CHEMICAL SAFETY REPORT

Public Version

Legal name of applicants: *Chemetall Limited*

Submitted by: *Chemetall Limited*

Substance: *4-Nonylphenol, branched and linear, ethoxylated*

Use title: *Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE for Aerospace uses that are exempt from authorisation under REACH Art. 56(6)(a) and as Grandfathered into UK REACH.*

Use number: *1*

 Copyright protected – No copying / use allowed

Disclaimer

This document shall not be construed as expressly or implicitly granting a license or any rights to use related to any content or information contained therein. In no event shall the applicants be liable in this respect for any damage arising out of or in connection with access, or use of any content or information contained therein despite the lack of approval to do so.

Table of Contents

 Copyright protected – No copying / use allowed

List of Tables

List of Figures

 Copyright protected – No copying / use allowed

 Copyright protected – No copying / use allowed

Declaration

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

Also, we request that the information blanked out in the "public version" of Chemical Safety Report is not disclosed. We hereby declare that, to the best of our knowledge as of today 26th 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.

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

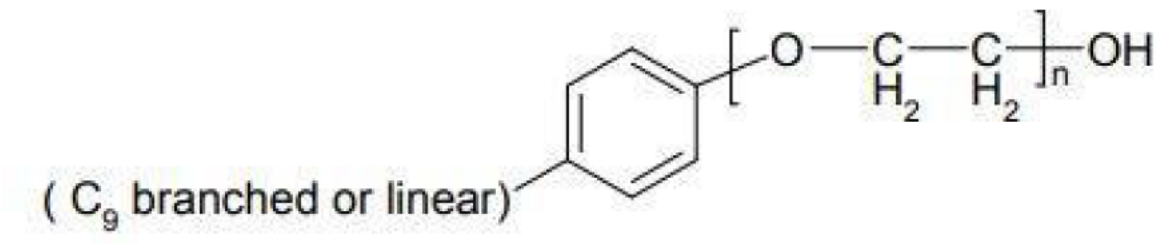
1.1. Name and other identifiers of the substance

Type of substance 4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]: 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-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]
Molecular formula:	(C2H4O)n C15H24O , with n≥1

Structural formula:



1.2. Composition of the substance

Overall information on composition:

Composition	**Related composition(s)**
4-Nonylphenol, branched and linear, ethoxylated [per REACH Annex XIV] (legal entity composition of the substance)	

Name: 4-Nonylphenol, branched and linear, ethoxylated [per REACH Annex XIV]

Degree of purity: 100 % (w/w)

Table 2. Constituents (4-Nonylphenol, branched and linear, ethoxylated [per REACH Annex XIV])

Constituent	Typical concentration	Concentration range	Remarks
4-Nonylphenol, branched and linear, ethoxylated [substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof] EC no.:	>=95 % (w/w)	>=95 - <=100 % (w/w)	

Table 3. Impurities (4-Nonylphenol, branched and linear, ethoxylated [per REACH Annex XIV])

Constituent	Typical concentration	Concentration range	Remarks
Unknown impurities EC no.:	<=5 % (w/w)	>=0 - <=5 % (w/w)	

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	4.55 mg/L (slightly soluble in water)	
Melting point/freezing point	-55°C	
Boiling point	354°C	
Flash point	193.5°C	
Density	0.99 g/cm³	
Partition coefficient	Log Pow 5.39	
Surface tension	31.56 – 55.92 mN/m	

Copyright protected – No copying / use allowed

Auto flammability/self-ignition temperature	410°C	

2. MANUFACTURE AND USES

2.1. Manufacture

Manufacture of the substance is outside of the scope of this AfA Review Report.

2.2. Identified uses

Table 5. Uses at industrial sites

	Uses at industrial sites
IW-2	**Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE for Aerospace 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.

 Copyright protected – No copying / use allowed

4. ENVIRONMENTAL FATE PROPERTIES

In line with Article 64(2)(d) of the REACH regulation, there is no information on the environmental fate properties of the substance presented within this CSR, as the substance is listed for its potential endocrine disrupting properties in the environment.

 Copyright protected – No copying / use allowed

5. HUMAN HEALTH HAZARD ASSESSMENT

In line with Article 64(2)(d) of the REACH regulation, there is no information on the risks to human health from use of the substance presented within this CSR, as the substance is listed for its potential endocrine disrupting properties in the environment.

Copyright protected – No copying / use allowed

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

In line with Article 64(2)(d) of the REACH regulation, there is no information on the risks to human health presented within this CSR, as the substance is listed for its potential endocrine disrupting properties in the environment.

 Copyright protected – No copying / use allowed

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

For fish species, Watanabe et al (2017) is the Key Study and the key value is a NOEC for fertilised eggs (fertility) in the Japanese medaka (*Oryzias latipes*) F0 and F1 generations of 0.000127 mg/L or 0.127 µg/L. For invertebrate species, Comber et al (1993) provided a 21-day NOEC (reproduction) of 0.024 mg/L nonylphenol for the preferred species, *Daphnia magna*. For algal species, the Scholz (1989) study was selected as a key study because it provides both an EC50 (1.3 mg nonylphenol/L) and EC10 (0.5 mg nonylphenol/L) concentration for growth inhibition for a common algal test species *Desmodesmus subspicatus*.

Additional information:
The review of nonylphenol exposure to aquatic organisms resulted in reliable toxicity tests covering freshwater and saltwater species of fish, invertebrates, algae and an amphibian. Toxicity test results indicated fish were more sensitive to the toxic effects of nonylphenol than invertebrates, algae or amphibians for acute, short-term exposures. Freshwater fish were more sensitive also when considering short-term, with the lowest LC50 for survival for fish and invertebrates of 0.01 and 0.08 mg nonylphenol/L, respectively. Toxicity data for long-term exposure to nonylphenol indicated the lowest NOEC value of 0.00127 mg nonylphenol/L for fertilised eggs in adult and first-generation fish was similar to the lowest NOEC of 0.001 mg nonylphenol/L for invertebrate growth inhibition.

