according to - Principle of test: Effect of NP were	NOEC (6d): 100 mg/kg soil dw test mat. (nominal) based on: growth inhibition EC50 (6d): 108 mg/kg soil dw test mat. (nominal) based on: growth inhibition (95%	2 (reliable with restrictions) weight of evidence read-across from

evaluated as inhibition of production of chlorophyll-a, measured using a fluorescence microplate reader - Short description of test conditions: Test well plates were maintained in the incubator at 24 °C, 100 rpm, 16 h:8 h light:dark cycle, and 4400−8900 lx. The change in chlorophyll-a, which indicates changes in soil algal growth, was measured after 6 days	C.I. - (86−136))	supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Justification for type of information: See read-across justification in original AfA		
Species/Inoculum: Aged compost and sandstone mix equivalent or similar to OECD Guideline 217 (Soil Microorganisms: Carbon Transformation Test)	NOEC (40d): 100 mg/kg soil dw test mat. (nominal) based on: respiration rate (4.7 to 1657.0)	2 (reliable with restrictions) weight of evidence experimental study **Test material** Technical grade nonylphenol, (full information in **Annex II**). **Reference** **Trocme M., Tarradellas J. and Vedy J-C. 1988**
Species/Inoculum: Aged compost and sandstone mix	NOEC (40d): 100 mg/kg soil dw test mat. (nominal) based on: respiration rate (4.7 to 1657.0)	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material** Technical grade nonylphenol, (full information in **Annex II**). **Reference**
Justification for type of information: See read-across justification in original AfA		
Species/Inoculum: *Chlamydomonas reinhardtii* (Chlorophyceae) according to - Principle of test: Effect of NP were evaluated as inhibition of production of	NOEC (6d): 600 mg/kg soil dw test mat. (nominal) based on: growth inhibition EC10 (6d): 449 mg/kg soil dw test mat. (nominal) based on: growth inhibition (95% C.I. - (249−548))	2 (reliable with restrictions) weight of evidence experimental study

chlorophyll-a, measured using a fluorescence microplate reader - Short description of test conditions: Test well plates were maintained in the incubator at 24 °C, 100 rpm, 16 h:8 h light:dark cycle, and 4400−8900 lx. The change in chlorophyll-a, which indicates changes in soil algal growth, was measured after 6 days	EC50 (6d): 907 mg/kg soil dw test mat. (nominal) based on: growth inhibition (95% C.I. - (871−944))	**Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Species/Inoculum: *Chlamydomonas reinhardtii* (Chlorophyceae) according to - Principle of test: Effect of NP were evaluated as inhibition of production of chlorophyll-a, measured using a fluorescence microplate reader - Short description of test conditions: Test well plates were maintained in the incubator at 24 °C, 100 rpm, 16 h:8 h light:dark cycle, and 4400−8900 lx. The change in chlorophyll-a, which indicates changes in soil algal growth, was measured after 6 days	NOEC (6d): 600 mg/kg soil dw test mat. (nominal) based on: growth inhibition EC10 (6d): 449 mg/kg soil dw test mat. (nominal) based on: growth inhibition (95% C.I. - (249−548)) EC50 (6d): 907 mg/kg soil dw test mat. (nominal) based on: growth inhibition (95% C.I. - (871−944))	2 (reliable with restrictions) weight of evidence read-across from supporting substance (structural analogue or surrogate) **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
Justification for type of information: See read-across justification in original AfA		

Discussion

The following information is taken into account for toxicity on soil micro-organisms for the derivation of PNEC:

A read-across approach from structural analogue, nonylphenol, to octylphenol is used to evaluate the octylphenol toxicity to soil microorganisms. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR).

Two studies are available for the soil microorganism endpoint using three species.

The study by Trocme et al (1989) provides the NOEC value of >100 mg/kg and Kwak et al (2017), using *C. infusionum*, provides the EC50 value of 108 mg/kg.

Value used for CSA:
Short-term EC50 or LC50 for soil micro-organisms: 108mg/kg soil dw
Long-term EC10/LC10 or NOEC for soil micro-organisms: 100mg/kg soil dw

Additional information:
The reliable study by Kwak et al (2017) evaluated the toxicity of nonylphenol on the growth inhibition of the soil microalgae, *Chlorococcum infusionum*, over a 6-day period. The reported EC50 for growth inhibition,

measured as a change in concentration of Chlorophyll-a, was 108 mg/kg dw soil. The estimated NOEC value was 100 mg/kg dw soil. The study by Trocme et al (1989) presents a long-term carbon transformation test by soil microorganisms in the presence of nonylphenol, equivalent to OECD 217 Guideline, where a NOEC of 100 mg nonylphenol/kg was derived. This study indicates that soil microorganisms are less sensitive to nonylphenol than soil invertebrates but may be more sensitive than terrestrial plants.

Kwak et al (2017) also evaluated the toxicity of nonylphenol on the growth inhibition of the soil microalgae, *Chlamydomonos reinhardtii*, over a 6-day period. The reported EC50 for growth inhibition, measured as a change in concentration of Chlorophyll-a amount, was 907 mg/kg dw soil and an EC10 of 449 mg/kg dw soil. NOEC estimated value was 600 mg/kg dw soil.

The endpoint is evaluated using weight of evidence as two studies using different species present equivalent NOEC values, providing strong evidence that the NOEC is at or more than 100 mg/kg. However, the study by Trocme et al (1989) does not provide an EC50 value for comparison, and instead this is relied upon from the Kwak et al (2017) study and for the species *C. infusionum*. Both studies are reliable with acceptable restrictions (Klimisch 2).

7.2.4. Toxicity to other terrestrial organisms

The results are summarised in the following table:

Table 17. Effects on terrestrial arthropods

Method	Results	Remarks
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Justification for type of information: Read-across approach - see read-across justification in original AfA.		
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for any hazard / risk assessment:

A read-across approach from the structural analogue, nonylphenol, to octylphenol is used to evaluate the octylphenol toxicity to terrestrial arthropods. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR).

Kwak et al (2017) was selected as key study for short-term exposure to terrestrial arthropods. The selected key value was the EC50 for mortality of 123 mg nonylphenol/kg for exposure of *Folsomia candida* to NP for 14 days. The key study by Scott-Fordsmand et al (2004) reported an EC10, based on *Folsomia fimetaria* reproduction, of 23 mg nonylphenol/kg. This study is reliable with restriction, using the *Folsomia* genus, an oven-dried soil, and is equivalent to an international ISO protocol. Importantly, this is the lowest EC10 in the reliable dataset.

Additional information:
The reliable Kwak et al (2017) study reported, also, short-term exposure results to the Collembola, *Lobella sokamensis*. Exposure of *L. sokamensis* to nonylphenol for 5 days, resulted in an EC50 of >250 mg nonylphenol/kg, with no mortality at the highest concentration tested.

There were six reliable studies relating to the long-term exposure of arthropods to nonylphenol. Two studies met the strict adequacy requirements of the IUCLID Robust Study Summary; these were the Scott-Fordsmand et al (2004) and the Domene et al (2009) studies. The long-term data for Collembola species ranged from 23 to 63.2 mg nonylphenol/kg, with test durations ranging from 21 to 64 days.

Four studies provided comparable data for *Folsomia sp.* exposure to nonylphenol for 21 or 28 days, with EC10 values of 23, 24, 27 and 88 mg nonylphenol/kg, relating to the studies by Scott-Fordsmand and Krogh (2004), Krogh (1996), Holm (undated, but reported in the nonylphenol EU Risk Assessment Report, 2002) and Kwak et al. (2017). Ramboll UK has not been able to review the Krogh (1996) and Holm studies directly, but the data from these studies is taken directly from the EURAR (2002) and offered as supporting information here. The study by Widarto et al (2007) presented a 64-day NOEC value, based on survival on *F. candida*, of 32 mg nonylphenol/kg. These four studies correspond closely to each other and provide strong evidence that no-effect or EC10 levels for Collembola are between 23 and 32 mg/kg.

Three studies [Widarto et al (2007), Krogh (1996) and Holm (undated)] , whilst considered acceptable for REACH purposes, were classified as 'reliable with restrictions' (Klimisch 2), as the studies were all shorter than the standard duration (28 days) and lacked crucial information, such as the purity of the chemical. The studies considered to provide adequate information for a Robust Study Summary, whilst being reliable, were those by Scott-Fordsmand et al (2004), Domene et al (2009) and Kwak et al (2017). The Kwak et al (2017) study reported long-term toxicity (28 days) EC10 and NOEC of 88 and 100 mg nonylphenol/kg, respectively. The Scott-Fordsmand et al (2004) study reported *F. fimetaria* a long-term toxicity EC10 of 23 mg/kg. The Domene et al (2009) study reported *F. candida*, the preferred test species, was exposed to nonylphenol in artificial soil for the recommended duration of 28 days. The resulting EC10 was 63.2 mg nonylphenol/kg. However, the Scott-Fordsmand et al. (2004) study is recommended as the key study, as this represents the most sensitive toxicity data and is supported by the evidence of similar or slightly higher toxicity-based NOEC/EC10 values. The study meets the reliability and adequacy requirements of REACH.

7.3. Atmospheric compartment

No relevant information available.

7.4. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 18. Effects on micro-organisms

Method	Results	Remarks
a mixed population of activated sewage sludge microorganisms freshwater not specified equivalent or similar to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010]	EC50 (3h): >10 mg/L test mat. (meas. (arithm. mean)) based on: inhibition of total respiration - respiration rate	2 (reliable with restrictions) key study experimental study **Test material** 4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2, (full information in **Annex II**). **Reference** **I. G. Sewell 1991**
Pseudomonas putida freshwater static equivalent or similar to Oxygen-Consumption-test (Huels method)	EC10 (5h): >1700 mg/L test mat. (nominal) based on: bacteria inhibition concentration	2 (reliable with restrictions) key study experimental study **Test material** 1,1,3,3-Tetramethylbutylphenol; 2-(1,1,3,3-tetramethylbutyl)phenol / 27193-28-8 / 248-310-7, (full

		information in **Annex II**). **Reference** **Schöberl P 1991**

Discussion

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

Endpoint concentrations were reported for EC50 at >10 mg octylphenol/L for the activated sludge mixture (Huls, 1991) and EC10 at >1,700 mg octylphenol/L for *Pseudomonas putida* (Sewell, 1991).

Value used for CSA:
EC50/LC50 for aquatic micro-organisms: 10mg/L EC10/LC10 or NOEC for aquatic micro-organisms: 1700mg/L

Additional information:
Reliable toxicity data for a study of octylphenol exposure to microorganisms included Hüls (1991), with *Pseudomanas putida*, and a study by Sewell (1991) using a mixture of activated sludge microorganisms. Test durations ranged from 3 hr (mixture) to 5 hr (*P. putida*) with endpoints determined by inhibition of respiration rate. Endpoint concentration was reported as EC50 >10 mg octylphenol/L for the activated sludge mixture, and EC10 >1,700 mg octylphenol/L for *Pseudomonas putida*. Both of these studies were selected as key studies.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

The results are summarised in the following table:

Table 19. Effects on birds

Method	Results	Remarks
Taeniopygia guttata long-term toxicity to birds: reproduction test (not specified) Doses: - The dosage was 1 µg/g body mass of 100 nmol octylphenol, resulting in 100 nmol/g of body mass per day of octylphenol. equivalent or similar to OECD Guideline 206 (Avian Reproduction Test) Not applicable	NOEL (7wk): 100 nmol/g bw/d test mat. based on: reproductive parameters (No data) No data	2 (reliable with restrictions) key study experimental study **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Millam J.R., Craig-Veit C.B., Quaglino A.E., Erichson A.L., Famula T.R. and Fry D.M. 2001**

Coturnix coturnix japonica long-term toxicity to birds: reproduction test (drinking water) Doses: 0.1 ug/L, 1 ug/L, 10 ug/L, 100 ug/L NP nominal drinking water concentrations according to OECD Guideline 206 (Avian Reproduction Test); Not applicable	NOEC (18wk): 0.01 mg/L drinking water test mat. based on: body weight - female NOEC (18wk): 0.001 mg/L drinking water test mat. based on: body weight - Male NOEC (18wk): 0.001 mg/L drinking water based on: Fertilization rate%, Hatchability% and av. 14 d survival rate - Fertilization rate% = Fertilized eggs/Eggs set X 100; Hatchability%= # embryos that liberate themselves from the eggs/eggs setX 100; 14 d survival rate= number of 14 d survivors/Number of the embryos that liberate themselves from the eggs X 100 NOEC (18wk): >0.1 mg/L drinking water test mat. based on: eggshell thickness (Highest concentration tested) NOEC (21wk): 0.1 mg/L drinking water test mat. based on: mean feed consumption (after 19 weeks of exposure) NOEC (8wk): >0.1 mg/L drinking water test mat. based on: reproductive parameters (Highest concentration tested) not applicable	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Yan Cheng, Zhengjun Shan, Junying Zhou, Yuanqing Bu, Pengfu Li, Shan Lu 2017**
Justification for type of information: Not applicable		
Coturnix coturnix japonica long-term toxicity to birds: reproduction test (drinking water) Doses: 0.1 ug/L, 1 ug/L, 10 ug/L, 100 ug/L NP nominal drinking water concentrations Not applicable	NOEC (19wk): 0.01 mg/L drinking water test mat. based on: body weight - female NOEC (19wk): 0.001 mg/L drinking water test mat. based on: body weight - Male NOEC (19wk): 0.001 mg/L drinking water based on: Fertilization rate%, Hatchability% and av. 14 d survival rate - Fertilization rate% = Fertilized eggs/Eggs set X 100; Hatchability%= # embryos that liberate themselves from the eggs/eggs setX 100; 14 d survival rate= number of 14 d survivors/Number of the embryos that liberate themselves from the eggs X 100 NOEC (19wk): >0.1 mg/L drinking water test mat. based on: eggshell thickness (Highest concentration tested) NOEC (21wk): 0.1 mg/L drinking water test mat. based on: mean feed consumption (after 19 weeks of exposure) NOEC (19wk): >0.1 mg/L drinking water test mat. based on: reproductive parameters (Highest concentration tested) not applicable	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference**
Justification for type of information: Read-across approach - see read-across justification in original AfA.		

Discussion

The following information is taken into account for effects on birds for the derivation of PNEC:

A reliable key study by Millam et al (2001), exposing Zebra Finch (*Taeniopygia guttata*) to OP for 7 weeks, reported a NOEL of 100 nmol/g bw/d, which converts to a NOEC of 70.8 mg/kg food, based on reproductive endpoints.

Value used for CSA:
Short-term EC50 or LC50 for birds: Long-term EC10/LC10 or NOEC for birds: 70.8mg/kg food

Additional information:
The key study is from the read-across substance octylphenol. Millam et al (2001) reported a NOEL of 100 nmol/g bw/d, which converts to a NOEC of 70.8 mg/kg food, based on Zebra Finch (*Taeniopygia guttata*) reproductive endpoints.

A read-across approach from structural analogue, nonylphenol, to octylphenol is used for a supporting study to evaluate the octylphenol toxicity to birds. The read-across justification is provided in a separate report in the original AfA (Section 13 of the CSR). A supporting long-term study exposed the Japanese quail, *Coturnix coturnix japonica*, for18 weeks via drinking water to nonylphenol concentrations from 0.0001 mg/l to 0.1 mg/l, in accordance with OECD 206 Guideline. A NOEC of 0.001 mg/l was determined for changes in the body weight of males, fertilization rate, hatchability and average of 14-day survival rate. A NOEC of 0.0001 mg/l was found for changes in female body weight. No effects were found up to the maximum concentration tested for several reproductive parameters (8 weeks), including changes in eggshell thickness, resulting in a NOEC of >0.1 mg/l. The food consumption was also measured for 21 weeks, starting from the 18th week of exposure. No detrimental effect was found. As the study did not measure nonylphenol concentrations in the bird's drinking water, the study is used as supporting information for the Millam et al (2001) study.

7.5.2. Toxicity to mammals

No relevant information available.

7.6. PNEC derivation and other hazard conclusions

7.6.1. PNEC derivation and other hazard conclusions

Table 20. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.39µg/L Intermittent releases:	Assessment factor: 10 Extrapolation method: sensitivity distribution PNEC aqua (freshwater) **PNEC aquatic (freshwater)** Adequate reliable data were available to derive the PNEC aquatic for freshwater species using species sensitivity distributions (SSD), according to the Aldenberg & Jaworska (2000) Method. For the PNECaquatic (freshwater), a total of 40 geometric mean NOEC or EC10 values were available for species, representing salmonid and cyprinid fish, aquatic invertebrates (crustaceae) and insects, algae, aquatic plants, nematodes, molluscs and amphibia exposed to nonylphenol or octylphenol. These nine groups of organisms and >15 species exceed the criteria for the SSD approach. The HC5 value from the SSD is 3.9 ug/l. An assessment factor of 10 was applied to the HC5 to derive the PNEC aquatic of 0.39 ug/l. In parallel, a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, original AfA (Section 13 of the CSR)). The precautionary approach was taken to lower the PNECaquatic to be protective of endocrine effects and uncertainties by increasing the standard AF from 1 to 5 up to 10. PNEC aquatic (freshwater) = 0.00039 mg/l or 0.39 ug/l

		(based on apical and endocrine endpoints and an AF of 10)
Marine water	PNEC aqua (marine water): 0.32µg/L Intermittent releases:	Assessment factor: 10 Extrapolation method: sensitivity distribution PNEC aqua (marine water) **PNEC aquatic (marine)** Adequate reliable data were available to derive the PNEC aquatic for freshwater and saltwater species using species sensitivity distributions (SSD), according to the Aldenberg & Jaworska (2000) Method. For the PNECaquatic (marine), a total of 45 geometric mean NOEC or EC10 values were available for combined freshwater and saltwater species, representing salmonid and cyprinid fish, aquatic invertebrates (crustaceae) and insects, algae, aquatic plants, nematodes, molluscs and amphibia exposed to nonylphenol or octylphenol. These nine groups of organisms and >15 species exceed the criteria for the SSD approach. The HC5 value from the SSD is 3.21 ug/l. An assessment factor of 10 was applied to the HC5 to derive the PNEC aquatic of 0.32 ug/l. In parallel, a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, original AfA (Section 13 of the CSR). The precautionary approach was taken to lower the PNEC aquatic to be protective of endocrine effects and uncertainties by increasing the standard AF from 1 to 5 up to 10. PNECaquatic (marine) = 0.00032 mg/l or 0.32 ug/l (based on apical and endocrine endpoints and an AF of 10)
Sediments (freshwater)	PNEC sediment (freshwater): 0.46mg/kg sediment dw	Assessment factor: 500 Extrapolation method: assessment factor PNEC sediment (freshwater) Two long-term reliable tests with an invertebrate (*Chironomus riparius*) and worm (*Tubifex tubifex*) were used to derive a PNEC using the Assessment Factor approach (AF = 50) which was based on the most sensitive EC10 of 231 mg/kg dw NP (Bettinetti and Provini, 2002). A read-across approach from nonylphenol was applied. However, in parallel, a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, original AfA (Section 13 of the CSR). The precautionary approach was taken to lower the PNEC sediment to be protective of endocrine effects and uncertainties by applying an additional AF of 10 (a total AF of 500). The PNEC sediment (freshwater) is based on the EC10 of 231 mg/kg, divided by 50 (for apical endpoints), and then by 10 (potential endocrine effects), resulting in a value of 0.46 mg/kg dw.
Sediments (marine water)	PNEC sediment (marine water): 0.61mg/kg sediment dw	Assessment factor: 100 Extrapolation method: assessment factor PNEC sediment (marine water) Three long-term reliable tests (two freshwater and one marine) representing three different living and feeding

		conditions (*Chironomus riparius*, *Tubifex tubifex*, and *Leptocheirus plumulosus*) were used to derive a PNEC using the Assessment Factor approach (AF=50), which was based on the most sensitive NOEC of 61.5 mg/L dw (Zulkosky et al., 2002) marine test with benthic crustacean, *Leptocheirus plumulosus*. A read-across approach from nonylphenol was applied. In parallel, a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, original AfA, Section 13 of the CSR). The precautionary approach was taken to lower the PNEC sediment to be protective of endocrine effects and uncertainties by applying an additional AF of 2 (a total AF of 100). The PNEC sediment (marine) is based on the NOEC of 61.5 mg/kg, divided by 50 (for apical endpoints), and then by 2 (potential endocrine effects), resulting in a value of 0.61 mg/kg dw.
Sewage treatment plant	PNEC STP: 0.1mg/L	Assessment factor: 100 Extrapolation method: assessment factor PNEC STP The PNEC is derived using the Assessment Factor approach (AF = 100), based on the reliable study (Huels 1991) test with activated sludge, measuring respiration inhibition, where the EC50 was equal to or greater than 10 mg/L OP for *Pseudomonas putida*.
Soil	PNEC soil: 2.3mg/kg soil dw	Assessment factor: 10 Extrapolation method: assessment factor PNEC soil The PNEC was derived using the Assessment Factor approach (AF = 10), based on most sensitive of three reliable long-term studies, representing organisms from three trophic levels (invertebrates + plants + microbes). Scott-Fordsmand et al (2004) provided a long-term study with *Folsomia fimetaria*, where the EC10 = 23 mg/kg NP. A read-across approach from nonylphenol was applied.
Air	no hazard identified:	The substance is not considered to be volatile and is unlikely to pose a hazard to the air compartment.
Secondary poisoning	PNEC oral: 2.36mg/kg food	Assessment factor: 30 The PNEC oral was derived by converting the NOAEL to a NOEC, in accordance with ECHA Guidance, based on a test with the bird, zebra finch reproductive endpoint (NOAEL = 20.632 mg/kg food) and assessment factor of 30.

<u>Conclusion on environmental classification</u>
Following the PBT assessment, octylphenol does not fulfil the screening criteria for bioaccumulation (B-criterion). Screening data show that octylphenol can be regarded as inherently biodegradable, although a conservative approach suggests that octylphenol may be considered potentially persistent, as the half-life for octylphenol for biodegradation in seawater is equivalent to the persistence screening criteria (P-criterion) of 60 d. Octylphenol is considered to be toxic to aquatic organisms, but the T-criterion was not met for avian toxicity. The overall conclusion is that octylphenol does not meet the PBT or vPvB criteria. No further testing or an emission characterization and risk characterization according to REACH Article 14 (4) is required.

General discussion

PNEC aquatic

The PNEC aquatics for freshwater and marine water were calculated using species sensitivity distributions (SSD) according to the Aldenberg & Jaworska (2000) Method. Ninety-five percent confidence limits are as follows:

	Upper 95% CL (ug/L)	Lower 95% CL (ug/L)
PNEC aquatic freshwater	1.58	0.31
PNEC aquatic marine	1.30	0.25

The effects assessment builds on the original EU Risk Assessment for 4-Nonylphenol (Branched) and Nonylphenol (EURAR 2002), the UK Environment Agency risk assessment report for nonylphenol (EA, 2009) and the Registrant's dossiers for nonylphenol and para-tert-octylphenol, submitted to the European Chemicals Agency in 2010. The earlier EURAR and Environment Agency reports classified an ecotoxicological study as valid and reliable for use in the risk assessment if the study fully described the test material used, the test organism, the test method and conditions and if the endpoint concentration was based on measured values. If only some of the criteria were met, then studies were noted as to be "used with care" for support of valid studies. A more rigorous approach involving application of the extended Klimisch system (HERAG, 2007) was used by Ramboll to evaluate studies for REACH registration. Study information not only had to be provided, but studies also had to be performed according to or similar to relevant Guidelines to be considered Klimisch 1. Only studies scoring a Klimisch 1 or 2 were used in the risk assessment as a key or supporting study.

The studies used as the basis for PNEC derivation in this effects assessment relate to apical endpoints, such as survival, growth and reproduction. This is in accordance with ECHA Guidance (Guidance on information requirements and chemical safety assessment Chapter R.10: Characterisation of dose [concentration]-response for environment, ECHA 2008). The preceding risk assessments indicate that octylphenol can exhibit oestrogenic effects on aquatic organisms. A literature search for potential endocrine effects was also undertaken as part of this effects assessment that similarly built on the same preceding reports by the European Union, Environment Agency and 2010 dossier registration. A detailed discussion of potential endocrine effects is provided in a separate report (Adverse Outcome Pathways) in the original AfA in section 13 of the IUCLID file.

A separate review of endocrine-mediated adverse effects was undertaken using an Adverse Outcome Pathways (AOP) approach and is reported in the original AfA in section 13 of the IUCLID file. The reviewed studies provide evidence of endocrine-mediated effects in aquatic and sediment invertebrates, in addition to fish. Generally, the sensitivities of fish and invertebrates (including crustacea, molluscs, insects, nematodes) to OP and NP exposure are similar, and the same appears to be true for endocrine effects. In addition, effects on amphibians were reported. There was no evidence from the literature review of endocrine effects in soil organisms. The review and the PNECs take account of aquatic and terrestrial organisms, including non-standard species, such as amphibia, and are protective of adverse endocrine effects in these ecosystems.

The minimum information requirements have been met for OP and NP. Both substances are widely studied, which provide a wealth of information across a range of species and taxa, toxicity endpoints and biological levels of organisation (key events in AOP). More than 80 studies have been evaluated in the AOP review. The SSDs underpinning the PNECs for the freshwater compartment are based on 34 and 40 mean species-endpoint toxicity values for nonylphenol and octylphenol, respectively, and nine taxa, exceeding the SSD minimum information requirements. All of these studies have been reviewed by Ramboll and scored Klimisch 1 or 2, meaning they are reliable and relevant. Where there may be uncertainties or restrictions in the reliability of the studies, these are recorded in the AOP report.

The studies include exposure to OP and NP at sensitive life stages of fish, invertebrates and amphibia development. They include exposure to adults, juveniles and eggs. Several highly reliable studies, such as Watanabe et al (2017) and the Medaka multi-generation study, also consider second and third generation. Other studies, such as Nice et al (2003), report delayed effects following short-term exposure to the alkylphenol and 10 months without exposure. In addition, some studies follow dose-response relationships, and in others the relationship is less clear; however, all reliable studies are considered in this review. The review is comprehensive and, as such, meets RAC's minimum information requirements for the assessment of endocrine-mediated effects.

The overwhelming weight of evidence from the studies reviewed is that there is a threshold for adverse effects of OP and NP to aquatic, sediment and terrestrial organisms. From more than 80 studies reviewed for the AOP assessment and the many studies reviewed for apical endpoints for the development of the SSDs, the vast majority derive no effect concentrations (or EC10) for apical and endocrine-mediated adverse effects. The NOEC is the value at which no effects are observed in an ecotoxicological study and relies on careful study design, proper analysis and interpretation of the results. When a study design is limited, such as two doses, for example, in the study by Nice et al (2003), and effects are observed at the lowest concentration tested, then the NOEC is difficult to derive from such a study, but does not mean that there is no threshold for effects. Thoughtful study design would benefit the understanding of endocrine-mediated effects from these substances. But as large datasets are always going to include imperfect data, the weight of evidence is with the derivation of NOECs and thresholds for nonyl- and octylphenol toxicity. Therefore, the development of PNECs is appropriate and scientifically justified.

It is important to state that the evidence gathered for the AOP review has not confirmed a complete pathway and adverse outcome for octylphenol or nonylphenol. The European Commission's protection goal for non-target organisms is at the population level, and relies on a weight of evidence approach, with evidence from field studies taking precedence. The evidence presented in the AOP review indicates endocrine-mediated adverse effects at the organs system and organism levels, but not at the population level resulting in an adverse outcome, and do not meet the European Commission's current policy.

The PNECs derived in the CSR, using apical endpoint data from chronic toxicity studies, are generally protective of most endocrine-mediated adverse effects. However, a precautionary approach to this assessment has been taken and the use of additional assessment factors or increased assessment factors have been recommended to be protective of endocrine effects and uncertainties.

PNECs developed in the CSR in 2010 by the Lead Registrants for OP and NP were based on chronic toxicity data related to the apical endpoints of growth, reproduction, and survival, and calculated using a species sensitivity distribution (SSD). The PNECs for OP were 0.63 µg/l for both freshwater and saltwater compartments.

The literature search undertaken for this CSR has revealed new chronic toxicity data that increased these PNEC values, as a result of more species-endpoints being added to the SSD. The additional search for endocrine-mediated adverse effects literature has also increased the database of information available for this hazard assessment.

The application of additional or greater AFs to these new HC5 or PNEC values is in line with the approach taken by RAC in its Opinion on nonylphenol and potential endocrine effects. The new PNECs – protective of apical and endocrine effects – are more precautionary than the PNECs provided by the Lead Registrants in 2010 (because of new data) and are very similar or more precautionary than the PNECaqua for the read-across substance NP of 0.39 µg/l derived by ECHA's Risk Assessment Committee (RAC) and Socio-Economic Committee (SEAC)[1]. A summary of the new PNECs and assessment factors used in their derivation are provided in the table below.

Environmental compartment	Substance	PNEC value based on chronic apical endpoints and standard Assessment Factors	Additional Assessment Factor for endocrine effects	New PNEC value protective of adverse endocrine effects
Freshwater	Octyl phenol	0.78 µg/l	Yes: AF of 10 increased from 5 applied to HC5 from SSD	0.39 µg/l
Saltwater	Octyl phenol	0.64 µg/l	Yes: AF of 10 increased from 5 applied to HC5 from SSD	0.32 µg/l
Sediment, freshwater	Octyl phenol	4.62 mg/kg dw	Yes: Additional AF of 10 applied to previous PNEC	0.46 mg/kg dw

Sediment, marine	Octyl phenol	1.23 mg/kg dw	Yes: Additional AF of 2 applied to previous PNEC	0.61 mg/kg dw
Soil	Octyl phenol	2.3 mg/kg dw	No	Not applicable

[1]Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC). Background document to the Opinion on the Annex XV dossier proposing restrictions on NONYLPHENOL and NONYLPHENOL ETHOXYLATES (09/09/2014).

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. PBT/vPvB criteria and justification

No relevant information available.

8.1.2. Summary and overall conclusions on PBT or vPvB properties

No relevant information available.

8.2. Emission characterisation

No relevant information available.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0 Introduction

Under the European Union (Withdrawal) Act 2018, the EU REACH Regulation was brought into UK law on 1st January 2021 and is known as UK REACH. EU REACH, and related legislation (see Section 9.1.1.3), were replicated in the UK with the changes needed to make them operable in a domestic context. As such, all references within this document to the EU REACH legislation still apply with regards to UK REACH and the reason the substance has been classified as a SVHC in the UK is the same as that in the EU.

Article 127G of the UK REACH Regulation relate to a transitional measure of Authorisation decisions made under EU REACH. Article 127G applies to existing EU AfAs that were submitted by GB-based companies prior to the UK leaving the EU. The initial application by companies including PPG under EU REACH was transitioned into UK REACH on 11th August 2021[1] under Authorisation Numbers UKREACH/21/02/0 and UKREACH/21/02/3.

Polysulfide sealants are most commonly placed on the market as two-component kits comprising, in separately contained units, a base and a hardener. The base and hardener are mixed together immediately prior to use. The hardener component contains a catalyst, which acts to initiate the curing process of the base component when the two are mixed together. The hardener component contains octylphenol ethoxylate (OPE). Octylphenol ethoxylates (OPEs) have been listed as entry 42 of Annex XIV to Regulation (EC) No 1907/2006. OPEs are listed "because (through their degradation) they are substances with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment"[2]. The Annex XIV listing is limited to the effects on the environment. PPG and Airbus have worked to develop and submit this Review Report for use of OPE in these two-component polysulfide sealant formulations within the aerospace industry, and this is submitted by PPG to support continued use of the sealants by Airbus and its supply chain. A 4-year review period is being applied for.

The hardener component of the polysulfide sealant contains a maximum of 0.5 % OPE. When the sealant is mixed prior to use in subsequent Aerospace manufacturing or Maintenance, Repair, and Overhaul (MRO) processes, the OPE concentration is reduced to significantly below the 0.1% threshold above which an authorisation is required according to Article 56(6)(a) of the REACH Regulation[3], making handling and use of the mixed sealant not subject to authorisation under REACH. As such, only activities relating to the initial formulation of the OPE containing hardener component and the subsequent mixing of the hardener with the base component, are subject to authorisation and need to be covered by this CSR. The subsequent use of the mixed polysulfide sealant in Aerospace products is relevant here only to explain the path of the substance across the life-cycle of the sealants. The schematic below shows where activities relating to the formulation and use of the polysulfide sealants are in and out of scope of this Review Report, with the red bordered activities being those that are covered by this Review Report.

The polysulfide sealants within the scope of this OPE Review Report can be described as a 'family' as they comprise a range of formulation variants, each of which has been developed to provide the performance characteristics to meet the requirements of specific uses. A detailed discussion of the properties of the sealants, and the steps that must be carried out to ensure a reformulated sealant meets the same performance standards before it can be introduced as a replacement are contained within the Analysis of Alternatives (AoA) submitted with this Review Report. Differences between the process (e.g., viscosity, dispersion) and functional performance criteria (e.g., adhesion, fluid resistance) of different sealants in the polysulfide family are of limited, if any, relevance for the CSR and so are not described here. The AoA-SEA details the historical and current R&D and substitution effort by the Applicant and Airbus. During the initial review period several OPE containing sealants have been removed from the market with the aim of Airbus and the Applicant to reduce the use of OPE containing sealants to reduce to zero within the applied for 4-year review period. Currently only 2 sealants are under the scope of this Review Report (Table 6 in the AoA-SEA). This CSR shows that the current use of OPE containing sealants leads to no release of OPE to the environment, however, this commitment to

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012455/decision-uk-reach-application-ref-ID203.pdf

[2] OPE: https://echa.europa.eu/documents/10162/17ab7722-0164-4fe8-80b6-8b4ac76e8f0f

[3] Article 56(6)(a) of 1907/2006: Paragraphs 1 and 2 shall not apply to the use of substances when they are present in ►M3 mixtures ◄: (a) for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);

removing OPE from the sealant formulation further emphasises the sustainability commitments of the Applicant and Airbus.

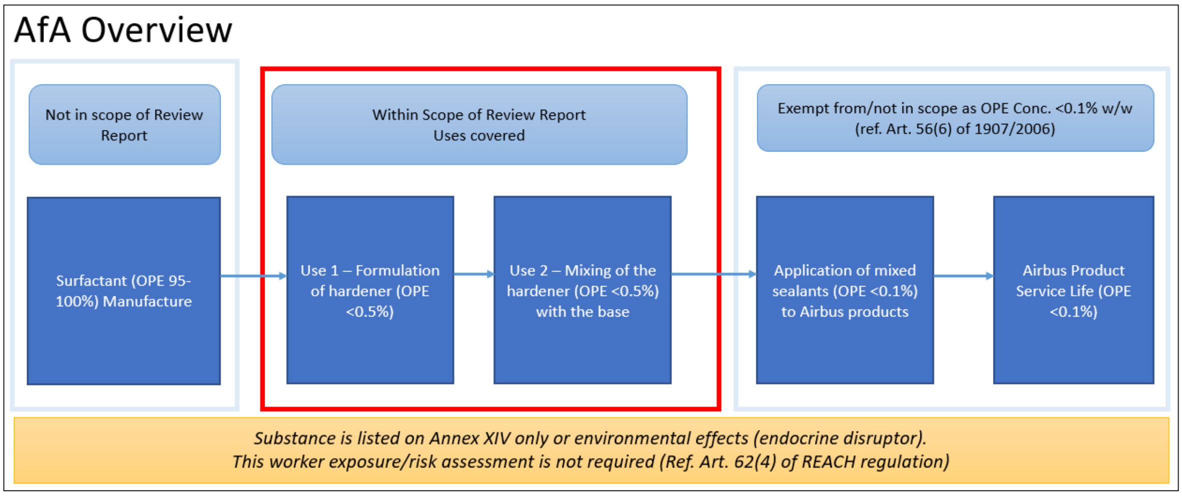


Figure 1: Overview of the scope of the Original AfA and Review Report.

The AoA-SEA also describes the need for these speciality sealants to ensure safe operation in different uses across a wide range of environmental conditions. Example uses of the polysulfide sealants include preventing moisture ingress around external panels, containing fuel within a fuel tank and preventing air egress around glazed panels in pressurised cabins.

These polysulfide sealant formulations are specified by Airbus for use in production, and in MRO, of Aerospace products. The sealants have multiple properties that are essential to their use during production, MRO process and/or to their performance during the subsequent service life of the aerospace products on which they are used. Production activities take place where Aerospace products, sub-assemblies and assemblies are assembled. Examples of production are provided in the SEA/AoA reports, which form part of this submission. As noted in the AoA/SEA, the polysulfide sealants are used widely throughout the manufacture of aerospace products at Airbus sites within the UK, as well as being available for MRO activities at airports, airfields, and dedicated facilities across the UK. Use of these sealants is restricted to industrial users. A non-exhaustive depiction of examples of the uses of sealants within the manufacture of Aerospace products is provided in Figure 2 below. Further explanation of these uses can be found in the accompanying AoA-SEA.

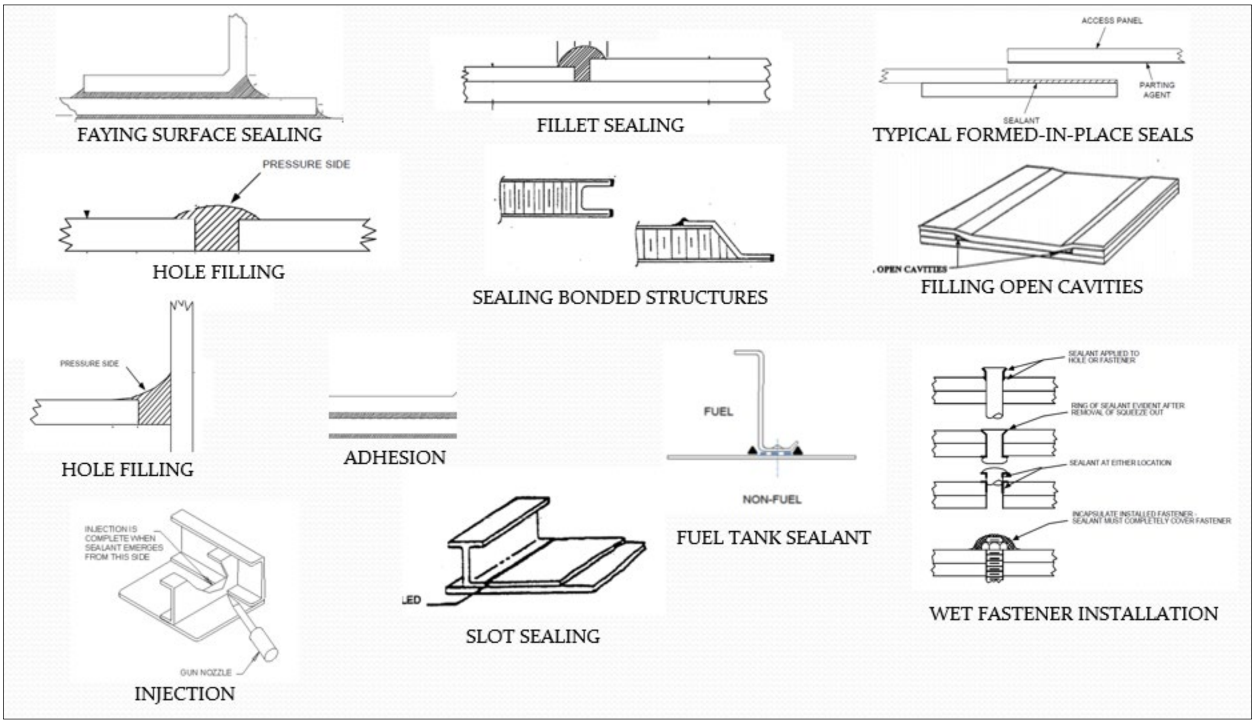


Figure 2: A non-exhaustive depiction of examples of the use of polysulfide sealants in Aerospace product manufacture

Within the UK, the formulation of the OPE containing hardener takes place at one site in Shildon, Co. Durham. The process is conducted according to stringent procedures and controls. Release to the environment is avoided through appropriate risk management measures (RMMs) and operational controls (OCs), including specific procedures for waste management, which are described in detail within this document. Water is not used, and wastewater is not generated or discharged during manufacture of the hardener component.

The activity of mixing the OPE containing hardener with the sealant base prior to use takes place across an estimated 45 sites or more in the UK. Specific process controls ensure complete mixing by downstream users, so all final mixed sealant materials contain below 0.1% OPE. Use by Airbus and its supply chain is subject to existing stringent procedures and controls that are in place to (i) ensure Aerospace products are manufactured and maintained in accordance with quality requirements to assure safety and (ii) minimise risks to health and the environment associated with the use of multiple constituents in the sealants. Release to the environment is avoided by using appropriate RMMs and OCs, including specific procedures for waste management, which are described in detail within this document.

In discussing the appropriate RMMs and OCs employed for use of the OPE containing hardener and the resulting mixed sealant, it is relevant and important to note that other ingredients comprise more than 99.9% of the mixed sealants, and the inherent properties of other constituents drive the classification and choice of RMM. For example, RMMs and OCs to prevent release to the aquatic environment are important for constituents other than OPE. Therefore, the overall level of control exerted to prevent release to the environment across the life cycle of the sealants is very high. It is also relevant that these sealant formulations are, by nature, hydrophobic – they are designed to repel water. Water is not used during mixing or use of the sealants. Furthermore, as soon as the OPE containing hardener and sealant base components are mixed, these sealants begin to cure. The mixed sealant becomes very viscous, eventually curing to form a flexible rubber-like solid. As such, it is neither operationally nor physically practical for the mixed sealant to be discharged to water systems.

The total per annum usage of OPE covered by this authorisation is very low (50 - 150 kg). The concentration of OPE in hardener after formulation is low (below 0.5 %), although above the 0.1% limit requiring authorisation. This document specifically details the handling processes relating to the repackaging of the hardener, as well as the subsequent mixing of the hardener with its base by downstream users.

The concentration of OPE in the final sealant after mixing is below 0.05 %, significantly below the 0.1% limit above which authorisation is required. As such, the handling and use of the final sealant after mixing is not subject to authorisation and is not included as an Exposure Scenario in the CSR. However, the CSR considers the RMMs and OCs relevant for the use and service life of the sealant to demonstrate that there is no risk of release of OPE to the environment throughout the sealant lifecycle. In doing so, it demonstrates that the ongoing use of the polysulfide sealants containing OPE according to the RMMs and OCs implemented by industry and prescribed within the Exposure Scenarios poses no risk to the environment.

This Review Report and CSR concerns the repackaging of the OPE containing hardener and use of the hardener during mixing, and subsequent use of the specialist family of polysulfide sealants. The uses are defined as such:

Use 1: The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants used by Airbus and their associated supply chains

Use 2: Mixing, by Airbus and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE containing hardener, resulting in mixtures containing <0.1% w/w of OPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a)[4]

Specific regulatory provisions applicable for these uses are as follows:

- As noted above, the concentration of OPE in the final sealant is below 0.1%. Therefore, according to Article 56(6)(a) of the REACH Regulation, activities involving use of the mixed sealant, or those which involve handling of cured sealant (e.g. removal of cured sealant during MRO activities, cleaning of mixing equipment, PPE contaminated with mixed sealant, handling of waste cured sealant) are not within the scope of authorisation.
- Article 62(4)(d) of REACH stipulates that the AfA and the subsequent Review Report shall contain a

[4] Use of substances when present in mixture below a concentration limit of 0.1% weight by weight (w/w) for substances referred to in Article 57(d), (e) and (f) REACH (Art. 56(6)(a) REACH) Link: https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf).

CSR covering the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV. Therefore, the CSR focuses on the exposure of the substance to the environment[5], as the substance is listed due to its endocrine disrupting properties.

- Further guidance has been prepared by the Risk Assessment Committee (RAC) in the document 'Risk-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO' agreed at RAC-43. This Question and Answer paper is intended to provide general advice to companies intending to apply for Authorisation of uses of OPE with regard to environmental risk assessment. Socio-Economic Analysis Committee (SEAC) has also prepared similar guidance 'SEA-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO' at SEAC-37 on 30 November 2017. These documents have been closely referenced in the production of this CSR.

With these references in mind, the applicant demonstrate within this CSR that, considering measures in place, emissions of OPE to the environment during the two uses applied for (as discussed within Section 9.0.1) are not only minimised but effectively precluded. Thus, the associated exposure (and risks) related to the continued use of the OPE during formulation, and use of the OPE containing hardener components during mixing, within the scope of this Review Report have also been minimised as far as technically and practically possible.