7.1.1. Fish

7.1.1.1 Short-term toxicity to fish

The results are summarised in the following table:

Table 6. Short-term effects on fish

Method	Results	Remarks
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater short-term toxicity to fish according to ASTM 1991 E729-88a Standard guide for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians	LC50 (96h): 221 µg/L not specified (meas. (arithm. mean)) based on: mortality (208-236) EC50 (96h): 109 µg/L not specified (meas. (arithm. mean)) based on: behaviour (100-118)	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Lepomis macrochirus freshwater short-term toxicity to fish according to ASTM 1991 E729-88a Standard guide for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians	LC50 (96h): 209 µg/L not specified (meas. (arithm. mean)) based on: mortality (184-238) EC50 (96h): 203 µg/L not specified (meas. (arithm. mean)) based on: behaviour (178-231)	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference**

Copyright protected – No copying / use allowed

		Brooke, L.T. 1993
Pimephales promelas freshwater short-term toxicity to fish according to ASTM 1991 E729-88a Standard guide for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians	LC50 (96h): 128 µg/L not specified (meas. (arithm. mean)) based on: mortality (116-141) EC50 (96h): 96 µg/L not specified (meas. (arithm. mean)) based on: behaviour (not reliable)	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Acipenser oxyrhynchus freshwater short-term toxicity to fish according to ASTM E729-96 and Committee on Methods for Toxicity Tests with Aquatic Organisms (1975) EPA/660/3-75-009	LC50 (96h): 0.05 mg/L not specified (nominal) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Dwyer, F.J., F.L. Mayer, L.C. Sappington, D.R. Buckler, C.M. Bridges, I.E. Greer, D.K. Hardesty, C.E. Henke, C.G. Ingersoll, J.L. Kunz, D.W. Whites, T. Augspurger, D.R. Mount, K. Hattala, G.N. Neuderfer 2005**
Hybopsis monacha freshwater short-term toxicity to fish according to ASTM E729-96 and Committee on Methods for Toxicity Tests with Aquatic Organisms (1975) EPA/660/3-75-009	LC50 (96h): 0.08 mg/L not specified (nominal) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Dwyer, F.J., F.L. Mayer, L.C. Sappington, D.R. Buckler, C.M.**

Copyright protected – No copying / use allowed

		Bridges, I.E. Greer, D.K. Hardesty, C.E. Henke, C.G. Ingersoll, J.L. Kunz, D.W. Whites, T. Augspurger, D.R. Mount, K. Hattala, G.N. Neuderfer 2005
Acipenser brevirostrum freshwater short-term toxicity to fish according to ASTM E729-96 and Committee on Methods for Toxicity Tests with Aquatic Organisms (1975) EPA/660/3-75-009	LC50 (96h): 0.05 mg/L not specified (nominal) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Dwyer, F.J., F.L. Mayer, L.C. Sappington, D.R. Buckler, C.M. Bridges, I.E. Greer, D.K. Hardesty, C.E. Henke, C.G. Ingersoll, J.L. Kunz, D.W. Whites, T. Augspurger, D.R. Mount, K. Hattala, G.N. Neuderfer 2005**
Fundulus heteroclitus saltwater short-term toxicity to fish no guideline followed	LC50 (96h): 0.95 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.14) LC50 (48h): 1.17 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.13)	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Kelly SA & Di Giulio RT 2000**
Pimephales promelas freshwater short-term toxicity to fish	LC50 (96h): 136 µg/L test mat. (meas. (not specified)) based on: mortality (95% CL 127 - 146µg/L)	2 (reliable with restrictions) supporting study experimental study

 Copyright protected – No copying / use allowed

		Test material para-nonylphenol, (full information in **Annex II**). **Reference** **TenEyck MC & Markee TP 2007**
Menidia beryllina saltwater short-term toxicity to fish according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): 70 µg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5; 4-nonylphenol / 104-40-5 / 203-199-4; para-nonylphenol (4-nonylphenol, PNP), (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Pouncher S & Pruell RJ 2000**
Puntius conchonius freshwater short-term toxicity to fish according to OECD Guideline 203 (Fish, Acute Toxicity Test)	LC50 (96h): 1.72 µmol/L test mat. (nominal) based on: mortality (95% CL 1.78 - 1.66µM)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Bhattacharya H, Xiao Q & Lun L 2008**
Cyprinodon variegatus saltwater short-term toxicity to fish according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): 142 µg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5; 4-nonylphenol / 104-

		40-5 / 203-199-4; para-nonylphenol (4-nonylphenol, PNP), (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Pouncher S & Pruell RJ 2000**
Fundulus heteroclitus saltwater short-term toxicity to fish no guideline followed	LC50 (96h): 24.7 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 3.7) LC50 (48h): 27.7 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 2.8)	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Kelly SA & Di Giulio RT 2000**
Fundulus heteroclitus saltwater short-term toxicity to fish no guideline followed	LC50 (96h): 1.18 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.20) LC50 (48h): 1.33 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.05)	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Kelly SA & Di Giulio RT 2000**
Fundulus heteroclitus saltwater short-term toxicity to fish no guideline followed	LC50 (96h): 0.97 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.23) LC50 (48h): 1.47 µmol/L test mat. (nominal) based on: mortality (standard error of the mean 0.16)	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Kelly SA & Di Giulio RT 2000**