Additionally, consideration is given to the lifecycle of the sealant after mixing, including use of the mixed sealant and the service life and end of life of the cured sealant. While these are not within the scope of authorisation, and thus do not require a formal risk assessment, the method of applying the sealant, and its service life and end of life are discussed to demonstrate that these activities are carried out in such a manner, and the intrinsic properties of the cured polysulfide sealants themselves are such that their use does not result in release of OPE to the environment across the lifecycle of the sealant.

Airbus and their associated supply chains require good manufacturing practices in place at all Downstream User sites carrying out the activities associated with the exposure scenarios covered within this CSR. This includes compliance with standard operating procedures and Exposure Scenarios communicated as part of extended Safety Data Sheets. This is necessary to ensure Aerospace products are safe to use. Adherence to these requirements means that release of OPE to the environment during use is precluded.

The term 'downstream user' encompasses all possible use actors in the supply chain who use the initial two component sealant from the formulator. It covers a range of actors who will handle and use OPE, the hardener, and the polysulfide sealant in line with the detail of the exposure scenarios included within this CSR. Throughout the CSR, a number of terms are used which fall under the banner of a 'downstream user', including:

- **Formulators (PPG)** that purchase the raw materials from **chemical manufacturers** or **importers** of OPE or OPE-containing mixtures. They develop mixtures which are proprietary (formulation composition is highly confidential) to meet the requirements of their customers in each market and supply formulations containing OPE to meet performance specifications and industrial approvals. Their customers are generally component manufacturers, OEMs, and MRO operations. .
- **Processors** that are involved in the process of producing parts or final products to meet the requirements of other companies (OEMs or component manufacturers);
- **Component manufacturers (Airbus Qualified Suppliers]** that 'build-to-print' (build components or systems following the detailed design requirements of the OEM) or design, produce and supply components, qualified by the OEMs to meet their performance requirements. The components will be used by downstream OEMs in the final stage of production. Component manufacturers may utilise processors or produce parts themselves. When producing parts themselves they may purchase sealants themselves, and mix *in situ*.
- **Original equipment manufacturers (OEMs) [Airbus]** that define the performance requirements of the components and the materials and processes used in manufacturing and MRO activities. OEMs are responsible for the integration and certification of the final product. OEMs use OPE-containing sealants in a similar manner to component manufacturers.
- **Maintenance repair and overhaul (MRO) shops [Airlines and Airbus]** that carry out Aerospace product maintenance, repair and overhaul activities using polysulfide sealants during their daily activities.

[5] In the Analysis of Alternatives (AoA) other endpoints also are considered for the comparison of potential alternatives.

9.0.1 Overview of uses and Exposure Scenarios

9.0.1.1 Overview of the processes

9.0.1.1.1 Use 1: The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants used by Airbus and their associated supply chains

The hardener is formulated at one site in the UK. The polysulfide sealant comprises two components – the base and the hardener. The base component does not contain OPE. The hardener component contains concentrations of OPE below 0.5%. As outlined above it is the formulation of this second component, the hardener, that is covered by Use 1 of this Review Report.

Between 50 and 150 kgs of OPE is used during formulation of the hardener per annum.

Hardener component formulation occurs up to twice per month throughout the year, and up to 24 days of production per year. It is a batch production process. The formulation of any one batch of hardener can be completed within a single day during an eight-hour shift.

The formulation process is described in Section 9.1. The process does not utilise water and no wastewater is generated from the process. The process involves both manual and automated processes.

The raw materials are delivered in containers to the site by road and manually transferred to the dedicated chemical storage area and, when required, from the storage area to the sealant mixing area. In the sealant mixing area, a small volume of OPE is weighed manually into a mixing cylinder, along with the other ingredients within the hardener. The mixture is blended and subsequently passed through a roller. After rolling, the mixture is transferred into a second mixing vessel where it is blended again.

Once the hardener has been fully formulated, it is a viscous liquid. It is transferred from the mixing cylinder via an outlet at the bottom of the cylinder into a sealed drum in the same dedicated area as the formulation processes are undertaken, and therefore the same RMMs and OCs are in place. Subsequent filling of containers for shipment to customers occurs in a separate area on site adjacent to the formulation area, and sealed drums are transported here by forklift. The hardener component can be shipped to customers within a two-compartment kit, small tin kits, or drums.

During the formulation process cleaning is undertaken by workers in order for the area to remain in good working order, as well as to prevent cross-contamination of formulations. Cleaning processes are undertaken with disposable rags soaked in solvent to remove excess material from the equipment. These rags are subsequently disposed of as hazardous waste.

Any OPE contaminated waste generated on site is collected, identified as hazardous by the waste codes assigned by the formulator, and handled by licensed third party waste management contractors. The waste is processed in line with the applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration as set out in the original AfA.

9.0.1.1.2 Use 2: Mixing, by Airbus and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing <0.1% w/w of OPE for Aerospace and Defence uses that are exempt from authorisation under REACH Art. 56(6)(a)

Polysulfide sealants are used widely and extensively in the manufacture and MRO of Aerospace products, reflecting their range of uses and their unique properties. They are fundamental to almost every stage of assembly and are equally necessary during MRO activities. As such, Aerospace sites carrying out manufacture and MRO of equipment may use varying quantities of several different polysulfide sealants in any day.

Two-component polysulfide sealants require that the base and the OPE containing hardener be systematically and thoroughly mixed by the downstream user in the correct ratio before being applied to the component. This may be completed in three ways:

i) Mixing within a two compartment kit (i.e. a Semkit®); or,

ii) Mixing in small scale batches by hand from can kits; or,

iii) Bulk mixing by machine from drum kits

These scenarios are each described in further detail below. Examples of each mixing type and the machinery used are provided later within this section in Figures 4 to 8. Figure 3 below shows the base and hardener containers for each type of mixing

Figure 3: Examples of the containers for each type of mixing. The red outline shows the hardener component, the yellow outline shows the base component.

shows the base component.

The hardener component is paired with an appropriate base component during formulation and is therefore always provided as a two component kit. The formulator fine-tunes the ratio of each batch of hardener and base together in order to achieve, on mixing, a final sealant with the necessary properties to match the particular set of requirements for that sealant formulation, dictated by the design specifications of the part/component being built, relevant for the end user. Thus, hardener from one kit is never used with the base from another as the performance of the resulting sealant would not be predictable and would not have demonstrably met the specification requirements. This further illustrates the rigorous level of control associated with the precision of formulation and successful completion of the mixing process necessary to assure the performance requirements of these sealants.

The mixing process initiates curing of the sealant. The work time and cure time are specific to the class (i.e. specific formulation variant) of sealant used (which is itself determined by the specific application) but are typically as short as possible for the given use. Thus, the sealant must be applied immediately following mixing, unless the intention is to freeze the mixed sealant to delay curing. This allows end users to access sealant later without the need to mix a new batch.

In every case, a high level of quality control is necessary to ensure the two components of the polysulfide sealant are fully mixed together before the sealant is used. Failure to mix the hardener with the base adequately, or entrainment of air in the mixture, could cause significant deficiencies with the performance of the sealant that may have repercussions for the performance and safety of the final assembly/product. Thus, mechanical mixing methods (where possible) are preferred over manual methods, particularly where higher quantities of sealants are used, to provide greater control of mixing and thus performance assurance.

Any OPE contaminated waste (including disposable gloves and aprons, rags, disposable equipment, empty packaging, etc.) generated during the mixing processes is collected, identified as hazardous by the waste codes assigned by the formulator, and handled by licensed third party waste management contractors. The waste is processed in line with the applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

The different mixing processes are described below.

i) Mixing within a two-compartment kit (i.e. a Semkit®), where the hardener component and the base component are combined within a closed vessel

The mixing process is completely contained within a purpose-designed unit referred to as a 'Semkit®'. Figure 4 provides an illustration of the use of this type of kit. The Semkit® is designed such that pre-determined volumes of the hardener and the base are housed within separate compartments of the same cartridge container. Prior to use, the operator must break the seal between the two components in the cartridge. This is done using a piston rod, which is inserted into the dasher rod, breaking the seal between the hardener and base and allowing them to be mixed within the cartridge body. The two components are then mixed in-situ by movement of the piston rod within the cartridge. Mechanised systems have been developed and are broadly used to facilitate mixing of the two compartment kits in this manner, though manual methods can also be used.

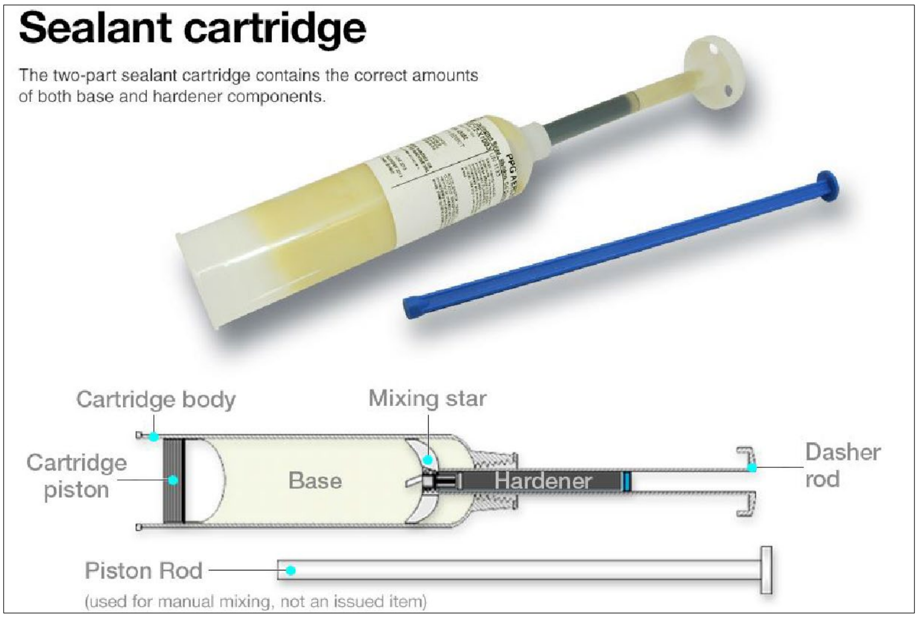


Figure 4: A two-compartment cartridge kit

During this mixing process, the base, within the cartridge body, and the hardener, within the dasher rod, are fully contained within the cartridge. There is no potential for release of the OPE-containing hardener or the mixed sealant to the environment. After dispensing the mixed sealant, the container is consigned as hazardous waste.

The Exposure Scenario, with related RMMs and OCs to prevent release to the environment, is described in Section 9.2.

ii) Mixing in small scale batches by hand from can kits

Small scale batch mixing by hand is used when low volumes of sealant are needed for spot repairs or specific adhesion purposes. This small batch hand mixing process is performed close to the point of sealant application. The hardener and the base are provided premeasured within individual cans, the size of which are relative to the ratio specified for the final mixed sealant (i.e., the tin for the hardener component is sized to provide the correct amount of material to blend with the full tin of base), thus providing sealant that meets specification. The entire contents of each tin may be mixed. The hardener component is measured and mixed by hand using a tool such as a disposable spatula, or a reusable spatula with disposable covering (e.g. masking tape), and weighed on a mass balance using a disposable measuring container or surface. This is combined with the relevant mass of the base component to create the specified mass ratio for the final mixed sealant. The two components are thoroughly blended by hand. Images showing the hand mixing process are shown in Figure 5 below.

Once the sealant has been dispensed, the disposable mixing container/surface is consigned as hazardous waste.

RMMs and OCs are in place during mixing by hand to prevent release to the environment. These are discussed in Section 9.2.

Figure 5: Small scale hand mixing of hardener with base

iii) Bulk mixing by machine from drum kits

The hardener and base components of the polysulfide sealant are supplied in separate drums. The drums contain pre-measured volumes of each component such that the correct ratio will be achieved on mixing the full contents of both. The larger container (up to 200 litres) holds the base component and the smaller container (up to 18 litres) holds the hardener component. These two drums are delivered to the downstream user together as a single kit.

The polysulfide sealant is mixed from the contents of the two drums. In order to combine the two components, a pump system, with a dedicated transfer line is used to pump the material from the drums into a bulk mixing machine. A disposable mixing rod is in place to combine the two components during the pumping process. The final sealant is pumped into one of three types of disposable containers for use on the shop floor, depending on the needs of the shop floor worker. Most commonly, a single compartment cartridge is used - the mixed sealant is pumped into the cartridge and a nozzle fitted for final use. Alternatively, the mixed sealant can be provided in a small pot for application with tools by the worker or in a syringe when only a small amount is required to be applied in a controlled manner. Images showing the bulk mixing equipment are in Figures 6 to 8 below.

RMMs and OCs are in place during machine mixing to prevent release to the environment. These are discussed in Section 9.2.

Figure 6: Bulk mixing machine

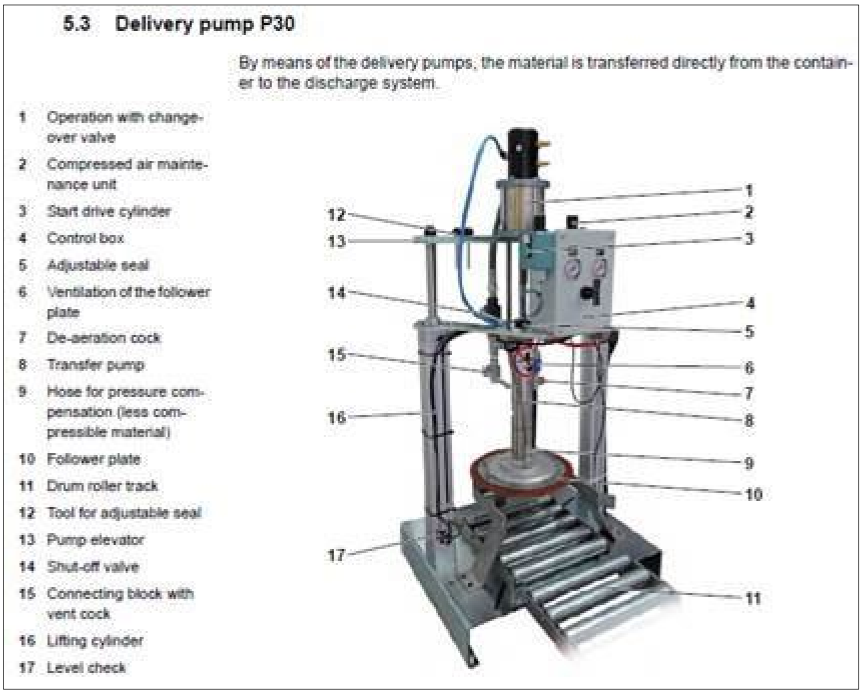


Figure 7: Annotated bulk mixing machine

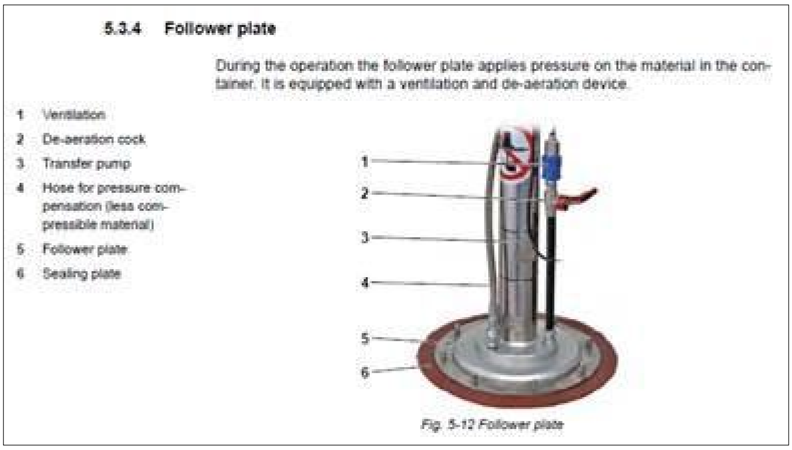


Figure 8: Annotated Follower Plate from the bulk mixing machinery

9.0.1.1.3 Post-Mixing, Service Life and End of Life

Following mixing, the concentration of OPE in the sealant is below 0.1% w/w. It is therefore not subject to authorisation, as detailed in Article 56(6)(a) of the REACH Regulation. Skilled workers apply the mixed sealant to Airbus components in accordance with specific procedures. The mixed sealant may be applied by:

- Extrusion of more viscous sealant from a cartridge, with or without use of a lightly pressurised tool (gun), and with subsequent manipulation with a disposable tool (e.g. spatula) where necessary
- Brush or roller application of less viscous sealant with disposable tools
- Spraying using pressurized tool (gun)
- Extrusion of the sealant to form small caps, which may be applied over fasteners (e.g. rivets, nuts, fastener heads).
- Pouring to fill low points in components and facilitate in service draining.

Occasionally cartridges or caps containing mixed sealant may be frozen at the point of mixing, in order to delay curing. The resulting frozen sealant product is known as Pre-Mixed and Frozen (PMF) sealant. Providing sealant in this form allows end users to access sealant later without the need to mix a new batch.

Once applied, the sealant is allowed to cure at either ambient or elevated temperatures. Elevated temperatures can be used to decrease the curing time. Curing can take between 6 hours to 70 days.

Once applied to Airbus products, the sealant is intended to remain in place over the lifetime of the assembly or, if relevant, until scheduled maintenance is due. It may need to be replaced in the shorter-term in case of damage. When repair is needed, the existing sealant is removed by cutting. Cutting is undertaken with a sharp, flat tool, such as a plastic spatula, or using solvent and a smooth polymer based tool, to remove the sealant in chunks and clean the surface back down to the material beneath for sealant reapplication. After cutting, it may be necessary to use an abrasive pad or wire brush to abrade the surface and remove any remnants of sealant on the surface. The subsequent waste sealant generated would be collected and consigned as hazardous waste. For major repairs, where sealants are part of the material being removed, sand or glass bead blasting may be used in a booth with a dust collection system.

During handling of the final mixed sealant, in uncured or cured form, procedures are in place to prevent potential release to the environment of OPE. They include the requirement to contain, manage, and dispose of residual and waste material and contaminated equipment (e.g., disposable equipment, rags/wipes, PPE, or other items) in accordance with the measures described in Section 9.2 of this CSR.

All wastes containing or contaminated with uncured or cured polysulfide sealant will be managed, and consigned as hazardous waste and collected by licensed third party contractors. The discharge of cured or uncured sealant to wastewater systems is not allowed under any circumstances. These measures ensure no direct release to the environment of OPE through the life cycle. A summary of the waste management processes is provided in Figure 9 below.

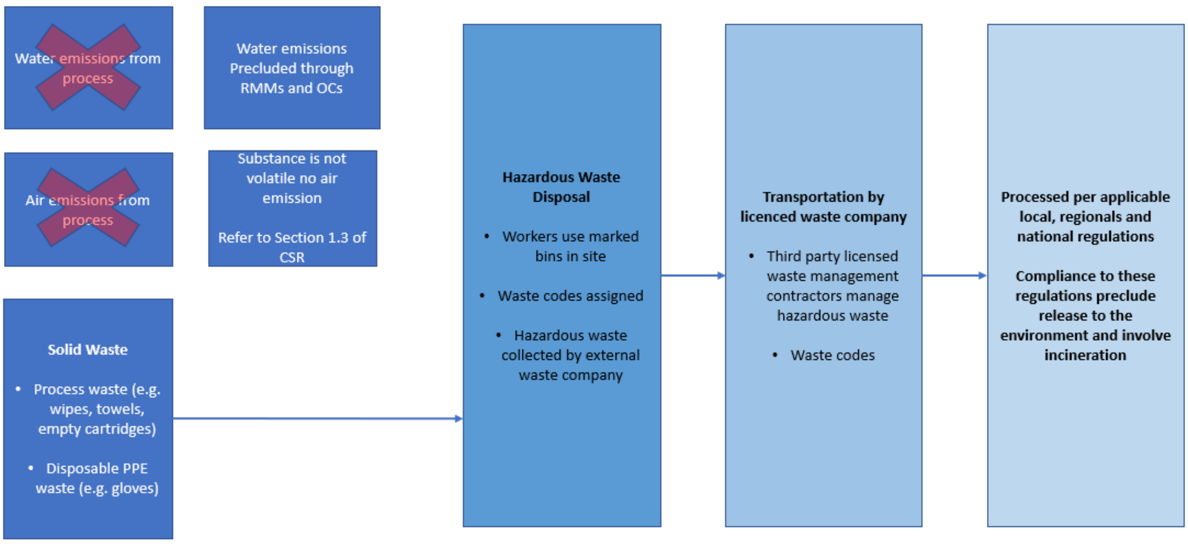


Figure 9: Flow diagram showing the waste management processes in place on site

Workers are skilled and trained with regards to chemical risk management and how to wear properly the PPE. Regular housekeeping and management systems will ensure a high standard of operational control.

Further information on the RMMs and OCs in place to prevent exposure to the environment is detailed under sections 9.1 and 9.2.

9.0.1.1.4 Usage information

Assessed Usage: 50 - 150 kg/year based on:

50 - 150 kg/year used in manufacture of polysulfide sealant at UK sites.

A total of 50 - 150 kg/year in Airbus polysulfide sealants

Tonnage supplied per market sector:

The following table lists all the exposure scenarios (ES) assessed in this CSR.

Table 21. Overview of exposure scenarios and contributing scenarios within the scope of the authorisation

Identifiers*	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
F-1	F	The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants used by Airbus and their associated supply chains - **ERC 2:** Formulation of hardener component (Formulation into mixture)	< 0.15
IW-1	IW	Mixing, by Airbus and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing <0.1% w/w of OPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a) - **ERC 6b:** Use and handling of the hardener component within two compartment kits (Use of reactive processing aid at industrial site (no including into or onto article)) - **ERC 6b:** Use and handling of the hardener component during small scale hand mixing (Use of reactive processing aid at industrial site (no including into or onto article)) - **ERC 6b:** Use and handling of the hardener component during bulk scale mixing (Use of reactive processing aid at industrial site (no including into or onto article))	< 0.15
*** Formulation: F-#, Industrial end use at site: IW-#**			

9.0.2 Introduction to the assessment

9.0.2.1 Environment

Scope and type of assessment:

The basis of the environmental exposure assessment is identification and characterisation of releases or emissions to the environment. It is based on a detailed analysis of releases of OPE (on their own, or in mixtures) to the environment following a survey of relevant operations and with reference to the physical-chemical properties of OPE, the hardener, and the uncured and cured sealant that determine the behaviour of the substance in the lifecycle and in the environment.

The qualitative assessment was conducted by capturing data from the formulator and Downstream Users. This information was verified by observation of operations during multiple site visits. These included:

- A site visit to a formulation site handling OPE to observe the formulation process and the subsequent packaging of the hardener for distribution
- Site visit to Airbus site. Operations observed included bulk mixing by machine, use of a Semkit®, and mixing by hand, and included production and MRO activities within designated facilities.
- A site visit to an MRO site, where the process of repairs and maintenance of aircraft was observed.

The site visits were considered representative due to the high level of consistency and uniformity of the operations across all facilities, as described in this document and observed through the data gathering exercise

The primary aim of the assessment was to describe all relevant processes and identify points in the process at which controlled or uncontrolled release of OPE to the environment could occur and to characterise any such releases. The potential for release to water, air, soil, and waste were assessed.

According to the Annex XV dossier, the primary environmental compartment of interest for OPE is the aquatic environment. Degradation of OPE to the respective alkylphenol (OP) is expected to occur in wastewater treatment plants, surface water and soils, and more slowly in sediments. The Annex XV dossier additionally provides some physical chemistry data for OPEO with grades of ethoxylation between 2 and 10. The substances are water soluble, ranging from 5.162 mg/L (OP2EO) to 2.31 mg/L (OP10EO), and have a low vapour pressure, ranging from 9.15E-06 (OP2EO) to 1.80E-14 (OP10EO). The partition coefficients (log Kow) are relatively high and decrease with increasing chain length, ranging from 4.59 (OP2EO) to 2.39 (OP10EO).

Thus, the qualitative assessment focused on use of water and/or discharge of wastewater and/or generation of waste materials in the formulation or mixing process, or in ancillary processes such as cleaning and maintenance. The potential for discharge to the ground or surface water systems was also carefully assessed. Potential for discharge to air via local air exhaust ventilation systems was considered in case re-deposition is possible.

The qualitative exposure assessment concludes that there are no releases or emissions to the environment from the uses covered by this Review Report. RMMs and OCs in place, as described in the relevant Exposure Scenarios in Sections 9.1 and 9.2, are effective in preventing release of OPE to the environment. The formulator must comply with the requirements of the Exposure Scenarios described in this CSR. Relevant RMMs and OCs are included in the extended SDS supplied by the formulator and must be implemented by Downstream Users. This allows a high level of certainty that there are no emissions to the environment.

The possible scope and benefit of quantitative assessment was evaluated based on the findings of the qualitative assessment. The methods available to quantify emissions were carefully evaluated with respect to the objectives of the assessment. In particular, the following considerations are pertinent:

- Are emissions to the environment from the uses covered by the authorisation predicted or foreseen based on the qualitative evaluation? As discussed above, the conclusion here is that there is no release to the environment.
- Is there a hypothesis that can be informed by quantitative analysis? In terms of determining this second point, further questions are relevant, e.g. Can meaningful sampling be conducted? Are analytical methods available that will provide meaningful results? Are there confounding factors (e.g. background concentrations) that need to be considered?

Based on this second point, quantitative analysis of environmental media, including water, air, sediment, and soil, was considered, but not conducted, for the following reasons:

- Because there is no release to the environment, there is no value in testing. The RMMs and OCs that are in place mean that release to the environment is precluded. The only hypothesis that could be tested is the null hypothesis.
- Meaningful sampling is not possible in most cases. For example, the uses covered by the authorisation do not require water and do not generate wastewater. Typically, a pathway and/or receptor is completely absent (i.e., wastewater drainage is not present near the process). As such, sampling is not logical or meaningful.
- Background concentration of OPE or OP in intake water to the site may produce a false positive in any wastewater from sites, leading to erroneous conclusions. The background level of OP in the environment is often similar to the achievable method detection limit[6].
- Achievable method detection limits for OPE and OP in water/wastewater are in the order of 0.1 µg/l[7]. Lower method detection limits are difficult to achieve.
- Thus, the outcome of analysis could not be interpreted in any meaningful way.
- There is no standard method for measuring the air emission of OPE, or OP, from the uses covered within this Review Report. Additionally, as OPE, and OP, are not volatile substances, measurements in air are not relevant. This therefore means it is not possible to assess the levels of these substances in air and provide a meaningful result or interpretation of data.

Where appropriate, other approaches have been used to test the findings of the assessment. These are described in the section below.

[6] https://echa.europa.eu/documents/10162/397abe32-ecb8-451c-87d2-33af413687dd Page 159
[7] Aquaref/Ineris report. Considerations Sur Certains Aspects Metrologiques Lies A La Mesure Du 4-Nonylphenol, Etat de l'art, évaluation de la pureté des étalons, de l'exactitude de mesure et des perspectives sur leur mesure, Thème D : Amélioration des opérations d'analyses physico-chimiques, December 2014.

The findings of the above emissions assessment were such that the need for a detailed exposure assessment was deemed unnecessary and the exposure assessment can be carried out using qualitative approaches. Since exposure is not predicted, the risk assessment can also be carried out based on a simple comparison of the findings of the exposure assessment with the outcome of the hazard assessment. A detailed hazard assessment is attached to Section 7 of the CSR.

Table 22. Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Freshwater	Qualitative	A detailed discussion on the hazard assessment is presented in Section 7. A freshwater PNEC protective of adverse endocrine effects of 0.39µg/l is derived based on all relevant data.
Sediment (freshwater)	Qualitative	
Marine water	Qualitative	
Sediment (marine water)	Qualitative	
Sewage treatment plant	Qualitative	
Air	Qualitative	
Agricultural soil	Qualitative	
Predator	Qualitative	

9.0.2.2 Humans via environment

Scope and type of assessment:

There is no potential for release to the environment from the uses covered in this Review Report. Therefore, there is no potential for exposure to OPE in the environment. Exposure to humans via the environment is not relevant.

9.0.2.3 Workers and Consumers

Scope and type of assessment:

In line with Article 62(4)(d) of the REACH regulation, 1907/2006/EC and available guidance from RAC, a human health risk assessment is not required as the OPE has been added to Annex XIV of the REACH Regulation on the basis of potential of its degradation products to have endocrine disrupting properties within the aquatic environment. Thus, no formal risk assessment for workers carrying out the formulation or mixing processes covered within this CSR is provided. Activities are qualitatively described below only to the extent they are necessary to inform assessment of release to the environment.

There are no consumer uses of either the OPE-containing hardener or of the mixed sealant described within this CSR.

9.1 Exposure scenario 1: The formulation of a hardener component containing OPE within Aerospace two-part polysulfide sealants used by Airbus and their associated supply chains

Specialised polysulfide sealants formulated by PPG Aerospace are specified by Airbus and their associated supply chains for use in the manufacturing and MRO of equipment. The polysulfide sealants comprise of two separate components – a base and a hardener. The hardener is within the scope of this Review Report and contains low concentrations (up to 0.5% w/w) OPEs.

This Exposure Scenario relates to the formulation of the hardener component of the polysulfide sealant by PPG Aerospace. During this formulation process, small quantities of OPE are mixed with other raw materials at the dedicated manufacturing facility in Shildon, Co. Durham. Further details on each facility are provided below.

The formulation process involves a number of well-defined activities or steps. The OPE surfactant is delivered to the site from the supplier in liquid form. When needed, the required amount is carefully transferred to a pan on floor scales and is subsequently added to the other raw ingredients of the hardener within a single mixing cylinder and blended together mechanically. A mechanical rolling process to reduce any remaining lumps of material follows this first mixing step. A secondary mixing step is performed to ensure homogeneity within the mixture, and the formulation is then dispensed into containers and packaged for distribution. The final hardener is a viscous liquid. The formulated hardener is transferred to a drum or tin and distributed along with its associated base component as a kit, or it is transferred into a two part component kit (i.e. Semkit®).

For some uses, the sealant can be provided in a pre-mixed frozen form by the formulator. In such cases, the formulator mixes the hardener and base components on-site. The final sealant is then extruded into cartridges and immediately frozen (to prevent curing) prior to shipping to the customer under temperature-controlled (typically below -45°C) conditions. The concentrations of OPE in the mixed polysulfide sealant is <0.1%w/w, and thus outside the scope of authorisation as discussed in Article 56(6)(a) of the REACH regulation.

The collection of OPE contaminated waste (including disposable gloves and aprons, rags, empty packaging, etc.) is managed by licensed third party waste management contractors for treatment as hazardous waste, in line with the applicable local, regional, and national regulations outlined in Section on regulatory requirements below. Compliance to these regulations precludes release to the environment and involves incineration.

Specific RMMs and OCs are in place to prevent release to the environment of the OPE by itself, or in the formulated hardener component. These RMMs and OCs are detailed below in Section 9.1.2.

9.1.1 Sites

9.1.1.1 Shildon

Site Location

The PPG Aerospace site manufacturing sealants and coatings in the UK is situated just outside the town of Shildon, County Durham, in the north-east of England. To the west of the town is the North Penines, while around 30 km to the east is the city of Middlesbrough and the North Sea coastline. There are no notable local surface waterways close to the town or the site.

Site Layout and Building Configuration

The PPG site at Shildon covers an area of 6.5 Ha, of which approximately 50% is covered with buildings, including a sealant mixing room that covers an area of 850 m^2. Access to the site is controlled at the entrance.

The OPE surfactant is delivered to the site in a 220kg drum on a truck. The drum, on a pallet, is carefully unloaded in the delivery area, and transferred on the pallet from the truck to the raw material warehouse by forklift.

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The warehouse is located within the main site building. Workers in this raw materials area and production area are trained in material handling and spill control procedures. The OPE surfactant is is stored in a closed container in the material warehouse, so there is no potential for spillage under normal usage conditions. The delivery area has an impermeable tarmac and concrete surface, and there are no surface drains present in the delivery area. Thus, release of any substance from the delivery area to soils or the drainage system is in any case prevented.

The use and handling of the OPE surfactant occurs entirely within the area dedicated to sealant production. There is no water supply or drainage within this filling room. In case of emergency, a low volume water bottle is provided for on site eye washing. Workers would rinse the eye with water, and subsequently mop up excess water from their face or the floor with a paper towel. The paper towel is subsequently disposed of as hazardous waste. The floor is coated with a chemically resistant antistatic 2-pack epoxy floor coating. Regular housekeeping processes are undertaken to maintain the cleanliness and integrity of the chemically resistant floor.

A spillage in the production area is unlikely but would be contained and immediately recovered with no impact to the floor or release to wastewater. In case of such a spill, a solvent impregnated rag would be used to capture any small release of the material from the chemically resistant floor. The nature of this flooring means that any spill can be completely captured and removed (and disposed by incineration as hazardous waste), with no residue being retained on the floor itself. Trained workers in this area would immediately recover any such spill using a disposable rag with solvent, which would be treated as hazardous waste and incinerated.

Filling of containers for distribution takes place on site in a separate filling area in an adjacent room to the production area. The formulated hardener is transferred to the filling room in a sealed drum. There is no water supply or drainage within this filling room. The hardener component can be shipped to customers within a two-compartment kit, small tin kits, or drums.

As in the production room, a spillage in the filling room is unlikely but would be contained and immediately recovered with no impact to the floor or release to wastewater. The floor in the filling room is also the same as that in the production area. Trained workers in this area would immediately recover any such spill using a disposable rag with solvent, which would be treated as hazardous waste.

Regulatory Requirements

The formulator is subject to UK national and local laws, any other relevant applicable local, regional, and national transposed acts/regulations, governing environmental protection, including:

- Directive 2008/98/EC on waste (Waste Framework Directive) and implementing regulations[8] – wastes must be managed according to this comprehensive framework. Obligations include classification and labelling of wastes and establishes a duty of care for waste management. Harmonised system for waste classification.
    - Commission Decision 2000/532/EC establishes the European List of Waste, which is the key document for classification of waste. It provides further provisions for the assessment of hazardous properties and the classification of waste
- Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy. The EQS Directive 2008/105/EC established environmental quality standards for priority substances including nonylphenol.
- Regulation (EC) No 1272/2008 on the classification, labelling, and packaging of substances and mixtures (CLP Regulation). Substances must be classified and labelled according to the regulation. Substances must be handled according to classification.
- Directive 1999/31/EC on landfills of waste, aimed at preventing or reducing negative effects on the environment, in particular the pollution of surface water, groundwater, soil and air, as well as any resulting risk to human health, from landfilling of waste.

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- Directive 2006/118/EC on protection of groundwater against pollution and deterioration to prevent and combat groundwater pollution in the European Union (EU), by setting quality standards by 2008, and propose reverse pollution trends by 2015.Directive 2008/105/EC of the European parliament and of the council of 16 December 2008 on environmental quality standards in the field of water policy, laying down environmental quality standards (EQS) for priority substances and certain other pollutants, with the aim of achieving good surface water chemical status. Nonylphenols are included in the list of priority substance in this directive. The formulation site is audited internally via a corporate Compliance and Assurance audit, which confirms that the regulations and directives discussed above, as well as company specific RMMs and OCs are being fully observed and followed. Additional external audits are undertaken by the relevant National authorities.

As with the transition of EU REACH into UK REACH the above Directives are all transposed into UK law and at the time of submission are applicable to formulation of the polysulfide sealant in the UK.

Management Systems

Considering the industrial nature of the site and the specific operations carried out, staff must be qualified and trained prior to working on the formulation process. PPG has a comprehensive EHS management system to comply with PPG and legal requirements. The management systems in place ensure that specific and stringent RMMs and OCs specified within this CSR are observed to prevent release of OPE.

Workers are skilled and receive regular training with regards to chemical risk management and how to properly wear and dispose of the PPE. Regular housekeeping and management systems are in place ensuring high standard of operational control. Training includes details on the management and disposal of wastes and contaminated tools that have been used during the formulation process, as well as how to undertake maintenance and cleaning tasks where appropriate. Training also covers spill handling, should this occur.

Appropriate signage is provided on site. This indicates details of PPE to be worn in the production area. Hazardous waste bins are colour coded for ease of recognition, and signage is attached to identify the bin as hazardous waste with the relevant waste code.

Visitors are security-checked before arrival on site and are escorted while on site by a trained individual. This worker will ensure that any visitor complies with the EHS management system in place, including wearing the appropriate PPE and following any restrictions on access for an untrained person.

9.1.2 Environmental contributing scenario: Formulation of hardener component (ERC 2)

Hardener component formulation occurs up to twice per month throughout the year, during up to 24 days of production per year. It is a batch production process. The formulation of any one batch of hardener can be completed within a single day during an eight-hour shift. One worker will be actively working on the batch of polysulfide sealant hardener within the production area throughout the process of formulating the hardener. This worker also undertakes any cleaning and maintenance tasks within each shift, and maintenance is an ongoing process throughout the formulation of the hardener component.

Housekeeping procedures are designed to ensure minimal potential for incidental spillage or release of the component on to the floor during the repackaging process, and that any spillage is immediately handled to avoid any health and safety hazards due to the presence of a slip hazard on the floor, and to prevent any potential contamination to work boots, which could be transferred beyond the production area. As detailed below, any contamination to the floor or other surfaces is cleaned immediately using a rag with solvent, which is subsequently disposed of as hazardous waste.

Incoming Goods and Storage

The OPE surfactant is brought onto site on pallets via a truck from the supplier (the manufacturer of the surfactant containing OPE). The surfactant is delivered in a 220 kg drum. At any one time, there would be a maximum of one full drum and one in-use drum present on site. Because of the quantities used on site, a drum would likely only need to be delivered once every 2 to 3 years.

Upon delivery, the drum is carefully unloaded on a pallet in the delivery area and transferred on the pallet to the raw material warehouse by forklift. The drum is secured to, and remains on, the pallet until it is required for repackaging purposes.

Formulation / Production

Formulation is undertaken within a dedicated sealant production room adjacent to the storage room. Typically, there may be up to two formulation processes of the hardener component per month, or 24 days of the year.

Prior to any mixing, initial equipment, and quality control checks are performed.

The drum containing the OPE surfactant is transferred on a purpose-designed trolley from the raw materials storage area to the weighing area in the production area. Handling of the drum and trolley operation is by workers trained to ensure maintenance of drum integrity during transportation from the storage area to the production area.

The drum is fitted with a manually operated tap by which the surfactant can be drawn off. The drum rests on its side within the trolley to assist dispensing of the surfactant. The OPE is weighed directly into a mobile mixing cylinder (>1000 litre capacity), which rests on floor scales and will already contain other constituents of the hardener component. The mobile nature of the cylinder allows it to be moved close to the surfactant drum to facilitate immediate transfer after weighing. The OPE is slowly dispensed into the mixing cylinder via an inlet to minimise potential for splashing or release outside the cylinder.

The mixing cylinder is then moved to the specified on-site mixing point. The mixing cylinder is not covered or lidded. The mixing process is slow, and the ingredients are not volatile. Throughout the mixing process, the mixing cylinder is open to allow access for addition of materials and inserting, for example, the mixing equipment. The mixture is automatically stirred and blended for a fixed period using a specialised automated mixing tool, which is lowered into the mixing cylinder to combine the constituents in a homogenised mixture.

Once fully blended, the tool is lifted from the mixing cylinder and any excess material is allowed to drain back into the mixing cylinder. This ensures no wastage during the production process. The mixing cylinder is then removed. A plastic sheet is placed on the floor below the mixing equipment to ensure any residual material is captured. The plastic sheet is disposed of as hazardous waste.

The mixing cylinder containing the blended material is wheeled to a triple roller. The mixture is carefully dispensed to and passed through the triple roller. The roller refines the mixture by breaking down any lumps of raw materials to ensure a homogeneous hardener component.

After passing through the triple roller, the material is transferred by funnel to a second mixing cylinder. Workers may use a tool to release material from the sides of the funnel as a final process to recover as much of the remaining material as possible and minimise waste. Any material recovered in this manner would be passed through the end of the funnel and into the mixing cylinder below. This mixing cylinder remains open during the process, to allow for the material to run freely into it out of the funnel and for mixing equipment to be inserted to allow a second mixing process to ensure homogeneity of the final hardener.

After use, the roller and funnel are scraped down to remove residual hardener, then cleaned using rags soaked in solvent. These small quantities of hardener and the used rags are disposed of as hazardous waste. This cleaning process is carried out by trained operators.

At this stage, a sample of the hardener is taken for on-site quality control testing to confirm that it meets the required specifications. The sample is removed by collecting a small amount in a disposable sample container via an outlet at the bottom of the mixing cylinder. The sample vessel is subsequently sealed and removed from the production area for testing on-site. In the laboratory, the hardener and the base are mixed to form the sealant, which is then tested for key parameters. The cured sealant and used sample container are disposed to hazardous waste bins in the laboratory following use. Every batch of hardener is tested in this way. There is no release to wastewater.

Batches of hardener that do not meet the quality standards in place on site at PPG are reworked where possible. In rare cases where this is not possible, the hardener is disposed of as hazardous waste.

For every hardener formulation process, a 1000 litre preparation of the hardener component contains a maximum of 0.5% (5 L) OPE.

There is no water supply to the production area, and the formulation of the hardener component does not require water. As such, there is no potential for the OPE to encounter water or be released to water during the process of formulation of the hardener component.

Filling

After formulation, the hardener is transferred from the mixing cylinder directly to a drum via an outlet in the bottom of the mixing cylinder. The drums are carefully filled before they are sealed. Drums of hardener may be labelled and placed in storage prior to shipment to downstream users to support bulk mixing operations, as described in Section 9.2.3.

The hardener may also be further packaged in two compartment kits or smaller containers on site. In this case, a filled drum is transported by forklift from the production area to a filling area, which is within the same building on site.

Within the filling area, a room is dedicated to the filling and packaging of two compartment kits. A two compartment kit is shown in Figure 4 in this CSR, in section 9.0.1.1.2. Filling of the two-compartment kits is conducted via dedicated lines fitted with a small pump and a delivery nozzle that transfer the hardener from the drum to worker stations. The workers fill the valved dasher rod (see Figure 4 within this CSR) with a small, fixed quantity of the hardener component in a controlled manner. The worker controls the rate at which the hardener is delivered. When filled to the requisite level, the filled dasher rod is removed from the delivery nozzle. At this point, the valve closes over the end of the dasher rod, fully containing the hardener component. The base component is pumped into the cartridge. The filled valved dasher rod is then partially inserted into the end of the cartridge, and the cartridge is packaged for shipment.

Alternatively, the formulated hardener component may be filled into smaller containers for shipment with its relevant base component as a two-tin kit. Filling of the hardener into tins is undertaken in a different room than the filling of the two-compartment kits; however, the process of filling is the same. Dedicated lines from the drum to a worker station transfer the hardener in a controlled manner, with supply of this managed by the worker through a small pump with a delivery nozzle. When filled to the requisite level, the worker halts the delivery of the hardener and subsequently seals the tin with an airtight lid, ready to be packed for shipment.

There is no potential for release of hardener to the environment during the filling processes. The dedicated line in place to pump the hardener from the drum to the worker station within the building is contained and prevents any release; there is no access to the hardener during transfer. As part of the filling process, the dasher rod is placed over the delivery nozzle, ensuring that there is no potential for incidental exposure from spillage as the component is pumped directly into the dasher rod.

Between uses, the filling machines are thoroughly wiped down with solvent impregnated rags, including the delivery nozzle and specific delivery lines. These rags, as well as any residual solvent, are subsequently disposed of as hazardous waste, which is processed for incineration by the contracted waste disposal company.

For maintenance purposes, pipework is flushed with solvent, which is added through the inlet, run through the machine, and then out of the outlet pipe. Solvent used during this cleaning process is captured and disposed of as hazardous waste in the marked bin(s) on site, then subsequently handled by a third-party waste management company, who process the hazardous waste for incineration.

PPG Aerospace may also mix the hardener and base on site and immediately freeze it prior to distribution to downstream users under temperature-controlled (typically below -45°C) conditions. The processes used for mixing prior to freezing is the same as those outlined in section 9.2. The workers next to the filling line carry out the process. The subsequently mixed and frozen sealant contains OPE at levels < 0.1% w/w, and is therefore exempt from authorisation in line with Article 56(6)(a) of REACH.