 Copyright protected – No copying / use allowed

Pleuronectes americanus saltwater short-term toxicity to fish according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): 17 µg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5; 4-nonylphenol / 104-40-5 / 203-199-4; para-nonylphenol (4-nonylphenol, PNP), (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Pouncher S & Pruell RJ 2000**
Cyprinodon variegatus saltwater short-term toxicity to fish equivalent or similar to EPA OTS 797.1400 (Fish Acute Toxicity Test) ; according to Test Standard 40 CFR 797.1400	LC50 (96h): 0.31 mg/L test mat. (meas. (not specified)) based on: mortality (95% CI 0.24-0.42 mg/L) NOEC (96h): 0.24 mg/L test mat. (meas. (not specified)) based on: mortality	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**
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 Fishes, Macroinvertebrates, and Amphibians not applicable	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	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 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**
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 Amphibians not applicable	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 mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
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	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**

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**

Discussion

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

Brooke (1993) presented results with the preferred species, *Pimephales promelas*, of 96 hr EC50 (growth) of 0.096 mg/L nonylphenol. The test was performed according to ASTM 1991 E729-88a standard guideline for conducting acute toxicity tests with fish, macroinvertebrates and amphibians.

Value used for CSA:
LC50 for freshwater fish: 0.096mg/L
LC50 for marine water fish: 0.017mg/L

Additional information:
Two key studies for short-term exposure to nonylphenol were selected based on their reliability, relevance and species sensitivity. Brooke (1993) provided nonylphenol toxicity information for the preferred species fathead minnow, *Pimephales promelas*; and Dwyer et al (2005) due to the range of organisms tested and their sensitivity to nonylphenol.

Brooke (1993) study also provided toxicity data on the bluegill sunfish, *Lepomis macrochirus* and rainbow trout, *Oncorhynchus mykiss*, indicating that these fish were less sensitive *than P. promelas* to nonylphenol. Sensitivity ranking based on LC50 concentration test results by Dwyer et al (2005) indicated the LC50 concentration of 0.27 mg nonylphenol/L to the preferred test species *P. promelas* was ranked 15 out of 18 fish species with *Acipenser oxyrhynchus* ranked the most sensitive species.

Nine reliable short-term (24 and 96-hr) toxicity studies that included 19 freshwater species from 15 genera and 4 saltwater species were selected to represent the acute response of fish to nonylphenol. Species included the preferred test species, *Danio rerio*, *Pimephales promelas* and the salmonid, *Oncorhynchus mykiss*. Survival L(E)C50 concentration for freshwater fish ranged from 0.05 mg nonylphenol/L for *Acipenser oxyrhynchus* (Dwyer et al, 2005) to 0.38 (24 h) mg nonylphenol/L for *Puntius conchonius* (Bhattacharya et al, 2008). Salt water species L(E)C50 concentration ranged from 0.017 mg nonylphenol/L for *Pleuronectes americanus* (Lussier et al, 2000) to 0.48 mg nonylphenol/L for *Cyprinodon bovines* (Dwyer et al, 2005). The 96-hr nonylphenol exposure LC50 concentration for the preferred species *P. promelas* ranged from 0.128 to 0.27 mg nonylphenol/L. The 96-hr nonylphenol exposure to embryo of the preferred standard species *D. rerio* ranged from 0.81 to 1.5 mg nonylphenol/L.

The supporting study results of Teneyck and Markee (2007) indicted an LC50 concentration of 0.136 mg nonylphenol/L for *P. promelas* that was in close agreement with the LC50 0.128 mg nonylphenol value presented by Brooke (1993). Supporting study results by Bhattacharya et al (2008) indicated acute exposure to nonylphenol can include non-lethal histopathological alterations, and the LC50 concentration of 0.397 mg nonylphenol/L for *Puntius conchonius* (Cyprinidae) expanded the range of variability to 0.08-0.29 mg nonylphenol/L for other Cyprinidae reported by Dwyer et al (2005). LC50 concentration data reported by

Lussier et al (2000) and Dwyer et al (2005) for a variety of fish suggest freshwater species tested were generally more sensitive to nonylphenol exposure than the marine species.

7.1.1.2. Long-term toxicity to fish

The results are summarised in the following table:

Table 7. 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**
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 experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
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 experimental study **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
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: growth rate 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: number hatched	2 (reliable with restrictions) supporting study experimental study **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**
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 experimental study **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**
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: fertility 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: 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** **Zha, J., Sun, L., Spear, P., Wang, Z. 2008**
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.	2 (reliable with restrictions) supporting study experimental study

equivalent or similar to OECD 229	(arithm. mean)) based on: fertility - and fecundity	**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 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, growth phase and reproduction phase until day 83. Fish not exposed to toxicant in growth or reproduction phases.	NOEC (28d): >0.002 mg/L test mat. (meas. (arithm. mean)) based on: growth rate NOEC (28d): >0.002 mg/L test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference** **Nimrod, A.C., and Benson, W. H. 1998**
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 experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
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 experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**).

		Reference **Brooke, L.T. 1993**
Oncorhynchus tshawytscha 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 experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Afonso, L., Smith, J., Ikonomou, M., Devlin, R. 2002**
Oncorhynchus mykiss (previous name: *Salmo gairdneri*) freshwater fish early-life stage toxicity according to ASTM E1241 - 05(2013) Standard Guide for Conducting Early Life-Stage Toxicity Tests with Fish	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	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**
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	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**

(~50% of LC50) µg/L] were used for the subacute semi-static in vivo exposure conditions in the current study. Fish 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		
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**

Discussion

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

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 0.127µg/L.

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

Additional information:
The study by Watanabe et al (2017) was selected as the key study because of the high level of documentation and this study provided the lowest NOEC value for standard test endpoints such as growth, reproduction and survival that indicated *Oryzias latipes* was more sensitive than other standard test species, such as *Pimephales promelas*.