PPE

Reusable personal protective equipment, such as overalls, safety boots, and eye protection, are worn on site and must be put on by workers prior to entering the production area.

Disposable personal protective equipment, such as gloves or aprons, is available for the user to put on *in situ* within the production area. Aprons are used to prevent contamination of overalls during production. In case PPE is contaminated with hardener during the process, the material is carefully captured and removed with a rag or wipe with solvent, which is disposed of as hazardous waste. Disposable aprons, covering the torso and upper legs, are used and are disposed of immediately after the process as hazardous waste in line with applicable local, regional, and national regulations, which is sent for incineration.

Further detail on the measures around the use of personal protective equipment are discussed in later sections of this CSR.

Risk Management Measures

During formulation and cleaning workers wear disposable gloves, eye protection, overalls, and disposable aprons to protect the overalls. The gloves and apron are disposed of as hazardous waste to the relevant marked bin.

Workers receive training in the correct handling of chemicals, including hardener containing OPE, and waste materials, such as PPE or rags that may be contaminated with OPE. Training includes instructions to manage contaminated materials as hazardous waste, including disposal to designated, marked bins.

RMMs and OCs are in place to avoid contamination of clothing. Rigorous on-site training of the workforce is undertaken by the applicant and includes the appropriate measures to take to avoid contamination of overalls. Robust worker training and use of aprons prevents contamination of reusable overalls. The equipment and processes are carefully designed to limit the potential for uncontrolled release, including splashing or overflow. In order to ensure this, measures include:

- All vessels have lids, which are lowered as possible after addition.
- As material is added, the mixing vortex will draw it into the centre of the mixing vessel.
- Vessels are not completely filled, leaving clearance to allow for any splashes to be captured due to the height of the mixing vessel.

Workers are instructed to not dispose of, launder, or wash any contaminated material in the workplace or home. Therefore, there is no significant residual contamination on overalls. Overalls are cleaned regularly in line with normal hygiene. The overalls are deposited in a closed laundry unit and collected by a licensed third-party industrial laundering facility. PPG advises the laundering contractor of potential contaminants by provision of the relevant SDS. In case local contamination of the overalls occurred, it would be removed from the clothing by the worker using a solvent impregnated rag; the rag would subsequently be disposed of as hazardous waste on-site, along with the removed material. As such, any subsequent laundering of the overalls is not anticipated to result in exposure of OPE to the environment. In the unlikely case that significant contamination of the reusable overalls with the OPE substance or the formulated hardener occurred, the overalls would be disposed of as hazardous waste in the marked bin on-site, which is subsequently processed by a third-party waste management company, resulting in incineration.

For eye washing purposes, low volume water bottles are provided. When the eye wash is used, water is dispensed directly from the bottle and any excess removed with a disposable paper wipe, which is disposed of in designated hazardous waste bins and managed as hazardous waste, as described below. No water is provided to the production area. There is no wastewater from the production area.

All contaminated equipment is cleaned by wiping with a rag with solvent. All materials containing or contaminated with OPE surfactant, hardener or sealant, including disposable PPE, contaminated rags, disposable tools, and plastic sheeting, are disposed of in designated hazardous waste bins and managed as waste, as described below.

Waste Management

Workers with appropriate training in waste management handle waste materials.

When empty, the drums are clearly labelled with details of their original contents and the relevant waste codes. The drums are crushed on site and treated as hazardous waste.

Disposable rags are used at several locations within a site to clean down equipment or wipe up localised spills. The rags are disposed of as hazardous waste. Contaminated PPE and plastic sheeting are also disposed of as hazardous waste. All hazardous waste is disposed of to the relevant marked container/bin on site.

Waste bins are provided in the production area and are colour coded and labelled for hazardous waste disposal, to ensure the workers can easily identify and use the relevant bin to dispose of hazardous waste. Typically, these bins are red in colour. The material within the bins is consigned as hazardous waste.

Spill Management

Workers are trained to manage spillages. In the rare event of a release during formulation or filling, workers use disposable rags to contain and clean up the spill. After removal of the bulk of the spill, the area may be wiped down with rags soaked in solvent. All the contaminated rags generated from such a process would be consigned as hazardous waste.

There is no potential for release of OPE to the environment during formulation of the OPE-containing hardener component.

9.1.2.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ Daily use at site: Up to 8 hours per day
▪ Annual use at site: Up to 24 days per year
▪ Percentage of tonnage used at regional scale: 100%
▪ Volume of OPE used per annum: 50 – 150 kg
▪ Volume of OPE used per working day: ~0.5 - 1 kg
Technical and organisational conditions and measures
▪ The hardener is prepared in accordance with a Standard Operating Procedure (SOP) that sets out the equipment to be used and process to be followed, including procedures to be observed in relation to environmental protection and waste management. ▪ All waste hardener and other waste (e.g. rags, containers, PPE) contaminated with hardener and/or OPE is collected and clearly labelled as hazardous waste in designated bins according to company procedures. All hazardous waste generated is incinerated. ▪ The process does not use water. Workers' training includes prohibition on the release of raw materials or sealant hardener to the wastewater system. ▪ RMMs and OCs including worker training are in place to avoid contamination of overalls. A licensed industrial laundry facility cleans contaminated clothing.
Conditions and measures related to sewage treatment plant
▪ Not applicable – there is no release to the sewage treatment plant
Conditions and measures related to treatment of waste (including article waste)
▪ All waste hardener and other solid waste (e.g., rags, containers, PPE) contaminated with hardener and/or OPE is collected and clearly labelled as hazardous waste in designated bins according to company procedures. The waste material is consigned as hazardous waste and collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. ▪ RMMs and OCs are in place to avoid contamination of overalls. ▪ The waste code relevant for the consignment of OPE contaminated materials is 08 04 09*.
Other conditions affecting environmental exposure
▪ Not applicable

9.1.2.2 Releases

There are no releases to the environment of OPE or the hardener component during formulation and filling of the polysulfide sealant.

Table 23. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing RMMs and OCs	Initial release factor: 0 % Final release factor: 0 % Local release rate: 0 kg/day Explanation / Justification: A range of RMMs and OCs are in place, which effectively precludes any release of OPE to the environment during formulation and packaging. There is no release to wastewater on site.

Releases to waste

All waste hardener and other waste (e.g., rags, containers, PPE) contaminated with hardener and/or OPE is collected and clearly labelled as hazardous waste in designated bins according to company procedures. The waste material is consigned as hazardous waste and collected and processed by licensed third party waste management contractors as hazardous waste in line with local, regional, and national waste regulations. All hazardous waste generated is incinerated. The applicant/formulator holds national contracts which cover agreed disposal routes and methods. The need for incineration of the hazardous waste is further confirmed by the waste code placed on the hazardous waste consignment for communication to the disposal company (08 04 09*).

9.1.2.3 Exposure and risks for the environment and man via the environment

Conclusion on risk characterisation: There is no release of OPE to the environment during formulation of the hardener component of the polysulfide sealants as described within this AfA Review Report. A range of RMMs and OCs are in place which effectively prevents any release of OPE to the environment during repackaging. Accordingly, there is no risk to the environment from the use detailed above.

9.1.3 Summary of RMMs and OCs

In line with Article 62(4)(d) of the REACH regulation, 1907/2006/EC, the worker exposure does not require a formal risk assessment (see Section 9.0).

A worker risk assessment is not required in line with Article 62(4)(d) of the REACH regulation. Worker's activities are summarised below, to the extent that they are relevant for an assessment of release to the environment. For example, explanation of measures relating to PPE are only described to the extent necessary to demonstrate absence of incidental environmental exposure from contaminated worker clothing.

- The OPE containing hardener is delivered to and handled on site in a sealed drum.
- OPE is dispensed from the drum and mixed with other raw materials to manufacture the hardener. The mixing process is automated and fully contained. The OPE is transferred manually in a controlled manner. The process is contained and the potential for spillage is limited.
- During formulation, workers wear gloves, protective overalls, and eye protection. A disposable apron is also worn over the overalls.

  Gloves - Workers wear disposable gloves within the production area and are instructed to dispose of the gloves after single use to the hazardous waste containers in the production area.

  Eye Protection - Eye protection is not expected to come into contact with chemicals during normal handling processes. Should contamination occur, goggles are disposed of to the hazardous waste containers in the production area.

  Disposable aprons – protective outerwear may be used when there is potential for contamination of overalls. These are disposed of in the same manner as the disposable gloves.

- Wastes generated during repackaging of the hardener include PPE, and contaminated rags used to clean equipment. These are handled and disposed of as hazardous waste.
- Hazardous waste bins are labelled with the waste description and / or waste code (08 04 09*). Materials in the bins are consigned as hazardous wastes and subsequently removed by a licensed third-party waste management contractor in line with applicable local, regional, and national regulations.
- The drums are clearly labelled with their former contents and are subsequently collected by licensed third party waste management contractors.

9.1.3.2 Exposure and risks for workers

A worker risk assessment is not required.

9.2 Exposure scenario 2: Mixing, by Airbus and their associated supply chains, including the Applicants, of base polysulfide sealant components with OPE-containing hardener, resulting in mixtures containing <0.1% w/w of OPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a)

Airbus and their associated supply chains specify and use polysulfide sealants in the course of production and MRO of Aerospace products.

Two-component polysulfide sealants require that the downstream user mix the base and the hardener in the correct ratio before application. This may be completed in three ways:

i) Mixing within a two-compartment kit (i.e. a Semkit®); or,

ii) Mixing in small scale batches by hand from can kits; or,

iii) Bulk mixing by machine from drum kits.

These scenarios are each introduced in section 9.0.1.1.2 and described in further detail below. Examples of each mixing type and the machinery used is provided within this document in Figures 4 to 8.

Polysulfide sealants may be used on any site up to 365 days per year. The work time for the sealants once mixed is limited, but multiple batches may be prepared in any day.

The collection of OPE contaminated waste (including disposable gloves and aprons, rags, disposable equipment, empty packaging, etc.) is managed by licensed third party waste management contractors for treatment as hazardous waste, in line with the applicable local, regional, and national regulations outlined in the Section on regulatory requirements. Compliance to these regulations precludes release to the environment and involves incineration.

9.2.1 Downstream Use Sites

9.2.1.1 Site Locations

The operations are carried out at numerous sites across the UK. The exact number is difficult to quantify but is estimated to be approximately 45.

The operations are carried out at production facilities and during MRO operations serving Aerospace industries across the UK. This includes:

- Component manufacturers (Airbus qualified suppliers)
- Original equipment manufacturer (OEM) production facilities (Airbus)
- The Applicant's production facilities
- Maintenance repair and overhaul (MRO) shops (Airlines and Airbus)
- Airport and airfields
- Military airfields and repair depots

9.2.1.1.1 Nature of Downstream Use Sites

ECHA provides guidance in Appendix R.12.3 of the 'Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.12: Use description'[9], which serves to define when a use should be considered as being a 'Use at [an] industrial site' or a 'Widespread use by professional workers'. Based on the characteristics defined by ECHA within this guidance, the uses defined within this CSR should be considered as being undertaken at an industrial site. This reflects the nature of the sites where mixing and subsequent use of the final sealant take place. The sites operate as either production or MRO sites. These types of business are specifically highlighted within the ECHA guidance document as relating to an industrial use. Furthermore, and as outlined below (9.2.0.3), these sites have to observe relevant UK national and local laws relating to permitting of industrial processes and environmental, health and safety concerns in the workplace, reinforcing the industrial

[9] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

nature of these sites. The guidance highlights that an industrial site would, for example, be where the production of cars and other vehicles takes place, further supporting the classification of the sites as industrial in nature.

Two main types of working environment are expected:

- Internal facility – purpose designed workshop for Aerospace product production, assembly, and MRO.
- Flight line environment – large aircraft hangar or backshop, or, for minor repairs, at the gate

9.2.1.2 Regulatory Requirements

The downstream user of the sealant is subject to UK national and local laws, and any other relevant applicable local, regional, and national transposed acts/regulations, governing environmental protection, including:

- Directive 2008/98/EC on waste (Waste Framework Directive) and implementing regulations[10] – wastes must be managed according to this comprehensive framework. Obligations include classification and labelling of wastes and establishes a duty of care for waste management. Harmonised system for waste classification.
- Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for the Community action in the field of water policy. The EQS Directive 2008/105/EC established environmental quality standards for priority substances including nonylphenol.
- Regulation (EC) No 1272/2008 on the classification, labelling, and packaging of substances and mixtures (CLP Regulation). Substances must be classified and labelled according to the regulation. Substances must be handled according to classification.

As previously noted, as with the transition of EU REACH into UK REACH the above Directives are all transposed into UK law and at the time of submission are applicable to downstream users of the polysulfide sealant in the UK.

9.2.1.3 Management Systems

Considering the industrial nature of the sites and specific operations carried out, staff must be qualified and trained, and controls and procedures are in place to ensure operations meet requirements for airworthiness. Workers also undergo regular recertification/refresher training to ensure that high standards are maintained. Advanced management systems ensure that the specific and stringent RMMs and OCs specified within this CSR are observed to prevent release through the handling of the OPE in hardener and the final sealant, during mixing and use on site.

Sealants using OPE are used during normal production (up to 365 days/year). A single worker may use sealant for the duration of a shift (typically 8 hours), allowing for breaks from the work. This includes surface preparation, mixing, applying, fairing, and disposing of sealant throughout their shift. Considering the use of the polysulfide sealant on multiple points throughout the body of an aircraft, the workforce may use sealant every working day of the year. The number of workers who will likely handle the polysulfide sealant will vary depending on operations and site size.

Workers are skilled and receive regular training and recertification/refresher training with regards to chemical risk management and how to properly wear and dispose of the PPE. Regular housekeeping and management systems are in place ensuring high standard of operational control.

Management systems are specific to individual organisations but typically include a number of ISO and AS standard management systems, such as ISO 14001, ISO 9001, AS 9100, which govern:

- Quality Management Systems
- Supplier Management Systems
- Environmental, Health and Safety Management Systems

A number of aspects of these management systems are relevant for handling of the sealant. They include:

[10] Specific national regulations implementing the EU Waste Directive are available online at https://eur-lex.europa.eu/legal-content/EN/NIM/?uri=CELEX:32008L0098

- **Workforce Training**. Training has to be undertaken prior to working with the sealants. Training introduces workers to the sealants and their use. Workers are instructed on the hazards associated with the sealants and how they should be handled.

  Workers are trained in the methods for mixing to ensure that the final sealant is fit for purpose and will meet the technical specifications necessary. Workers are trained to apply the sealant in a variety of situations e.g., between gaps or on surfaces (see Figure 2 in section 9.0 for a non-exhaustive list of examples), and to manipulate this using appropriate tools to achieve the required finish and specification requirements. This training is essential to ensure the final seal meets relevant technical and customer specifications.

  Workers are instructed in the management and disposal of wastes and equipment contaminated with hardener and/or sealant. Workers are instructed to dispose of all waste and/or contaminated equipment generated during the process to the labelled hazardous waste bin.

  Training is provided on the proper use and disposal of the relevant PPE during mixing and use of the sealant and how to manage PPE, tools, and equipment should it, despite precautions, become contaminated with the hardener or base component or the mixed sealant. Training also covers management of any accidental spill of the materials.

  Workers are instructed to use the appropriate hazardous waste bins to dispose of any contaminated disposable PPE. Non-disposable PPE such as goggles will be cleaned with a solvent covered rag to remove any polysulfide sealant present, and this rag will then be disposed of as hazardous waste.

  Workforce training is necessary for quality control as well as environmental and waste management purposes. Workers undertake this training prior to use of the sealants. Training completion is assessed, and workers must demonstrate their understanding of all the requirements. Workers cannot carry out these activities until completion of training. Records of training are maintained by the organisation and renewed regularly, with Environmental Health and Safety training to be reviewed regularly.

- **Quality Control.** To ensure the quality of applied polysulfide sealant, companies have in place a number of quality checks on the shop floor to review work prior to parts being released to the next stage of manufacture or to the customer. These processes involve a check of the finished work by at least the operator and their supervisor.

  Sealant that does not meet standards would be rejected during quality control and the work re-done or even parts replaced when the sealant cannot be fully removed, resulting in considerable avoidable cost. An inadequate finish, such as failure to cover completely a surface or the presence of air bubbles, could equally result in rejection of either part of, or all of, an Airbus product, with similar consequences.

- **Controlled Access**. Access to operational areas of the site is controlled. For example, at several sites, each area is managed by a named operator with deputies, and they oversee access rights. Access to buildings and production areas may be controlled or restricted to designated and trained personnel by key, badge, key card, or other access restrictions. Typically, signs and barriers are in place to clarify access requirements.

  Access to storage areas, or production and MRO areas, may be granted to untrained personnel or visitors to observe the process of applying and handling the sealants, as well as other, non-sealant specific, observations. However, such access is typically granted only on an accompanied basis (i.e., with a trained worker present). Untrained personnel would not actively handle the sealant. Furthermore, such personnel would be instructed to remain at the outskirts of the work area in order to avoid any contact with the polysulfide sealant, as well as acting as a health and safety measure to prevent injury. These measures are discussed in on site health and safety briefings prior to allowing any visitor on site.

- **Waste Management**. Specific procedures are in place to control waste handling and management. While the measures in place are specific to each facility, common approaches include

  - the identification of waste hardener and sealant as hazardous waste according to Waste Codes (e.g., 08 04 09*)
  - labelling and often colour-coding of designated waste storage bins to which hardener or final sealant should be disposed on the shop floor
  - collection of hazardous waste by trained personnel

- storage of hazardous waste in an appropriately designed, secure and contained waste disposal facility
- consignment of the material as hazardous waste and processed by licensed third party waste management contractors
- compliance with all relevant UK local, regional, and national waste management regulations.

- **Environmental Management**. Specific procedures are in place to ensure the facility is designed and the process organised so there is no potential release of OPE to the environment. For example, the presence of berms or physical barriers around hazardous waste storage areas, secondary containment to capture spills, and the presence of spill response equipment, may all be in place to prevent and/or respond to a release of OPE.
  - Given the viscous nature of the OPE-containing sealant hardener prior to mixing, a widespread spillage is not anticipated. The material spreads minimally, if at all. Within the filling areas, the floor is a standard resistant industrial floor, which will prevent any migration of the material to soil. Prior to being used for mixing, all materials, including the OPE-containing sealant hardener, are stored within a container, which conforms to dangerous goods handling regulations, ensuring that there is minimal potential for accidental release. In the unlikely case of any spillage to the flooring during use, a solvent impregnated rag or paper towel would be used to wipe up the material, and this is subsequently disposed of into the waste bins marked for hazardous waste.
- **Housekeeping**. The highest level of housekeeping will be maintained in both internal and external assembly and repair areas. This is necessary to ensure manufacturing meets the stringent requirements of the Airbus companies. These requirements are upheld via a rigorous system of internal checks.

  Various Foreign Object Damage (FOD) controls also require Airbus facilities are maintained to a high standard of housekeeping and orderliness. FOD, including waste/detritus, metal shavings and dust, can be introduced at any point during manufacture and MRO. To reduce the potential for FOD, "clean-as-you-go" procedures require workers to clean and remove FOD, declutter, and organise work areas on a regular basis throughout manufacturing processes.

Explanation on the approach taken for the ES

This detailed Exposure Scenario has been developed based on observation and information provided by multiple companies involved in these activities. The conditions under which the activity is carried out as well as the duration and frequency of each task is described.

Environment contributing scenario(s):	
Use and handling of the hardener component within two compartment kits	ERC6b
Use and handling of the hardener component during small scale hand mixing	ERC 6b
Use and handling of the hardener component during bulk scale mixing	ERC 6b

9.2.2 Environmental contributing scenario: Use and handling of the hardener component within two compartment kits (ERC 6b)

In this use, RMMs and OCs in place on site mean that the handling of the hardener component and/or the final cured sealant, which is not subject to authorisation, as discussed earlier in this CSR, during the mixing of two compartment kits does not result in potential release of OPE to the environment. The hardener component is completely contained within the two-compartment sealant kit as delivered to the site. The kits are typically stored in a stockroom or designated cupboard prior to use. The kit contains the hardener within a valved dasher rod within the kit and it is dispersed into the base sealant component within the main cartridge by the action of the operator. The hardener, base, and resulting sealant are completely contained during this mixing process so there is no release of the hardener component to the environment during this process.

The figures below first show an example image of the two compartment sealant kits (Figure 10), and the working process of the two compartment kit and demonstrates how this mixing process is conducted (Figure

11), as well as emphasising the contained nature of the mixing processes.

Figure 10: Example of a two-compartment kit

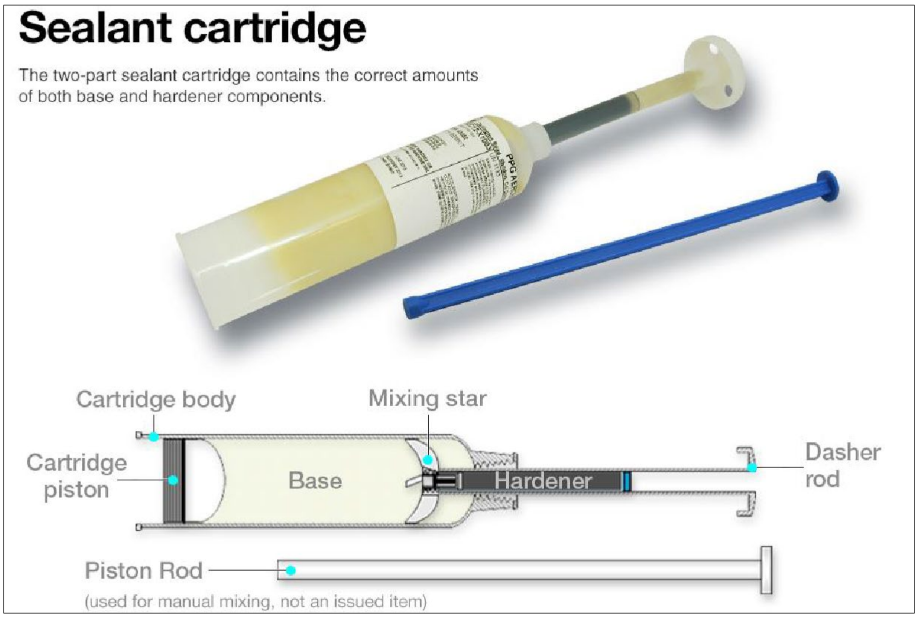

Figure 11: A two-compartment kit for mixing of the base and hardener components and subsequent extrusion

The use of the two-compartment kit for mixing of the hardener component with the base component is a three-stage process. First, a piston rod is inserted into the dasher rod, breaking the seal between the hardener and base and allowing them to be mixed within the cartridge body. The two components are then mixed *in-situ* by movement of the piston rod within the cartridge. The piston is withdrawn by ~25mm to allow for injection of around a third of the hardener component. After this is complete, the dasher is pulled out further and another third of the hardener component is injected. Finally, the dasher is fully pulled out and the remaining hardener is injected.

The process of mixing the hardener through the base component within the cartridge can be carried out by manual methods or by machine. By either route, due to the contained nature of the cartridge, no exposure of the OPE containing hardener component to the environment is possible under typical operation of the cartridge. In both cases, the same process as detailed above is followed – the only difference in processes is the machine mixing approach requires no human intervention aside from placing the two compartment kit into the machine. The machine mixing approach harmonises the mixing process and saves worker effort and time, however workers use both methods of mixing the two-compartment kit prior to use. Figure 12, Figure 13, and Figure 14 below shows an example of the machine used for mixing.

Figure 12: Machine used for mixing of two-compartment sealant kits

Figure 13: Mixing with PPG Cartridge (1)

Figure 14: Mixing with PPG Cartridge (1)

Whether mixed by manual or machine methods, the operators wear the relevant PPE. After mixing, any disposable PPE are disposed of as hazardous solid waste in a bin on site. This bin is coloured and marked with specific waste codes to communicate to both the trained professional workers and waste management contractors the type of waste and nature of any contamination that is contained within it. When these bins are not labelled with the specific waste code, they are clearly labelled to direct workers which hazardous wastes to dispose there.

The valved dasher rod identified above (Figure 11) as containing the hardener component, is removed with the piston rod after mixing has been completed. As this may, in theory, contain residual quantities of the hardener component within it even after mixing has been completed, the worker treats this as hazardous waste (Figure 15). As such, it is disposed of as hazardous solid waste in a marked bin on site.

Figure 15: A worker disposing of the dasher rod and piston rod as hazardous waste

The same process is followed when disposing of the empty cartridges after complete extrusion of the final mixed sealant. While the final sealant contains OPE at levels below 0.1%, the empty cartridge is still handled as hazardous waste in line with the above detailed processes for waste handling.

The handling and manual mixing of the two components in the manner described above does not involve the use of water and there is no generation of any liquid waste, either as water or as solvent. RMMs and OCs in place preclude the hardener or mixed sealant coming into contact with water. As such, there is no release to any wastewater treatment plant or to any water source local to the sites.

Regarding cleaning and maintenance, the 2-compartment kit mixing machinery is cleaned with a pre-impregnated wipe, by a worker wearing the PPE. The PPE used is a combination of the previously mentioned equipment, namely, disposable gloves, reusable overalls, googles, and a disposable apron. The exact combination of PPE depends on the results of the mandatory risk assessment carried out for each activity. The wipe and any disposable PPE are subsequently handled as hazardous waste and disposed of into the marked bin on site, before being sent for incineration off-site by a licensed third-party waste management contractor. Workers are trained not to use water to clean any PPE that has been contaminated with sealant. Any single use, disposable PPE is disposed of as hazardous waste, in line with the handling of PPE discussed above. Where durable PPE, such as goggles, is in use, a solvent soaked rag or solvent wipe is used to clean any contamination prior to curing. The rag or wipe is subsequently disposed of as hazardous waste.

Measures are in place to prevent the release of sealant, either on its own or on contaminated materials, to the wastewater system. These include the use of disposable PPE, provisions of training for all workers using the sealant, and appropriate signage to remind skilled workers of good housekeeping practices and warning against release of material to the wastewater system. Disposable materials contaminated with sealant, as well as disposable PPE are treated as hazardous waste. Additionally, mixing locations typically operate without water sources, serving further to prevent release of the material to wastewater during handling and use. It should be noted that given its hydrophobic nature, disposal of sealant to the wastewater system would not be effective.

Given the above RMMs and OCs in place, the release to the environment of the OPE containing hardener component or the mixed sealant is precluded when mixing is undertaken within a two-compartment kit.

9.2.2.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ Daily use at site: Up to 24 hours
▪ Annual use at site: Up to 365 Days per Year
▪ Percentage of tonnage used at regional scale: 100%
Technical and organisational conditions and measures
▪ No release of hardener or sealant, in uncured or cured form, in process or wash water to wastewater. Workers are trained to never release hardener or sealant to the wastewater system. ▪ Workers are trained in handling of the sealant, including waste management processes, and provided with appropriate PPE and instruction in the use of PPE. ▪ Signs to remind access limitations and waste management practices and prohibitions on disposal to wastewater are provided at appropriate points in the workplace.
Conditions and measures related to treatment of waste (including article waste)
▪ All OPE contaminated waste is collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. • Any OPE contaminated waste generated during the mixing process is collected and disposed of into a marked hazardous waste bin. • Hazardous waste is subsequently processed by a specialised licensed third-party waste management contractor, and the waste codes communicate to these contractors that the waste should be incinerated due to its contents. • Incineration will prevent release of the OPE substance to the environment. • Contracts are established with the waste management contractor by the downstream user, and these require that the waste contractor will comply with all relevant local, regional, and national waste management regulations, and that incineration of the waste must be undertaken. Regular reviews of the contractors handling and treatment processes are undertaken by the downstream users to ensure continued compliance. • Specific procedures are in place at downstream user sites to control waste handling and management. These include correct identification of waste as hazardous, assigning the correct waste code to the hazardous bins, accurate labelling of hazardous waste bins, trained staff collecting the hazardous waste, and compliance with all relevant local, regional, and national waste management regulations. Further, all workers are trained to correctly dispose of the waste material. • All workers must undertake training prior to the use of sealants, with training completion being assessed by completion of a form which is kept on record. Unless training is completed successfully, workers are not permitted to handle the OPE material at the site.
Other conditions affecting environmental exposure
▪ Not applicable

9.2.2.2 Releases

There are no releases to the environment of the OPE containing hardener component of the two-part sealant when mixing within the two-compartment kit, whether by hand or machine, in line with the above RMMs and OCs.

Table 24. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing RMMs and OCs	**Initial release factor:** 0 % **Final release factor:** 0 % **Local release rate:** 0 kg/day **Explanation / Justification:** There is no release to wastewater on site. RMMs and OCs in place on site prevent any potential release to the environment of the OPE containing hardener or sealant.

Releases to waste

Any OPE contaminated waste generated on site is collected, identified as hazardous by the waste codes assigned by the formulator, and handled by licensed third party waste management contractors. The waste is processed in line with the applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

9.2.2.3 Exposure and risks for the environment and man via the environment

Conclusion on risk characterisation: No risk to the environment from the use detailed above, due to no exposure to the environment of OPE contained within the hardener component.

9.2.3 Environmental contributing scenario: Use and handling of the hardener component during small scale hand mixing (ERC 6b)

In this use, RMMs and OCs in place on site mean that the handling of the hardener component and/or the final cured sealant (which is not subject to authorisation, as we discuss earlier in this CSR) during the small-scale hand mixing of polysulfide sealants does not result in potential release of OPE to the environment.

The sealant is delivered to site in kit form, with two separate containers, a larger container (90ml to 450ml) holding a base component and a smaller container (10ml to 50ml) holding a hardener component (Figure 16). The containers are filled to provide the base and hardener in the correct ratios to allow correct mixing of the sealant. The formulator distributes the hardener compound in a container with volumes ranging from 10ml up to 50ml. The kit also comprises the sealant base component that has been batch tested to match the OPE containing hardener. The specific batches of each component have been validated together by the formulator such that, when combined, they will provide a final sealant that meets the specification requirements.

The OPE is a minor constituent within the hardener component. The two components, hardener and base, are stored together on site in a cupboard which contains them until required. They are stored in pairs, as the composition of the hardener and the partner base are specific and necessary to give a final sealant with the relevant specifications.

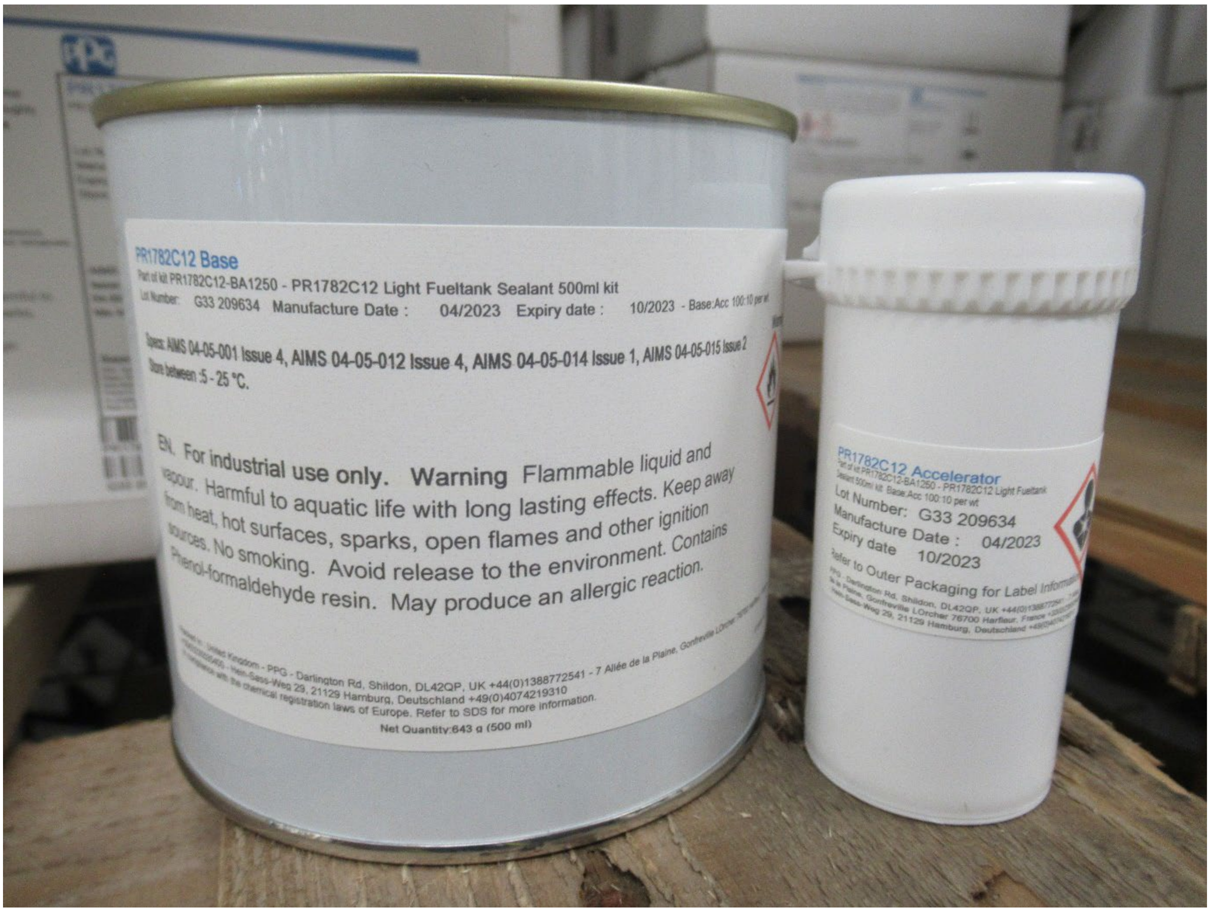

Figure 16: Example of a two-container kit used for small scale hand mixing

When undertaking small scale hand mixing of the hardener component with the base component, not all the contents of the containers may be used. In this case, the worker must weigh out the amounts of each component in the correct ratios as outlined by the original formulator to provide a final sealant that meets specification requirements. A disposable vessel is used to weigh and mix the materials. The two components are measured from the container using disposable spatulas, or a reusable spatula with a disposable covering. The worker, wearing PPE, transfers the individual components to the disposable vessel on a mass balance to measure the relevant quantities to give the right ratio.

Subsequently, the hardener component and the base component are mixed by hand using the spatula within the disposable weighing vessel. Once adequately mixed (e.g., visually confirm the mixed sealant is in line with the colour specifications, with no marbling or other inconsistencies within the blend), the concentration of OPE is below 0.1%w/w. The mixture is applied to the relevant surface. The end use may be for spot repairs to damaged sealant, or alternatively for sealing of smaller surfaces and objects where the two-compartment kit detailed in 9.2.1 would provide an excess of sealant for the job.

Workers wear the relevant PPE. After mixing, any disposable PPE are placed in hazardous waste bins on site. This bin is coloured and marked with specific waste codes to communicate to the trained professional workers and waste management contractors the type of waste and nature of any contamination. When these bins are not labelled with a specific waste code, they are clearly labelled to direct workers which hazardous wastes to dispose there and, upon collection, are placed into a larger labelled bin, which communicates the waste code to a waste management contractor.

When the hardener has been used or in case the expiry date has passed, the container may contain residual quantities of the hardener component within it. The used container is treated as hazardous waste and disposed of in a marked bin on site, as described above. Empty weighing vessels and disposable spatulas are treated as hazardous waste following use. As such, these waste materials are handled in the same manner as the contaminated disposable PPE detailed above – it is disposed of as hazardous waste in a marked bin on site.

The handling and hand mixing of the two components in the manner described above does not involve the use of water and there is no generation of any liquid waste, either as water or as solvent. RMMs and OCs in place preclude the hardener or mixed sealant coming into contact with water. As such, there is no release to any wastewater treatment plant or to any water source local to the sites.

Measures are in place to prevent the release of sealant, either on its own or on contaminated materials, to the wastewater system. These include the use of disposable PPE to protect workers from direct contact with the sealant or from contaminating their clothing, training for all workers using the sealant, and appropriate signage to remind skilled workers of good housekeeping practices and warning against release of material to the wastewater system. Disposable materials contaminated with sealant, as well as disposable PPE, are treated as hazardous waste. Additionally, mixing locations typically operate without water sources, serving further to prevent release of the material to wastewater during handling and use. It should be noted that given its hydrophobic nature, disposal of sealant to the wastewater system would not be effective.

Additionally, mixing locations typically operate without water sources, serving further to prevent release of the material to wastewater during handling and use.

Given the above RMMs and OCs in place, there is no potential for release to the environment of either the OPE containing hardener component or the sealant to the environment when small scale hand mixing is undertaken.

9.2.3.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ Daily use at site: Up to 24 hours per day
▪ Annual use at site: Up to 365 days per year
▪ Percentage of tonnage used at regional scale: 100%
Technical and organisational conditions and measures
▪ No release of hardener or sealant, in uncured or cured form, in process or wash water to wastewater. Workers are trained to never release hardener or sealant to the wastewater system. ▪ Workers are trained in handling of the sealant, including waste management processes, and provided with appropriate PPE and instruction in the use of PPE. ▪ Signs to remind access limitations and waste management practices are provided at appropriate points in the workplace.
Conditions and measures related to treatment of waste (including article waste)
▪ All OPE contaminated waste is collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. • Any OPE contaminated waste generated during the mixing process is collected and disposed of into a marked hazardous waste bin. • Hazardous waste is subsequently processed by a specialised licensed third-party waste management contractor, and the waste codes communicate to these contractors that the waste must be incinerated due to its contents. • Incineration will prevent release of the OPE substance to the environment. • Contracts are established with the waste management contractor by the downstream user, and these require that the waste contractor will comply with all relevant local, regional, and national waste management regulations, and that incineration of the waste must be undertaken. Regular reviews of the contractors handling and treatment processes are undertaken by the downstream users to ensure continued compliance. • Specific procedures are in place at downstream user sites to control waste handling and management. These include correct identification of waste as hazardous, assigning the correct waste code to the hazardous bins, accurate labelling of hazardous waste bins, trained staff collecting the hazardous waste, and compliance with all relevant local, regional, and national waste management regulations. Further, all workers are trained to correctly dispose of waste. ▪ All workers must undertake training prior to the use of sealants, with training completion being assessed by completion of a form which is kept on record. Unless training is completed successfully, workers are not permitted to handle the OPE material at the site.
Other conditions affecting environmental exposure
▪ Not applicable

9.2.3.2 Releases

There are no releases to the environment of the OPE containing hardener component of the two-part sealant when manually mixing in line with the above RMMs and OCs.

Table 25. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing RMMs and OCs	**Initial release factor:** 0 % **Final release factor:** 0 % **Local release rate:** 0 kg/day **Explanation / Justification:** There is no release to wastewater on site. RMMs and OCs in place on site prevent any potential release to the environment of the OPE containing hardener or sealant

<u>Releases to waste</u>

Any OPE contaminated waste generated on site is collected, identified as hazardous by the waste codes assigned by the formulator, and handled by licensed third party waste management contractors. The waste is processed in line with the applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

9.2.4 Environmental contributing scenario: Use and handling of the hardener component during bulk scale mixing (ERC 6b)

Delivery of the two-drum kit is by road, paired on a pallet, to a contained area. This is necessary so the relevant hardener component is stored and used with the correct base component to provide a final sealant that meets the specification for any particular use (e.g., capping a fastener versus a fillet seal versus a faying surface). An example of the two drum kit is shown below (Figure 17).

Figure 17: Example of drums used for bulk scale mixing. One large drum of base and one small drum of hardener constitute one kit.

The kits are delivered to the mixing area on site and mixed by machine. When undertaking bulk mixing of the hardener component with the base component, particular measures are in place to ensure that material is removed from the drums as completely as possible. These include the use of ‘follower’ plates, as seen in Figure 20, which move the contents of the drum down and minimise any residual material on the walls. In doing this, the company minimises material and financial loss due to wastage. As can be seen in Figure 18, two follower plates attach to two individual transfer pump systems, one to pump the hardener component into the machine, and the other to pump the base material into the machine for mixing. The hardener and base component are pumped through the machine and into a single dedicated delivery line, where it is mixed to form the final sealant. Mixing is aided by the presence of a specialised static mixer rod which is present within the dedicated delivery line, and which works to mix the two components together to form the final sealant. The mixer rod is removed from the dedicated delivery line after use and disposed of as hazardous waste in the appropriate marked bin on site.

The mixed sealant is then pumped into the relevant containers – usually single compartment cartridges. Occasionally, it might be delivered to a pot for application by hand using a disposable spatula or similar disposable tool or a disposable syringe for small applications. The bulk mixing machines are shown below (Figure 18, Figure 19, and Figure 20).

Figure 18: Example of a bulk scale mixing machine

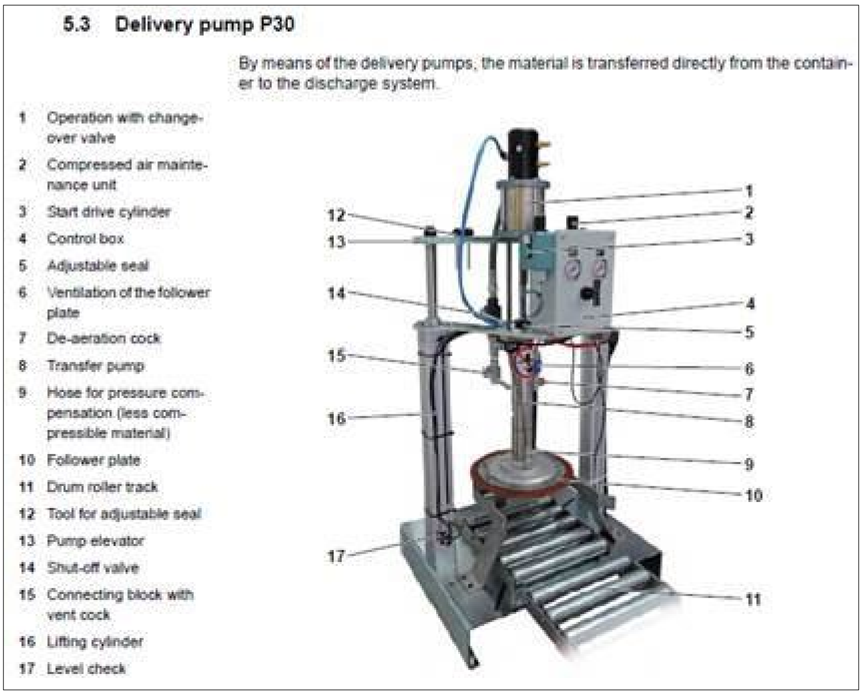

Figure 19: Annotated bulk mixing machine

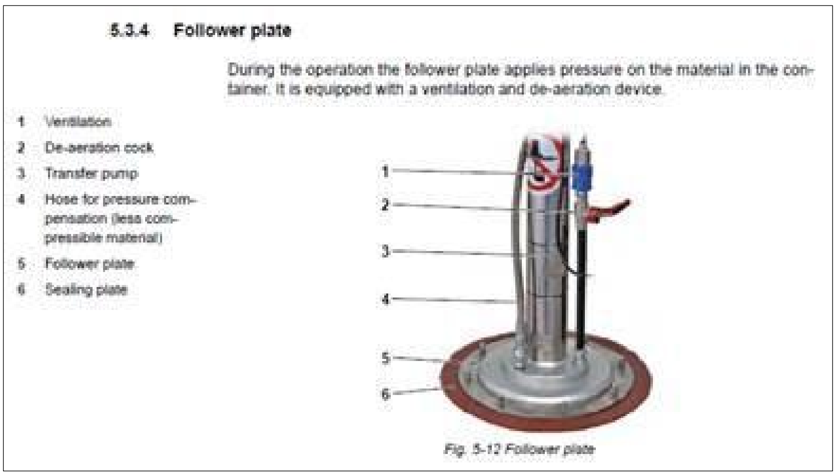

Figure 20: Annotated Follower Plate from the bulk mixing machinery

Workers wear the relevant PPE. After mixing, any disposable PPE are disposed of as hazardous solid waste in a bin on site. This bin is coloured and marked with specific waste codes to communicate to both the trained professional workers and a waste management contractor the type of waste and nature of any contamination. When these bins are not labelled with the specific waste code, they are clearly labelled to direct workers which hazardous wastes to dispose there and, upon collection, are placed into a larger labelled bin. Prior to any activity involving handling and mixing of the hardener, a workplace risk assessment is undertaken. This workplace risk assessment highlights very low risk of contamination of clothing, with no significant residual contamination present on overalls. Risk assessments are maintained on file, and workers can access these at any time. Given the minimised contact with mixtures during bulk mixing due to the containment and automation in place, it is not anticipated to see extensive contamination of clothing through these processes. During the processes of handling and mixing the hardener component, workers will wear the appropriate PPE. The PPE available to workers are disposable gloves, reusable protective overalls and goggles, and a disposable protective apron which may be worn to further protect the reusable overalls from exposure to the materials. The exact combination of PPE depends on the results of the mandatory risk assessment carried out for each activity. Disposable PPE is disposed of to the marked hazardous waste containers and the hazardous waste is subsequently processed by a specialised licensed third-party waste management contractor, and the waste codes communicate to these contractors that the waste should be incinerated due to its contents.