 Copyright protected – No copying / use allowed

Several studies including nine different species of freshwater fish exposed to nonylphenol were found to be reliable (Klimisch 1 or 2). The studies included tests with preferred test species *O. latipes*, *P. promelas*, *Danio rerio* and *Oncorhynchus mykiss*, but reliable studies with marine fish species were not found. Test duration ranged from 21 to 365 days with NOEC endpoints reported for survival, growth, and reproduction (also expressed as fecundity or fertility). The range of NOEC values for survival were comparable and ranged from >0.0019 mg nonylphenol/L for *O. latipes* to 0.0775 mg nonylphenol/L for *P. promelas* (Brook 1993) compared to a NOEC range for growth from 0.006 mg nonylphenol/L for *O. mykiss* (Brooke 1993) to 0.038 mg nonylphenol/L for *Pimephales promelas* (Brooke 1993b), and a NOEC range for fertility of 0.0082 to 0.051 mg nonylphenol/L reported by Yokota et al (2001) and Kang et al (2003), respectively, for *O. latipes*. Based on the data available, inhibition of growth and reduction in reproduction (fertility) appeared to be an equally sensitive response to exposure of nonylphenol to fish. Of the species tested, the preferred species *O. mykiss* and *O. latipes* appeared to be equally sensitive to nonylphenol exposure for the growth endpoints and more sensitive than *P. promelas* for the same endpoint.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 8. Short-term effects on aquatic invertebrates

Method	Results	Remarks
Daphnia magna freshwater semi-static according to ASTM 1991 E729-88a Standard guide for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians	EC50 (48h): 84.4 µg/L not specified (meas. (arithm. mean)) based on: mortality (76.0-94.6)	1 (reliable without restriction) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Hyalella azteca freshwater flow-through according to ASTM 1991 E729-88a Standard guide for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians	LC50 (96h): 20.7 µg/L not specified (meas. (arithm. mean)) based on: mortality (16.8-25.6) EC50 (96h): 20.7 µg/L not specified (meas. (arithm. mean)) based on: mobility (16.8-25.6)	1 (reliable without restriction) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Ophiogomphus sp. freshwater flow-through according to ASTM 1991 E729-88a Standard guide for conducting acute toxicity tests with fishes, macroinvertebrates, and amphibians	EC50 (96h): 596 µg/L not specified (meas. (arithm. mean)) based on: mobility (497-714)	1 (reliable without restriction) supporting study experimental study **Test material** 4-nonylphenol / 104-

		40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Daphnia magna freshwater static according to EU Method C.2 (Acute Toxicity for Daphnia)	EC50 (48h): ca.140 µg/L test mat. (nominal) based on: mobility (116 - 168 µg/L) EC50 (24h): ca.218 µg/L test mat. (nominal) based on: mobility	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Scholz N 1992**
other aquatic arthropod: *Homarus americanus* saltwater static according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): 0.071 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; PNP; para-nonylphenol, (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000**
other aquatic crustacea: *Leptocherius plumulosus* saltwater flow-through according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): 0.062 mg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; PNP; para-nonylphenol, (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000**

other aquatic arthropod: *Dyspanopeus sayi* saltwater flow-through according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): >0.195 mg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; PNP; para-nonylphenol, (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000**
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater flow-through according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians TBC	LC50 (96h): 0.061 mg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; PNP; para-nonylphenol, (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000**
Palaemonetes vulgaris saltwater flow-through according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (96h): 0.059 mg/L test mat. (meas. (not specified)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; PNP; para-nonylphenol, (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000**

other aquatic mollusc: *Mulinia lateralis* saltwater static according to ASTM E729-88 (1988) Standard practice for conducting toxicity tests with fishes, macroinvertebrates and amphibians	LC50 (48h): 0.037 mg/L test mat. (nominal) based on: inhibition of fertilisation	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4; PNP; para-nonylphenol, (full information in **Annex II**). **Reference** **Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000**
Americamysis bahia (previous name: *Mysidopsis bahia*) saltwater flow-through equivalent or similar to EPA OTS 797.1930 (Mysid Acute Toxicity Test) ; according to Test Standard 40 CFR 797.1930	LC50 (96h): 0.043 mg/L test mat. (meas. (arithm. mean)) based on: mortality (95% CI 0.037-0.054 mg/L) NOEC (96h): 0.018 mg/L test mat. (meas. (geom. mean)) based on: mortality	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**
Daphnia magna freshwater static according to OECD Guideline 202 (*Daphnia sp.* Acute Immobilisation Test)	EC50 (48h): 0.19 mg/L test mat. (meas. (arithm. mean)) based on: mobility (95% CI 0.17-0.21 mg/L) EC50 (24h): 0.3 mg/L test mat. (meas. (arithm. mean)) based on: mobility (95% CI 0.26-0.35 mg/L)	1 (reliable without restriction) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Comber MHI, Williams TD & Stewart KM 1993**
Ceriodaphnia dubia not specified static according to Mount DI & Anderson-	LC50 (48h): 0.47 mg/L (nominal) based on: mortality (concentration based upon mean LC50 concentration from 4 tests (0.34 - 0.71 mg/l) 95% CL only calculated for 2 of the 4	2 (reliable with restrictions) supporting study experimental study

Carnahan L. Methods for aquatic toxicity identification evaluations: Phase I toxicity characterisation procedures. EPA - 600/3-88-034 US EPA, Duluth 1988; according to Mount DI & Anderson-Carnahan L. Methods for aquatic toxicity identification evaluations: Phase II toxicity identification procedures. EPA - 600/3-88-035 US EPA, Duluth 1988; according to Mount DI & Anderson-Carnahan L. Methods for aquatic toxicity identification evaluations: Phase III toxicity confirmation procedures. EPA - 600/3-88-036 US EPA, Duluth 1988	tests)	**Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Ankley GT, Peterson GS, Lukasewycz MT & Jensen DA 1990**
Ceriodaphnia sp. freshwater static according to OECD Guideline 202 (*Daphnia sp.* Acute Immobilisation Test); according to Taiwan EPA standard protocol (Taiwan EPA, 2005b)	LC50 (48h): 0.02 mg/L test mat. (nominal) based on: mortality (95% CI 0.016-0.023) LC50 (24h): 0.026 mg/L test mat. (nominal) based on: mortality (95% CI 0.021-0.031 mg/L) NOAEL (48h): <0.01 mg/L test mat. (nominal) based on: mortality NOAEL (48h): 0.01 mg/L test mat. (nominal) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5; 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Hong L & Li MH 2007**
Daphnia magna freshwater flow-through according to OECD Guideline 202 (*Daphnia sp.* Acute Immobilisation Test)	LC50 (48h): 0.18 mg/L test mat. (nominal) based on: mobility (95% CI 0.15-0.22 mg/L)	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Hirano M, Ishibashi H, Matsumura N, Nagao Y, Watanabe N, Watanabe A, Onikura N, Kishi K & Arizono K 2004**
Daphnia magna saltwater flow-through	LC50 (48h): 0.051 mg/L test mat. (nominal) based on: mortality (95% CI 0.042-0.063 mg/L)	2 (reliable with restrictions) supporting study

according to US EPA 600/4-90-027F (Methods for measuring the acute toxicity of effluents and receiving waters to freshwater and marine organisms) Nonylphenol had the highest lethal toxicity against both *A. bahia* and *D. magna* when compared to the effects of 7 additional endocrine disrupting chemicals (estradiol-17b, bisphenol A, methoprene, ecdysone-a, ecdysone-b, tebufenozide and ponaterone A). *A. bahia* was shown to have high sensitivity to environmental xenobiotic chemicals and was more sensitive to all the tested chemicals than *D. magna.*	LC50 (96h): 0.045 mg/L test mat. (nominal) based on: mortality (95% CI 0.037-0.057)	experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Hirano M, Ishibashi H, Matsumura N, Nagao Y, Watanabe N, Watanabe A, Onikura N, Kishi K & Arizono K 2004**
Daphnia magna freshwater static according to ISO 6341 (Water quality - Determination of the Inhibition of the Mobility of *Daphnia magna* Straus (Cladocera, Crustacea))	EC50 (48h): 0.14 mg/L test mat. (nominal) based on: moulting (95% CL 0.13 - 0.16 mg/~L) EC50 (24h): 0.09 mg/L test mat. (nominal) based on: mobility (95% CL 0.04 - 0.15 mg/L) EC50 (48h): 0.13 mg/L test mat. (nominal) based on: mobility (95% CL 0.12 - 0.14 mg/L) EC50 (24h): 0.09 mg/L test mat. (nominal) based on: moulting (95% CL 0.04 - 0.15 mg/L)	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 CA, Roche JJ & Fogarty AM 2006**
Ceriodaphnia dubia not specified static according to US EPA. Methods for measuring the acute toxicity of effluents and receiving waters to freshwater and marine organisms, 4th Ed. EPA 600-4-90-027F. Washing ton DC, US EPA 1993.	EC50 (48h): 0.22 mg/L test mat. (nominal) based on: mobility (95% CL 0.18 - 0.27 mg/L)	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**
other aquatic arthropod: *Ophiogomphus sp.* freshwater flow-through according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute	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**

Toxicity Tests on Test Materials with Fish, Macroinvertebrates, and Amphibians not applicable		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 according to ASTM E729 - 96(2014) Standard Guide for Conducting Acute Toxicity Tests on Test Materials with Fish, 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 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: *Ficopomatus enigmaticus* saltwater static according to EPA/600/4-91/003 (*Arbacia punctulata*, Fertilization Test Method	EC50 (24h): 1.38 µg/L test mat. (nominal) 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	2 (reliable with restrictions) supporting study experimental study **Test material**

1008.0) not applicable	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	Nonylphenol, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Matteo Oliva, Elvira Mennillo, Martina Barbaglia, Gianfranca Monni, Federica Tardelli, Valentina Casu, Carlo Pretti 2018**
Justification for type of information: not applicable		
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 Amphibians not applicable	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, branched, technical mixture (tNP), (full information in **Annex II**). **Reference** **Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010**
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 Fish, 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		

Discussion

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

Brooke (1993) presented results for the preferred species, *Daphnia magna*, of 48hr LC50 (survival) of 0.085 mg/L nonylphenol. The test was performed according to ASTM 1991 E729-88a Standard guideline for conducting acute toxicity tests with fish, macroinvertebrates and amphibians.

Value used for CSA:
EC50/LC50 for freshwater invertebrates: 0.085 mg/L
EC50/LC50 for marine invertebrates: 0.03 mg/L

Additional information:
Several aquatic studies with nonylphenol short-term exposure of 48 and 96 hours to aquatic invertebrates were found reliable. The reliable data included the preferred test species Daphnia magna and seven other freshwater taxa with reported L(E)C50 endpoints based on survival, immobility, and moulting frequency, plus seven marine taxa with L(E)C50 concentrations based on survival. The range of L(E)C50concentrations for freshwater organism exposure (48-hr) was 0.02 mg nonylphenol/L for *Ceriodaphnia cornuta* (Hong et al, 2007) and *Hyalella azteca* (Spehar et al, 2010) to 0.74 mg nonylphenol/L for *Physella virgata* (Spehar et al, 2010) for survival and immobility, and 0.596 mg nonylphenol/L for loss of equilibrium after 96 hr exposure to *Ophiogomphus sp.* (Brooke 1993). The L(E)C50 values reported for the preferred test species *D. magna* ranged from a single report of 0.085 mg nonylphenol/L based on survival (Brooke 1993) to close values of 0.10 to 0.19 mg nonylphenol/L based on immobility reported in four other studies (Scholz, 1992; Hirano et al, 2007; Comber et al, 1993; Spehar et al, 2010; and Brennan et al, 2006). The range of effects on survival for marine species ranged from a LC(E)50 concentration of 0.03 mg nonylphenol/L for *Mulinia lateralis* (48 hr) (Lussier et al, 2000) to 0.2 mg nonylphenol/L at 96 hr exposure to *Dyspanopeus sayi* (Lussier et al, 2000). Sperm toxicity and larval development after 24 hr exposure to nonylphenol to the aquatic worm *Ficopomatus enigmaticus* determined EC50 of 0.001 and 0.007 mg nonylphenol/L, respectively (Oliva et al, 2018).