Regarding cleaning and maintenance, the follower plate (Figure 20) used within bulk mixing processes is cleaned during the change of a drum of material. This process is undertaken by a worker wearing the appropriate PPE. The PPE used is a combination of the previously mentioned equipment, namely, disposable gloves, reusable overalls, googles, and a disposable apron. The exact combination of PPE depends on the results of the mandatory risk assessment carried out for each activity. The worker would use a wipe pre-impregnated with solvent and clean the follower plate of any residual material from the previous drum. The wipe and any disposable PPE are then handled as hazardous waste, placed in the relevant marked bin, and sent for incineration off-site by a third-party waste management contractor.

The formulator distributes the hardener in a drum. At end of life, once all the contents have been used or the expiry date has passed, the used drum is consigned as hazardous waste.

Subsequent to mixing, the sealant is distributed to the point of use on site. The worker applies the sealant, and when empty, the container is disposed of. Once mixed, the concentration of OPE within the final polysulfide sealant is below 0.1%, given the ratio of the hardener component to the base component. However, the empty container, whether a single compartment cartridge, pot, or syringe, is still consigned as hazardous waste.

The handling and bulk mixing of the two components in the manner described above does not involve the use of water and there is no generation of any liquid waste, either as water or as solvent. There is no water supply to the process. As such, there is no release to any wastewater treatment plant or to any water source local to the sites.

Measures are in place to prevent the release of sealant, on its own or on contaminated materials, to the wastewater system. These include the use of disposable PPE to protect workers from direct contact with the sealant, training for all workers using the sealant, and appropriate signage to remind skilled workers of good housekeeping practices and warning against release of material to the wastewater system. Disposable materials contaminated with sealant, as well as disposable PPE are treated as solid hazardous waste. Additionally, mixing locations typically operate without water sources, serving further to prevent release of the material to wastewater during handling and use. It should be noted that given its hydrophobic nature, disposal of sealant to the wastewater system would not be effective.

Given the above RMMs and OCs in place, when bulk mixing is undertaken it does not result in the potential release of OPE to the environment.

9.2.4.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ Daily use at site: Up to 24 hours per day
▪ Annual use at site: Up to 365 days per year
▪ Percentage of tonnage used at regional scale:100 %
Technical and organisational conditions and measures

▪ No release of hardener or sealant, in uncured or cured form, in process or wash water to wastewater. Workers are trained to never release hardener or sealant to the wastewater system. ▪ Workers are trained in handling of the sealant, including waste management processes, and provided with appropriate PPE and instruction in the use of PPE. ▪ Signs to remind access limitations and waste management practices are provided at appropriate points in the workplace.
Conditions and measures related to treatment of waste (including article waste)
▪ All OPE contaminated waste is collected and processed by licensed third party waste management contractors as hazardous waste in line with applicable local, regional, and national regulations. • Any OPE contaminated waste generated during the mixing process is collected and disposed of into a marked hazardous waste bin. • Hazardous waste is subsequently processed by a specialised licensed third-party waste management contractor, and the waste codes communicate to these contractors that the waste must be incinerated due to its contents. • Incineration will prevent release of the OPE substance to the environment. • Contracts are established with the waste management contractor by the downstream user, and these require that the waste contractor will comply with all relevant local, regional, and national waste management regulations, and that incineration of the waste must be undertaken. • Regular reviews of the contractors handling and treatment processes are undertaken by the downstream users to ensure continued compliance. • Specific procedures are in place at downstream user sites to control waste handling and management. These include correct identification of waste as hazardous, assigning the correct waste code to the hazardous bins, accurate labelling of hazardous waste bins, trained staff collecting the hazardous waste, and compliance with all relevant local, regional, and national waste management regulations. Further, all workers are trained to correctly dispose of waste. • All workers must undertake training prior to the use of sealants, with training completion being assessed by completion of a form which is kept on record. Unless training is completed successfully, workers are not permitted to handle the OPE material at the site.
Other conditions affecting environmental exposure
▪ Not applicable

9.2.4.2 Releases

There are no releases to the environment of the OPE containing hardener component of the two-part sealant when bulk mixing by machine, in line with the above RMMs and OCs.

Table 26. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing RMMs and OCs	**Initial release factor:** 0 % **Final release factor:** 0 % **Local release rate:** 0 kg/day **Explanation / Justification:** There is no release to wastewater on site. RMMs and OCs in place on site prevent any potential release to the environment of the OPE containing hardener or sealant

<u>Releases to waste</u>

Any NPE contaminated waste generated on site is collected, identified as hazardous by the waste codes assigned by the formulator, and handled by licensed third party waste management contractors. The waste is processed in line with the applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

9.2.4.3 Exposure and risks for the environment and man via the environment

Conclusion on risk characterisation: There is no release of OPE to the environment during the use described above. Accordingly, there is no risk to the environment from the use detailed above.

9.2.5 Summary of RMMs and OCs

A worker risk assessment is not required in line Article 62(4)(d) of the REACH regulation. Workers' activities are summarised below, to the extent that they are relevant for an assessment of release to the environment. For example, explanation of measures relating to PPE are only described to the extent necessary to demonstrate absence of incidental environmental exposure from contaminated worker clothing. In case PPE is contaminated with hardener during the process, the material is carefully captured and removed with a rag or wipe, which is disposed of as hazardous waste.

During mixing of the sealant, several RMMs and OCs are in place to ensure the hardener constituents, including OPE, are not released to the environment.

The polysulfide sealants contain multiple ingredients. A range of environmental hazards is associated with these materials. The RMMs and OCs in place at the facility therefore have to manage adequately the range of hazards associated with all constituents. Consequently, the overall level of protection is high, and RMMs and OCs are in place so that the mixing processes do not result in potential release to the environment of OPE.

Risk management measures are in place to avoid contamination of clothing. Therefore, there is no significant residual contamination on overalls. Overalls are cleaned regularly in line with normal hygiene.

The RMMs below are observed during all activities involving handling and mixing the hardener component. When mixing sealant, workers wear gloves, protective overalls, and eye protection. A disposable apron may also be worn over the overalls.

During handling and mixing of the hardener, workers will wear a combination of disposable and reusable PPE. After use, disposable PPE is removed carefully by the worker and disposed of to the hazardous waste containers in the production area.

Reusable PPE would, if contaminated with either OPE or formulated hardener, be cleaned with a rag soaked in solvent. The rags are subsequently disposed of to the hazardous waste containers in the production area. Once clean, the reusable PPE is returned to storage for future use.

Wastes that may be generated during formulation and mixing of the hardener include disposable PPE, waste two compartment kits, waste containers from the two container kits and rags with solvent that are used to clean equipment. All wastes are handled and disposed as hazardous waste.

Hazardous waste bins are labelled with the waste description and/or waste code. Materials in the bins are consigned as hazardous wastes and subsequently removed by licensed third party waste management contractors in line with applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

9.2.5.1 Exposure and risks for workers

A worker risk assessment is not required.

9.3 Service Life of Polysulfide Sealants

Following mixing, the concentration of OPE in the sealant is below 0.1%w/w. Activities after mixing are not subject to authorisation in accordance with Article 56(6)(a) of REACH. These activities are discussed below only to provide relevant context relating to releases/emissions in the life cycle of the substance.

9.3.1 Downstream Use Sites

9.3.1.1 Site Locations

See Section 9.2.1.

9.3.1.2 Nature of Downstream Use Sites

See Section 9.2.1.1.

9.3.1.3 Regulatory Requirements

See Section 9.2.1.2

9.3.1.4 Management Systems

See Section 9.2.1.3

The highest level of housekeeping is maintained in assembly and repair areas. This is necessary to ensure manufacturing meets the requirements of the Aerospace industry. These specifications are upheld via a rigorous system of internal checks throughout the process, which ensure that the sealant is correctly and accurately applied to give the desired seal, and that the seal will maintain functionality during the lifetime of the aircraft, i.e., that liquid ingress or egress will not occur on an in-use aircraft.

Environment contributing scenario(s):	
Use and handling of the hardener component within two compartment kits	ERC6b
Use and handling of the hardener component during small scale hand mixing	ERC 6b
Use and handling of the hardener component during bulk scale mixing	ERC 6b

Explanation on the approach taken for the ES

This detailed Exposure Scenario has been developed based on observation and information provided by multiple companies involved in these activities. The conditions under which the activity is carried out as well as the duration and frequency of each task is described.

9.3.1.5 Use of the Sealants

Immediately following mixing, the sealant is applied by skilled workers according to specific procedures. The mixed sealant may be applied by:

- Extrusion of more viscous sealant from a cartridge, with or without use of a lightly pressurised tool (gun), and with subsequent manipulation with a disposable tool (e.g., spatula) where necessary.
- Brush or roller application of less viscous sealant with disposable tools.
- Spraying using pressurized tool (gun)
- The sealant will be extruded to form small caps, which may be applied over fasteners (e.g., rivets, nuts,

fastener heads).

- Pouring to fill low points of components and facilitate in service draining.

Occasionally two-compartment kits or caps containing mixed sealant may be frozen at the point of manufacture to delay curing. This allows downstream users to access sealant without the need to mix a new batch.

The schematic diagrams below highlight the use, and subsequent disposal of the final polysulfide sealant (containing below 0.1% of OPE) during production (assembly) and MRO respectively. They represent the use and handling of the polysulfide sealant.

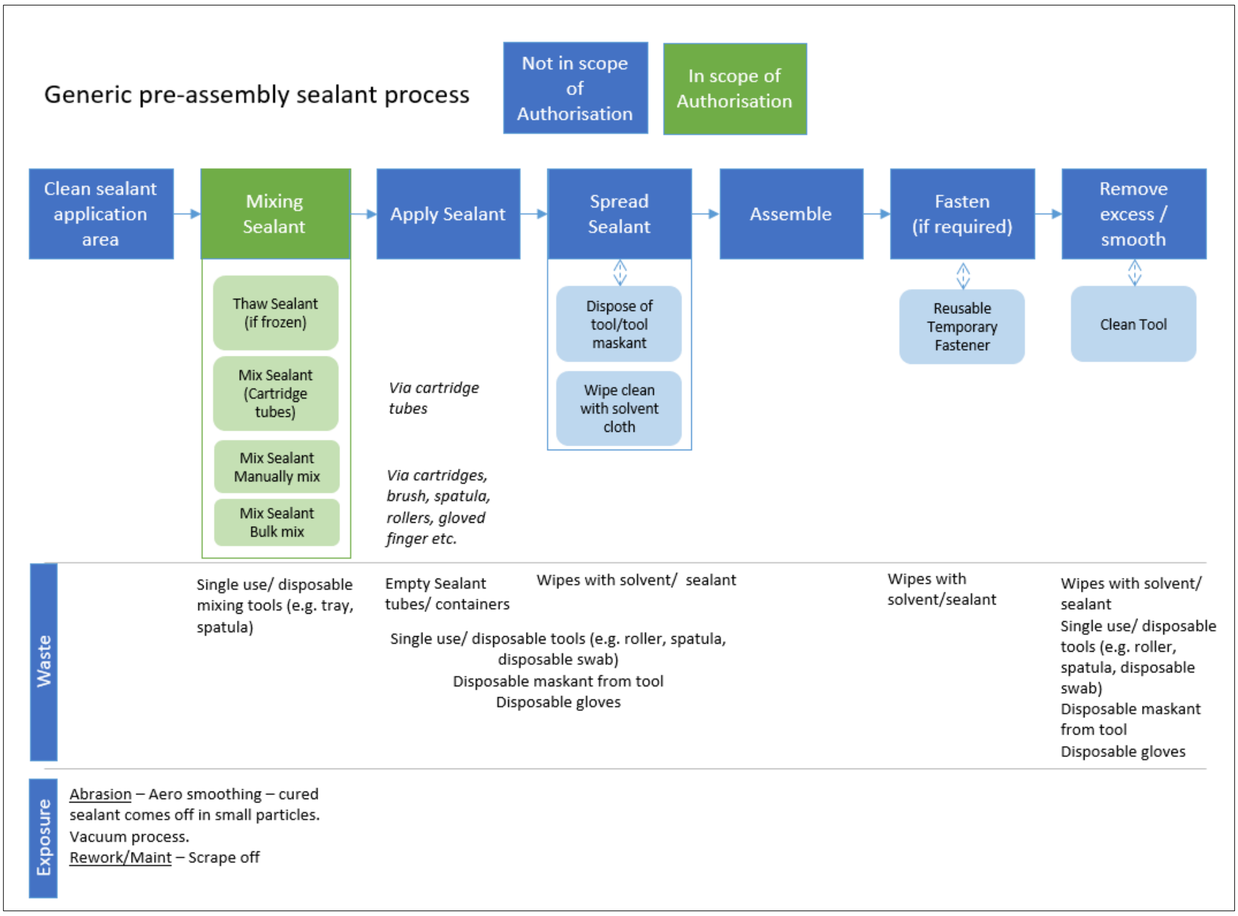

Figure 21: Generic pre-assembly processes of sealant use

The process for post-assembly sealant use is the same as in Figure 21 above, except cured sealant is removed as part of the initial application area cleaning activity. The below chart shows the various mixing processes undertaken for OPE-containing polysulfide sealants which are considered within this Review Report.

The sealant is manually applied using disposable tools such as a Semkit® container (for application within a pressurised cartridge holder), spatula, roller, or brush. This equipment allows the material to be dispensed and applied in a controlled and accurate manner to avoid waste. Disposable tools are also used to spread or smooth the sealant. The tools may be wiped clean with a rag or paper towel. All waste tools, rags, and towels contaminated with sealant are collected and disposed to waste bins marked for hazardous waste. A gloved finger may be used to smooth sealant after application, as an alternative to use of a disposable tool. When a gloved finger is used, the glove will subsequently be carefully removed and disposed of as hazardous waste.

The mixing process initiates curing of the sealant. The work life and cure time are specific to the class of sealant used (itself determined by the specific use). The mixed (semi-cured or cured) sealant quickly solidifies. As it is, by design, insoluble and water resistant, the polysulfide sealant is not amenable to discharge to wastewater.

Due to the viscous nature of the sealant, spillages are not anticipated to occur but in case a small amount of sealant was released to the floor during use, it would be picked up or wiped up with a solvent soaked rag/paper towel, which would then be disposed to waste bins marked for hazardous waste.

In a flight line environment, where sealant repair or maintenance may be conducted in either a large hangar or the open air, only small spot repairs, of the nature described in the small-scale hand mixing scenario above (section 9.2.2), as opposed to larger scale work, are undertaken. As such, only low volumes of the polysulfide sealant are applied. When applying the sealant, it is directed to the specific point of use in small quantities. In case a larger repair that could not be handled by a small spot application of polysulfide sealant was needed, the part would be removed from the body of the aircraft, and subsequent repair and/or maintenance would be carried out in a dedicated internal workshop.

Following application, the surface of the sealant may be abraded or trimmed to shape. Offcuts or dust from the process is recovered with a wipe, which is subsequently disposed of as hazardous waste.

The application of the sealant does not involve the use of water and there is no generation of any liquid waste, either as water or as solvent. On many sites, there is no water supply to the assembly area in which the polysulfide sealants are used. Workers wear the same personal protective equipment (PPE) as for mixing. After mixing, any disposable PPE are disposed of as hazardous waste in a bin on site whether contaminated or not.

If a Semkit® is used, the valved dasher rod identified in Figure 4 that contains the hardener component is removed with the ramrod after mixing has been completed. The worker treats this as hazardous waste and disposes of it to the marked bin on site. Any other generated process waste, including empty Semkits, used wipes or rags, and disposable tools, are also treated as hazardous waste and disposed of accordingly. A summary of the waste management processes in place on any site mixing or handling the polysulfide sealants is provided within this CSR as Figure 9.

The collection of OPE contaminated waste (including disposable gloves and aprons, rags, disposable equipment, empty packaging, etc.) is managed by licensed third party waste management contractors, in line with the applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

Workers are trained, and signs remind skilled workers of good housekeeping practices.

The same process is followed when disposing of the empty cartridges after complete extrusion of the final mixed sealant. While the final sealant contains OPE at levels below 0.1%, the empty cartridge is still handled as hazardous waste in line with the above detailed process for waste handling.

Hazardous waste bins are marked with specific waste codes to communicate to both the trained professional workers and waste management contractors the type of waste and nature of any contamination that is contained within it. When these bins are not labelled with the specific waste code, they are clearly labelled to direct workers which hazardous wastes to dispose there and, upon collection, are placed into a larger labelled bin, which communicates the waste code to the waste management contractors. This waste is collected on site and subsequently removed by licensed third party waste management contractors and disposed of in line with applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

There is no water use in the area where sealant is used, as exposure of the sealant to water during mixing or curing would lead to quality issues. As such, there is no release to any wastewater treatment plant or to any water source local to the sites.

9.3.1.5 Releases

There are no releases to the environment of the OPE containing sealant when applying the sealant to the equipment, in line with the above RMMs and OCs.

Table 27. Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Qualitative description based on existing RMMs and OCs	**Initial release factor:** 0 % **Final release factor:** 0 % **Local release rate:** 0 kg/day **Explanation / Justification:** There is no release to wastewater. RMMs and OCs in place on site prevent any potential release to the environment of the OPE containing hardener or sealant.

Releases to waste

All OPE contaminated wastes generated during this mixing process are disposed of as hazardous waste in the relevant marked bin. This is subsequently removed by licensed third party waste management contractors who handle the waste in line with applicable local, regional, and national regulations. Compliance to these regulations precludes release to the environment and involves incineration.

9.3.1.6 Service Life of the Equipment

The sealant is designed to remain in place until maintenance is due or over the lifetime of the equipment. However, it may need to be replaced in the shorter-term in case of damage. These post-mixing activities, with cured sealant, are not subject to authorisation given that the level of OPE is below 0.1 %. They are discussed here only to the extent necessary to provide detail on release of OPE over the lifecycle of the sealant.

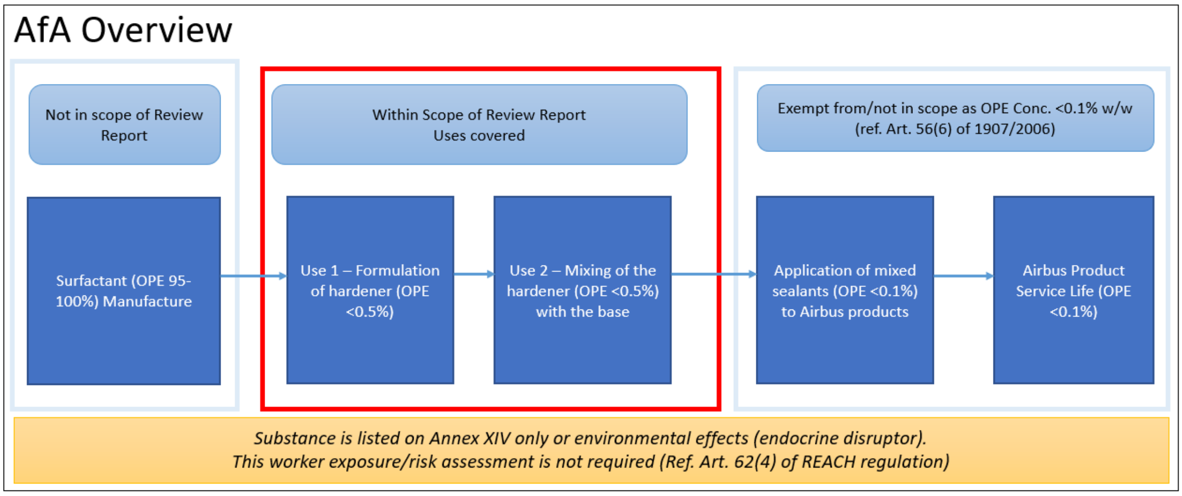

Figure 22: Overview of the scope of the Review Report. The red bordered activities are covered by this Review Report.

When repair is needed, the old sealant is removed by cutting it away with a sharp tool, non-metallic tool or a pneumatic tool kit for desealing. The removed sealant is collected and disposed as hazardous waste. In some cases, the surface may subsequently be abraded with an abrasive pad to remove any remnants of sealant. The surface is then cleaned with a wipe to remove residual sealant. The removed sealant, abrasive pad, and wipe are consigned as hazardous waste.

Migration of OPE from the article over the service life of sealants in Aerospace products will be limited, if it occurs at all. Page 41 of the NPE Annex XV dossier notes that the ethoxylates in sealants is likely to be encapsulated in the article.

The OPE is present in very low concentrations (below 0.05%w/w) in the mixed sealant. Interaction of the ethoxylate with the cross-linked matrix and any other residual (non-reacted) components would be expected to significantly retard migration of ethoxylate from the matrix.

- Sealants within the fuel tank will be exposed to fuel, and potentially water. In case any OPE was to migrate from the sealant to the fuel or water, it would be completely combusted in the aircraft engine.
- Sealants on exterior (e.g., sealing between the panels of the aircraft fuselage) locations that are accessible and visible are mainly covered with paint and/or primer, which would substantially retard or even prevent contact with water (wash water, rainwater, etc.).
- Sealants on interior (e.g., control panel fixing) locations by their nature are not exposed to the environment.

Internally, cured sealant may be exposed to some fluids at locations within the aircraft, for example from condensation on cold surfaces, from washing, or from toilet wastes. Even in these cases, the potential for migration of OPE from the sealant to water is expected to be limited, as only a small fraction of the sealant will be exposed at the surface and per the Annex XV dossier notes, the OPE is likely to be encapsulated and not able to migrate. The potential for migration of OPE depends on the surface area of the sealant in each application where it is present. Transport of OPE from within the polysulfide sealant to the surface will be by diffusion. This implies that the OPE (below 0.05% concentration in the sealant) will be depleted in a thin region near the surface, and that subsequent transport from within the bulk of the sealant will occur much more slowly and represent a smaller fraction of the total transport out of the sealants over their lifetime, noting the cross-linked nature of the matrix would be expected to significantly retard migration of OPE from the matrix.