In the interpretation of the results reported by Hirano et al (2004), Comber et al (1993) and Brennan et al (2006) the use of the term survival versus immobility for *D. magna* as test endpoints could not be distinguished and were considered an equivalent determination of lethality. Results reported by Hong et al (2007) regarding *C. cornuta* (48 hr survival LC50 of 0.02 mg nonylphenol/L) and Spehar et al, 2010 regarding *H. azteca*, may be more sensitive to nonylphenol exposure than the preferred test species *D. magna*, but it was difficult to confirm as there were no other reliable data available for both species as an individual taxon. Indeed, test results for *C. dubia* exposure to nonylphenol (Isidori et al, 2006 and Ankley et al, 1990) do not suggest that the *Ceriodaphnia* genus is more sensitive than *D. magna*.

Results of the Lussier et al., (2000) study are consistent with results of Hirano et al, (2004) and Ward and Boeri (1990) suggest marine invertebrates may generally be more sensitive to the toxic effects of nonylphenol than freshwater invertebrates.

7.1.2.2. Long-term toxicity to aquatic invertebrates

The results are summarised in the following table:

Table 9. Long-term effects on aquatic invertebrates

Method	Results	Remarks
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) key study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference**

 Copyright protected – No copying / use allowed

		Comber, M.H. I., Williams, T.D., and Stewart, K. M. 1993
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-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**). **Reference** **England, D.E. 1995**
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** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Brooke, L.T. 1993**
Daphnia magna freshwater long-term toxicity to aquatic invertebrates equivalent or similar to ISO 2000 Water Quality-Determination of Long-erm 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**
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: reproduction NOEC (21d): >0.01 mg/L test mat. (nominal) based on: mortality - parent generation	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**
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, (full information in **Annex II**). **Reference** **Baldwin, W., Graham, S., Shea, D., LeBlanc, G. 1997**
Chironomus tentans 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	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 experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Kahl, Michael, Makynen, E., Kosian, P., Ankley, G. 1997**
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. (nominal) based on: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Sun, H. and Gu, X.**

		2005
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**
Americamysis bahia (previous name: *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	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	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** **Kuhn, A., Munns Jr., W.R., Champlin, D., McKinney, R., Tagliabue, M., Serbst, J., Gleason, T. 2001**
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., and Nakanishi, J. 2002**

Tisbe batagliai saltwater long-term toxicity to aquatic invertebrates no guideline available	NOEC (53d): 0.02 mg/L test mat. (meas. (arithm. mean)) based on: mortality NOEC (53d): 0.02 mg/L test mat. (meas. (arithm. mean)) 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** **Bechmann, R. 2005**
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 96 hrs test. This study performed test for 72 hrs, 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: growth 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: reproduction	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Hoss, S., Juttner, I., Traunspurger, W., Pfister, G., Schramm, K.W., Steinberg, C. 2002**
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** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Scholz N 1992**
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		
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		
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 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	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 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-**

Tubifex worms (Europrix) were provided as a dietary supplement twice a week.		**DAURES 2010**
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 days 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 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	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** **Masaya Uchida, Masashi Hirano, Hiroshi Ishibashi, Jun Kobayashi, Yoshihiro Kagami, Akiko Koyanagi, Teruhiko Kusano, Minoru Koga, Koji Arizono 2016**

Discussion

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

Comber et al (1993) provided 21-day NOEC (reproduction) of 0.024 mg/L nonylphenol for the preferred species, *Daphnia magna* in accordance with OECD 202 Guideline methodology.

Value used for CSA:
EC10/LC10 or NOEC for freshwater invertebrates: 0.024 mg/L
EC10/LC10 or NOEC for marine invertebrates: 0.009 mg/L

Additional information:
The 21-day study by Comber et al, (1993) was selected as the key study because the study provided NOEC values for standard long-term test endpoints of survival and reproduction for the preferred test organism, *Daphnia magna*, and was adequately documented and performed according to Guidelines. The reported NOEC of 0.05 mg nonylphenol/L by Baldwin et al (1997) and 0.06 mg nonylphenol/L by Brennan et al (2006) for inhibition of reproduction to the preferred test species *D. magna* was similar to findings of the key study; with Sun and Gu (2005) reporting 0.013 mg nonylphenol/L (no analytical monitoring) at the low end of the range and Brooke (1993) and Spehar et al (2010) reporting 0.12 mg/L at the high end of the range.

Long-term exposure of nonylphenol to aquatic invertebrates included reliable supporting studies covering several different freshwater taxa including the preferred test organism D. *magna*. Also, several reliable studies for marine organisms were available, such as *Americamysis bahia* (Kuhn et al, 2001, Hirano et al, 2009); *Tisbe batagliai* (Bechmann, 1999); and *Tigriopus japonicus* (Marcial et al, 2003). The range of NOEC values for survival was from 0.025 mg nonylphenol/L (Sun and Gu, 2005) to 0.04 mg nonylphenol/L (Brennan et al, 2006) for *D. magna*. The NOEC for reproduction ranged from 0.001 mg nonylphenol/L for *Ceriodaphnia dubia* (7 days) (Isidori et al, 2006) to 0.116 mg/l and >0.1 mg nonylphenol/L reported for 21-day tests with *D. magna* by Brooke (1993) and Scholz (1992), respectively. For the marine species, the NOEC of 0.0095mg nonylphenol/L for reproduction (Kuhn et al, 2001) of *A. bahia* and 0.02 mg nonylphenol/L mortality and reproduction of *Tisbe batagliai* (Bechmann, 1999) were within the ranges reported for freshwater organisms.

 Copyright protected – No copying / use allowed

Insufficient data were available to confirm which of the species tested was most sensitive, but the findings of Isidori et al (2006) suggest that inhibition of reproduction for *C. dubia* can occur at a concentration lower than reported for *D. magna* or the marine species tested.

7.1.3. Algae and aquatic plants

The results are summarised in the following table:

Table 10. Effects on algae and aquatic plants

Method	Results	Remarks
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) key study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Scholz N 1989**
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) key 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**
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	1 (reliable without restriction) key study experimental study **Test material** 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5, (full information in **Annex II**).

	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	**Reference** **Ward, T.J. and R.L. Boeri 1990**
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 12:12 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 yield, mg L−1 (4 days)	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**
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	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

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 litre. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth		**Annex II**). **Reference** **T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015**
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 litre. 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**
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	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**

introduced in the medium at amount of 15 mg of absolutely dry biomass (ADB) per litre. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth		
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 litre. 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**
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 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. ± 0.07) 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**
Microcystis aeruginosa (algae) BG11 medium toxicity to aquatic algae and	EC50 (14d): 0.45 mg/L test mat. (nominal) based on: growth rate (S.D. ± 0.05) NOEC (14d): 0.2 mg/L test mat. (nominal)	2 (reliable with restrictions) supporting study

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 litre. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth	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)	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 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 litre. 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**
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	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**).

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 litre. The duration of cultivation is 14 days. - Parameters analysed / observed: microalgae growth		**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 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**
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**
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**
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. (meas. (not specified)) based on: cell number and growth rate EC20 (96h): 829 µg/L test mat. (meas. (not specified)) based on: cell number and growth rate LOEC (96h): 1480 µg/L test mat. (meas. (not specified)) based on: cell number and growth rate Chronic value (96h): 1013 µg/L test mat. (meas. (not specified)) 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 names: *Raphidocelis subcapitata*, *Selenastrum capricornutum*) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with *Scenedesmus subspicatus* and *Selenastrum capricornutum*)	EC50 (72h): 0.5 mg/L test mat. (meas. (arithm. mean)) based on: growth rate (+/- 0.76 SD)	2 (reliable with restrictions) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Graff L, Isnard P, Cellier P, Bastide J, Cambon J-P, Narbonne J-F, Budzinski H & Vasseur P 2003**
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, (full information in **Annex II**). **Reference** **Brooke LT 1993**
Pseudokirchneriella subcapitata (previous names: *Raphidocelis subcapitata*,	EC50 (72h): 0.53 mg/L test mat. (meas. (arithm. mean)) based on: growth rate (+/-	2 (reliable with restrictions)

Selenastrum capricornutum) (algae) freshwater toxicity to aquatic algae and cyanobacteria according to ISO 8692 (Water Quality - Fresh Water Algal Growth Inhibition Test with *Scenedesmus subspicatus* and *Selenastrum capricornutum*)	0.11 SD)	supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Graff L, Isnard P, Cellier P, Bastide J, Cambon J-P, Narbonne J-F, Budzinski H & Vasseur P 2003**
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 according to ASTM 1991. E1415-91 Standard Guide for Conducting Static Toxicity Tests with *Lemna gibba*.	NOEC (96h): ca.0.901 mg/L test mat. (meas. (not specified)) based on: frond number LOEC (96h): ca.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, (full information in **Annex II**). **Reference** **Brooke LT 1993**

Discussion

Effects on algae / cyanobacteria

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

The Scholz (1989) study was selected as a key study because it provides both an EC50 (1.3 mg nonylphenol/L) and EC10 (0.5 mg nonylphenol/L) concentration for growth inhibition for a common algal test species

Desmodesmus subspicatus.

Ward and Boeri (1990) was also selected as a key study because it provides EC50 toxicity information for the preferred algal test organism *Pseudokirchneriella subcapitata* and of the marine algae *Skeletonema costatum*, determining 96h EC50s were of 0.41 mg/L and 0.027 mg nonylphenol/L, respectively.

Value used for CSA:
EC50 for freshwater algae: 0.41 mg/L
EC50 for marine water algae: 0.027 mg/L
EC10/LC10 or NOEC for freshwater algae: 0.5 mg/L
EC10/LC10 or NOEC for marine water algae: 0.5 mg/L

Additional information:
The Scholz (1989) study was selected as a key study because it provides both an EC50 (1.3 mg nonylphenol/L) and EC10 (0.5 mg nonylphenol/L) concentration for growth inhibition for a common algal test species *Desmodesmus subspicatus*. Ward and Boeri (1990) was also selected as a key study because it provides EC50 toxicity information for the preferred algal test organism *Pseudokirchneriella subcapitata*. In addition, the results of the Ward and Boeri (1990) study combined with the supporting results of Brooke (1993) and Graff et al (2003) suggest the preferred test algae *P. subcapitata* to be more sensitive than *D. subspicatus* to effects of nonylphenol on growth inhibition. The growth inhibition EC50 for the preferred test species *P. subcapitata* ranged from 0.41 to 0.53 mg nonylphenol/L. Reliable marine algae test results with nonylphenol were limited to a single study with *Skeletonema costatum* (Ward and Boeri 1990) which showed growth inhibition at 96 hr to be 0.027 mg nonylphenol/L, an order of magnitude lower than for the freshwater algae *P. subcapitata*. 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 NOEC and EC50 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. subcapitata* at 96 hr (Ward and Boeri 1990) to 1.3 mg nonylphenol/L at 72 hr for *D. subspicatus* (Scholz 1989). An EC50 concentration of0.027 mg nonylphenol/L was reported by Ward and Boeri (1990) for cell growth of the marine diatom *S. costatum*. The available EC50 concentration data for cell growth indicates that for the algae tested the preferred freshwater test species *P. subcapitata* was more sensitive to nonylphenol exposure than *D. subspicatus*, but the marine diatom *S. costatum* was the most sensitive to effects of nonylphenol.