A semi-quantitative assessment can be applied in order to provide more clarity on the impact of releases in the life cycle. A mass-balance approach can be considered using highly conservative assumptions to demonstrate that, even under worst case assumptions, releases of OPE to the environment from the sealant life cycle will be minimal and can be considered negligible. The hypothesis considers some release from the sealant is possible when the surface of the sealant is exposed to water (e.g., rain, wash water). As discussed above, any such release is likely to be substantially limited by the cross-linked nature of the sealant, which will retard migration of OPE to and from the surface of the sealant. A simple model for release therefore considers the fraction of sealant that might be exposed at the outer surface of the aircraft (i.e., located on the exterior surface of the aircraft and not protected by paint or primer). It also considers that a fraction of the OPE at the surface of the sealant may be released to the environment. The assumptions on the fraction of sealant used in external application and exposed at the surface of the equipment and the fraction of OPE in the sealant that could be released to the environment are purposefully very high, and much higher than would be expected in reality. The assessment shows that, even in such unrealistic circumstances, the amount of OPE released to the environment annually would be very low. In case OPE was released to the environment, by nature of the use, the release would be highly dispersed. Furthermore, complete degradation would be expected quite rapidly in soils and water. This shows that release in the life cycle of sealants, even under an unrealistic worst-case scenario, will not contribute to significant concentrations of OPE in the environment.

Table 28. Estimation of annual OPE release to the environment via a semi-quantitative mass-balance approach

Considering UK-wide release OPE from polysulfide sealant to water		
	Value	**Check**
Maximum Usage of OPE used in production of hardener for use in UK	150 kg/year	From formulator
Concentration of OPE in Sealant in Airbus product	<0.1%	0.001
Volume sealant used by Airbus and associated supply chain in UK per year	250 t/a	Provided by applicant
% Released to the environment during production and downstream use	0%	No release to environment
Maximum Usage of OPE in sealant in Airbus product	150 kg/year	Assume all product is used in the UK, when in reality the market is wider
% of Sealant used in applications that have contact to surface water	5%	Assumes 95% applications are internal or coated with primer so no release to surface water possible.
Usage of OPE in sealant in applications that could be exposed to surface water	7.5kg	UK wide
% of total OPE in sealant that could be released to surface water considering e.g., contact of sealant with water at surface, Kow (i.e. partitioning to water rather than sealant), etc.	10%	Approximation total exposed surface area. Assumes e.g., only 10% ethoxylate in surface facing edge of sealant

		available for release to the environment and all of that released in first year. 90% remains in sealant at end of life.
Usage of OPE in sealant in scope of this Review Report released to surface water UK-wide	0.75 kg/year	Released globally across all flight paths. Assumes all exposed OPE is released to water. However, the major fraction of any material released would be retained in soil, where it would eventually degrade.
UK area	0.25 million km^2	
Usage of OPE in sealant in scope of this Review Report released to surface water UK-wide	<3µg/m^2/year	Assumes all material released in the UK, which is a dramatic over-estimate. Furthermore, the major fraction of any material released would be retained in soil, where it would eventually degrade.

There are no known instances in which polysulfide sealants in aerospace applications in the scope of this Review Report will be released to the environment. A hypothetical 'worst case' situation is presented and shows that even under circumstances when parameters impacting release are set to be unrealistically high, the release to the environment would be negligible. Based on these 'worst case' assumptions in such a hypothetical scenario, the total amount of OPE released to the environment (should there be exposure of cured sealants to the environment and any leaching at all) in one year is 0.75 kg. Considering the wide dispersive nature of the release across the UK, the predicted concentration even under these conservative assumptions is negligible and below both background levels and currently available analytical detection levels, and far below levels of concern to ecosystems.

9.3.2 End of Life of Polysulfide Sealants

At end of life, all aircraft parts must, as part of aviation requirement [AMC 145.A.42; AMC M.A. 504 (d)(2) and AMC M.A. 504 (e)] to avoid being used as suspect unapproved parts, be destroyed to avoid reuse as counterfeit parts. At the end of life, parts are collected in designated, secure boxes and sent to a licensed scrap dealer who treats the metals according to UK national requirements. The Aerospace industry has specialised waste contractors familiar with these requirements.

9.4 Conclusion of the Hazard Assessment

The potential impact of the repackaging of an OPE containing hardener, and the subsequent mixing of this hardener with a base as part of a two-component sealant, has been assessed within this CSR.

The OPE substance has been listed for authorisation due to endocrine disrupting potential of its degradation product, octylphenol, in the environment. As such, an assessment of the exposure and risks to workers is not required, in line with Article 62(4) of REACH, which stipulates that the CSR included within an AfA/Review Report need only cover the risks arising from the intrinsic properties specified in Annex XIV.

A summary of the environmental risk assessment presented through section 9 of this CSR is presented in Figure 23 below:

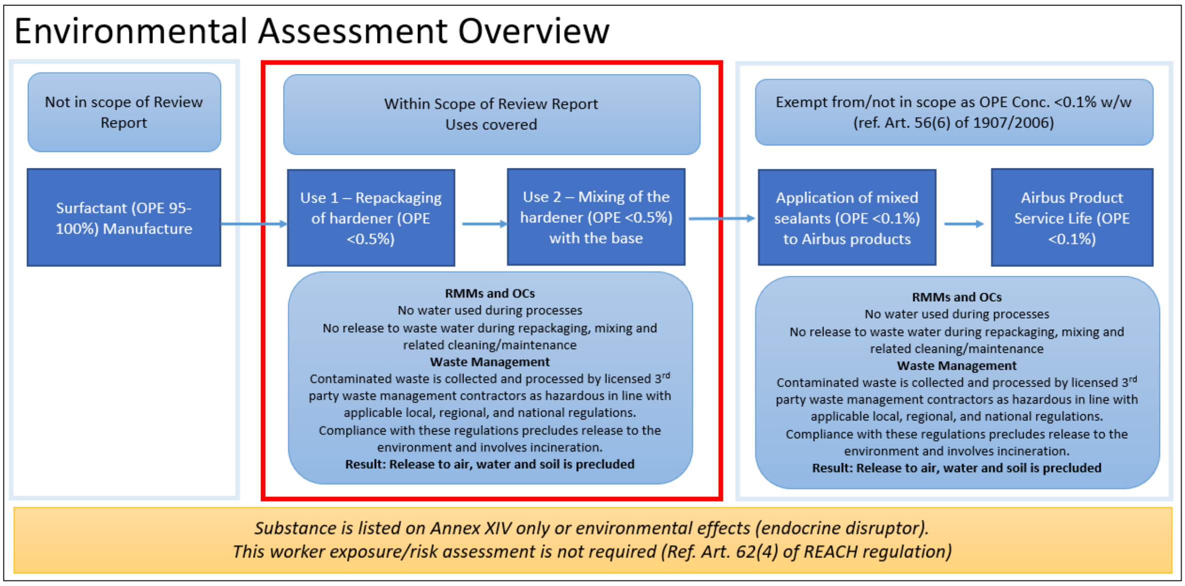

Figure 23: Overview of the Environmental Risk Assessment

A number of stringent RMMs and OCs are in place during both the formulation and mixing processes involving this hardener that preclude the release of the OPE to the environment during handling and use. As such, there is no anticipated risk to the environment during formulation of the hardener by the formulator, or during subsequent mixing of the hardener with the base by Aerospace companies and their supply chains, and continuation of these activities can be considered safe for the purpose of this Review Report.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1 Human health (related to combined exposure)

A human health assessment for workers or consumers has not been carried out, as the risk to human health is not relevant to this Review Report.

10.2 Environment (combined for all emission sources)

10.2.1 All uses (regional scale)

Environment

Throughout the use and handling of the polysulfide sealant and the hardener component containing OPE within it, stringent RMMs and OCs are in place to prevent release of the OPE to the environment. These include workforce training, waste management, and location design, which work together to preclude release to the environment.

Further detail on the RMMs and OCs in place is detailed in section 9 of this CSR, with specific information on the management systems in place provided in 9.0.2.4.

Due to these specific RMMs and OCs, release to the environment is precluded throughout use of the OPE and OPE containing polysulfide sealants, as described within this CSR. There is therefore only a qualitative risk assessment conducted, with no quantitative risk assessment undertaken.

It is considered that use of OPE and OPE containing polysulfide sealants as described within this CSR poses no risk to the environment.

Humans via environment

Remarks: Exposure to humans via the environment is not relevant to this Review Report. Therefore, an assessment has not been conducted.

10.2.2 Local exposure due to all wide dispersive uses

Environment

Remarks: Not relevant as only one wide dispersive use is covered by this CSR.

Humans via environment

Remarks: Exposure to humans via the environment is not relevant to this Review Report. Therefore, an assessment has not been conducted.

10.2.3 Local exposure due to combined uses at a site

There are no combined uses at the assessed sites within this CSR. The two exposure scenarios occur at separate sites within the UK. As such, an assessment of the local exposure due to combined uses at a single site is not relevant.

Annexes

1. Annex: References

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2. Annex: Information on Test Material

Test material: **1,1,3,3-Tetramethylbutylphenol; 2-(1,1,3,3-tetramethylbutyl)phenol / 27193-28-8 / 248-310-7**
Form:

Composition type: Constituent	**Reference substance:** 1,1,3,3-Tetramethylbutylphenol EC no.: CAS no: IUPAC name: 1,1,3,3-Tetramethylbutylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** (1,1,3,3-tetramethylbutyl)phenol EC no.: 248-310-7 CAS no: 27193-28-8 IUPAC name: 2-(1,1,3,3-tetramethylbutyl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Octylphenol PT - Substance type: pure active substance - Physical state: not mentioned - Stability under test conditions: stable - Storage condition of test material: not mentioned

Test material: **4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2**
Form: **solid: particulate/powder - migrated information: powder**

Composition type: Constituent	**Reference substance:** 4-(1,1,3,3-tetramethylbutyl)phenol EC no.: 205-426-2 CAS no: 140-66-9 IUPAC name: 4-(2,4,4-trimethylpentan-2-yl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): para-tert-octylphenol - Substance type: Solid - Physical state: Powder - Analytical purity: 99.34 % - Lot/batch No.: 5743 - Stability under test conditions: Stable - Storage condition of test material: Room temperature in darkness

Test material: **4-tert-octylphenol**
Form:

Composition type: Constituent	**Reference substance:** 4-tert-octylphenol EC no.: CAS no: IUPAC name: 4-tert-octylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-tert-octylphenol - Analytical purity: technical grade 97% - Source: Aldrich Chemical Company (Milwaukee, WI, USA)

Test material: **4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2**
Form:

Composition type: Constituent	**Reference substance:** 4-(1,1,3,3-tetramethylbutyl)phenol EC no.: 205-426-2 CAS no: 140-66-9 IUPAC name: 4-(2,4,4-trimethylpentan-2-yl)phenol	**Concentration range:**

Details on test material: - Name of test material: phenol, 4-(1,1,3,3-tetramethylbutyl) - Substance type: mono-alkylphenol - Physical state: white granules - Analytical purity: 98.97% GC - Purity test date: 20/09/90 - Lot/batch No.: 4-OP/352 - Storage condition of test material: room temperature in the dark

Test material: **Nonylphenol, branched, technical mixture (tNP)**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol, branched, technical mixture (tNP) EC no.: CAS no: IUPAC name: Nonylphenol, branched, technical mixture (tNP)	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Nonylphenol, branched, technical mixture (tNP) - Supplier: Riedel de Haen (Seelze, Germany) - Analytical purity: > 94 %

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: Source: Fluka Chemical, New Yok, NY Technical grade - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: 85%

Test material: **4-octylphenol / 1806-26-4 / 217-302-5**
Form:

Composition type: Constituent	**Reference substance:** p-octylphenol EC no.: 217-302-5 CAS no: 1806-26-4 IUPAC name: 4-octylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-OP - Analytical purity: 99% - Isomers composition: combination of straight chain and branched chain - Lot/batch No.: Aldrich Chemicals 04210JN

Test material: **4-(1,1,3,3-tetramethylbutyl)phenol / 140-66-9 / 205-426-2; p-tert-octylphenol**
Form:

Composition type: Constituent	**Reference substance:** p-tert-octylphenol EC no.: CAS no: IUPAC name: p-tert-octylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** 4-(1,1,3,3-tetramethylbutyl)phenol EC no.: 205-426-2 CAS no: 140-66-9 IUPAC name: 4-(2,4,4-trimethylpentan-2-yl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report):4-tert-octylphenol - Analytical purity: 99% - Source: Contensio Chemicals GmbH, Mar., Germany - Contained isomeric monooctylphenols 90 % p-1,1,3,3-tetramethylbutylphenol

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: not provided -Source of test material: Lancaster Synthesis Lancashire

Test material: **4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5**
Form:

Composition type: Constituent	**Reference substance:** Phenol, 4-nonyl-, branched EC no.: 284-325-5 CAS no: 84852-15-3 IUPAC name: 4-(2,4-dimethylheptan-3-yl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): nonylphenol -Source: Schenectady International - Analytical purity: not given, but after communication with author, believe it was high purity - Isomers composition: “mixture of isomers” - Physical state: liquid

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Source of test material: Sigma-Aldrich Chemical Company Deisenhofen, Germany - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: 98% -90% 4-NP, 10% 2-NP

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Substance type: technical grade - Physical state: solid - Analytical purity: 98% - Source: obtained from Sigma Aldrich Deisenhofen, Germany

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0**
Form:

Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**

Details on test material: - Source of test material: Aldrich Chemical Company Milwaukee, WI - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: 90%

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0**
Form:

Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**

Details on test material: - Source of test material: Schenectady Chemical Co. - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: technical grade 99% - mixture of ring and chain isomers (96% para- 3%-ortho-)

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): nonylphenol - Analytical purity: laboratory grade -Source of test material: Sigma

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Source of test material: Kanto Chemicals, Tokyo, Japan - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: 97.4% mixture of isomers

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: analytical grade 97.4% -Source of test material: Kanto Chemical Tokyo, Japan

Test material: **4-(tert-octyl)phenol**
Form:

Composition type: Constituent	**Reference substance:** 4-(tert-octyl)phenol EC no.: CAS no: IUPAC name: 4-(tert-octyl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-(tert-octyl)phenol - Physical state: dissolved in solvent triethylene glycol solvent of 100 µg/L concentration - Analytical purity: 95%

Test material: **p-t-octylphenol**
Form:

Composition type: Constituent	**Reference substance:** p-t-octylphenol EC no.: CAS no: IUPAC name: p-t-octylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): p-t-octylphenol - Source: Nacalia Tesque, Nakagyou, Kyoto, Japan - Purity: 98-99%

Test material: **2-octylphenol / 67554-50-1 / 266-717-8**
Form:

Composition type: Constituent	**Reference substance:** octylphenol EC no.: 266-717-8 CAS no: 67554-50-1 IUPAC name: 2-octylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): octylphenol - Analytical purity: 98% - Source: Merk Schuchardt Chemicals Eurolab Dresden, Germany - Batch No.: 587 197 844

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Nonylphenol -Purity: 85% of p-isomer mix with branched side chain

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Nonylphenol - Source: Sigma-Aldrich Deisenhofen, Germany - Purity: technical grade

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: at least 97% - Source of test material: Sigma Chemical, St. Louis, MO USA

Test material: **4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5**
Form:

Composition type: Constituent	**Reference substance:** Phenol, 4-nonyl-, branched EC no.: 284-325-5 CAS no: 84852-15-3 IUPAC name: 4-(2,4-dimethylheptan-3-yl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): nonylphenol -Batch # IP890218 - Analytical purity: >95% - Composition of test material, percentage of components: para-nonylphenol Source of test material was Schenectaday Chemicals, Inc. from Enviro Systems, Inc., via Exxon Biomedical December 1992.

Test material: **4-nonylphenol / 104-40-5 / 203-199-4; Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Nonylphenol -Source: Fluka Chemical, Ronkonkoma, NY -Purity: not provided

Test material: **4-(2,4-dimethylheptan-3-yl)phenol / 84852-15-3 / 284-325-5; Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** Phenol, 4-nonyl-, branched EC no.: 284-325-5	**Concentration range:**

	CAS no: 84852-15-3 IUPAC name: 4-(2,4-dimethylheptan-3-yl)phenol	

Details on test material: - Name of test material (as cited in study report): para-C9-Nonylphenol -Source: Schenectady International Inc. -Purity: 90%

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0**
Form:

Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**

Details on test material: - Source of test material: Aldrich Chemical Company Milwaukee, WI - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: 90%

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): nonylphenol - Analytical purity: 91.8% - Composition of test material, percentage of components: 86.1% 4-nonylphenol - Isomers composition: 86.1% 4-nonylphenol Study states chemical was supplied by ICI Surfactants, Wilton Middlesbrough. Chemical is standard industrial feedstock used to manufacture NPEs.

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Nonylphenol -Source: Tokyo Chemical Synthesis Ind. Co. Ltd, Japan -Purity: 99%

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Nonylphenol - Source: Lancaster Ltd, Germany - Purity: not provided

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity: 95% -Source: Schenectady Chemicals Inc.

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type:	**Reference substance:** p-nonylphenol	**Concentration range:**

Constituent	EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Source: Nacalia Tesque, Nakagyou, Kyoto, Japan - Purity: 98-99%

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): p-Nonylphenol -Source: unknown - Purity: unknown

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Nonylphenol - Substance type: pure active substance - Physical state: liquid - Stability under test conditions: 6 months - Storage condition of test material: not mentioned

Test material: **2-octylphenol / 67554-50-1 / 266-717-8**
Form:

Composition type: Constituent	**Reference substance:** octylphenol EC no.: 266-717-8 CAS no: 67554-50-1 IUPAC name: 2-octylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): octylphenol, para-tert-octylphenol - Physical state: solid, white powder - Analytical purity: high purity grade - Lot/batch No.: Lot#BC-5143 - Storage condition of test material: at room temperature (22 °C) - Source: Schenectady Chemicals, Inc.

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Nonylphenol - Substance type: pure active substance - Physical state: liquid - Lot/batch No.: no data - Expiration date of the lot/batch: no data - Stability under test conditions: no data - Storage condition of test material: no data

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0; Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): nonylphenol - CAS: 25154-52-3 -

Purity: ~90% - Isomers composition: technical grade mixture of ring and chain isomers

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0; Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): nonylphenol - CAS: 25154-52-3 - Purity: ~90% - Isomers composition: technical grade mixture of ring and chain isomers

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Nonylphenol -Source: Sigma-Aldrich, UK -Purity: 99% mixed isomers mixture of ring and chain isomers

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Nonylphenol -Source: Sigma-Aldrich, UK -Purity:99% mixture of ring and chain isomers

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Nonylphenol -Source: Fluka, Buchs, Switzerland -Purity: technical grade

Test material: **4-nonylphenol / 104-40-5 / 203-199-4**
Form:

Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4 CAS no: 104-40-5 IUPAC name: 4-nonylphenol	**Concentration range:**

Details on test material: Source: Lancaster Synthesis Ltd., UK - Name of test material (as cited in study report): 4-n-nonylphenol - Analytical purity: <98%

Test material: **4-nonylphenol (technical grade)**
Form:

Composition type: Constituent	**Reference substance:** 4-nonylphenol (technical grade) EC no.:	**Concentration range:**

	CAS no: IUPAC name: 4-nonylphenol (technical grade)	

Details on test material: - Technical grade used - Supplier: Kao - Purity: 95%

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: No data

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: Name of test material (as cited in study): 4-Nonylphenol (CAS No. 104-40-5) - Analytical purity: 99-100% - Supplier: Merck

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: -Name of test material (as cited in study report): Nonylphenol -Source of test material: Aldrich, Cat. no. 29.005.8 - Purity: 100% pure

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0**
Form:

Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**

Details on test material: No Data

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: -Source of test material: This study tested many chemicals including nonylphenol and listed the following companies as suppliers; Aldrich Chemie, Baker J.T, BDH, EGA-Chemie, Fluka A.G and Merck -Name of test material: Nonylphenol -Analytical Purity: 95%

Test material: **Nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Nonylphenol EC no.: CAS no: IUPAC name: Nonylphenol	**Concentration range:**

Details on test material: - Source of test material: This study tested many chemicals including nonylphenol and listed the following companies as suppliers; Aldrich Chemie, Baker J.T, BDH, EGA-Chemie, Fluka A.G and Merck - Name of test material: Nonylphenol - Analytical Purity: 95%

Test material: **Technical grade nonylphenol**
Form:

Composition type: Constituent	**Reference substance:** Technical grade nonylphenol EC no.: CAS no: IUPAC name: Technical grade nonylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Technical grade nonylphenol - Analytical purity: 85% 4-nonylphenol - Impurities (identity and concentrations): Lesser proportions of 2-nonylphenol and decylphenol (percentages not given) - Manufacturer: Fluka AG

Test material: **1,1,3,3-Tetramethylbutylphenol; 2-(1,1,3,3-tetramethylbutyl)phenol / 27193-28-8 / 248-310-7**
Form:

Composition type: Constituent	**Reference substance:** 1,1,3,3-Tetramethylbutylphenol EC no.: CAS no: IUPAC name: 1,1,3,3-Tetramethylbutylphenol	**Concentration range:**
Composition type: Constituent	**Reference substance:** (1,1,3,3-tetramethylbutyl)phenol EC no.: 248-310-7 CAS no: 27193-28-8 IUPAC name: 2-(1,1,3,3-tetramethylbutyl)phenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): Octylphenol PT - Substance type: pure active substance - Physical state: solid - Stability under test conditions: stable - Storage condition of test material: not mentioned

Test material: **4-octylphenol / 1806-26-4 / 217-302-5**
Form:

Composition type: Constituent	**Reference substance:** p-octylphenol EC no.: 217-302-5 CAS no: 1806-26-4 IUPAC name: 4-octylphenol	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-Octylphenol - Analytical purity: 99% - Supplier: Aldrich Chemical Company, Milwaukee, Wisconsin, Cat No. 38, 444-5