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:

Two reliable supporting study 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 and LOEC for *L. minor* frond production were similar in both studies with 0.901 mg nonylphenol/L and 2.08 mg nonylphenol/L, respectively.

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:
Two reliable supporting studies were available (as above). Determination of the NOEC and LOEC was dependent upon the exposure treatment dilution series in the test. No exposure treatment was intermediate of the

NOEC and LOEC concentration treatments and further precision for these endpoint concentrations was not determined.

7.1.4. Sediment organisms

The results are summarised in the following table:

Table 11. Effects on sediment organisms

Method	Results	Remarks
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 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 µg/g dw test mat. (not specified) based on: reproduction - cocoon production (295-384.4) EC10 (28d): 382.7 µg/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**
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**
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 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.	NOEC (28d): >61.5 mg/kg sediment dw test mat. (meas. (arithm. mean)) based on: reproduction NOEC (28d): >61.5 mg/kg sediment dw test mat. (meas. (arithm. mean)) based on: mortality	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Zulkosky, A.M., Ferguson, P.L.,**

		McElroy, A.E. 2002

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

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: 231 mg/kg sediment dw
EC10, LC10 or NOEC for marine water sediment: 61.5 mg/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 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 12. Effects on other aquatic organisms

Method	Results	Remarks
Bufo boreas boreas freshwater static according to ASTM E729-96 and Committee on Methods for Toxicity Tests with Aquatic Organisms (1975) EPA/660/3-75-009	LC50 (96h): 0.12 mg/L not specified (nominal) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4, (full information in **Annex II**). **Reference** **Dwyer, F.J., F.L. Mayer, L.C. Sappington, D.R. Buckler, C.M. Bridges, I.E. Greer, D.K. Hardesty, C.E. Henke, C.G. Ingersoll, J.L. Kunz, D.W.**

 Copyright protected – No copying / use allowed

		Whites, T. Augspurger, D.R. Mount, K. Hattala, G.N. Neuderfer 2005
Dreissena polymorpha freshwater semi-static no guideline available	LC10 (50d): 0.68 mg/L not specified (nominal) based on: mortality NOEC (50d): 0.1 mg/L test mat. (nominal) based on: all parameters measured (NOEC is inferred)	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**
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**

Discussion

The following information is taken into account for any hazard / risk assessment:
Dwyer et al (2005) reported a 96 hr LC50 of 0.12 mg/L nonylphenol for *Bufo boreas boreas*.
Quinn et al (2006) reported a 50-day LC10 (survival) of 0.68 mg/L nonylphenol for *Dreissena polymorpha*.

Additional information:
A reliable study on exposure of the boreal toad *Bufo boreas boreas* (Amphibia) tadpoles to nonylphenol reported by Dwyer et al (2005) with 96 hr test results based on tadpole survival. Dwyer et al (2005) reported an LC50 concentration of 0.12 mg nonylphenol/L for boreal toad survival. A supporting study by Park et al (2010) provided reliable results for *Bombina orientalis* embryos and tadpoles exposed for 7 and 10 days resulting in a NOEC for mortality and metamorphosis and a LOEC for body length of 0.1 µmol/L.

7.2. Terrestrial compartment

Additional information:
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 (LC/EC50 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.

The key study for avian toxicity 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.

Read Across
A reliable study regarding toxicity of octylphenol to birds was used according to a read-across approach to fill data requirements for nonylphenol for these endpoints. [VR1] 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 Section 13. 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 property 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 $PNEC_{sediment}$ and $PNEC_{soil}$ 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.	0.02 to 0.47	0.07 to 0.28

48 hr L(E)C50		
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 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 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 for terrestrial toxicity data relating to NP studies to be read-across to octylphenol endpoints and used in PNEC $_{soil}$ derivation.

7.2.1. Toxicity to soil macro-organisms

The results are summarised in the following table:

Table 13. Effects on soil macro-organisms

Method	Results	Remarks
Eisenia sp. [Annelida] (annelids) toxicity to soil macro-organisms 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 ww test mat. (nominal) based on: mortality	2 (reliable with restrictions) key study experimental study **Test material** Nonylphenol - Technical Grade, (full information in

		Annex II). **Reference** **Johnson I., Weeks J.M. & Kille P. 2005**
Enchytraeus crypticus (annelids) toxicity to soil macro-organisms 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))	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**
Caenorhabditis elegans [Nematoda] (nematods) toxicity to soil macro-organisms 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**
Eisenia andrei [*Annelida*] (*Clitellata*) toxicity to soil macro-organisms 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**
Dendrobaena octaedra (annelids) toxicity to soil macro-organisms except arthropods: long-term (laboratory study) Substrate: natural soil - 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 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 1.4C, 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	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 (28d): 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** **Dorthe Jensen, Mark Bayley, Martin Holmstrup 2009**
Eisenia fetida [Annelida] (annelids) toxicity to soil macro-organisms 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 sp. [*Annelida*] (*annelids*) toxicity to soil macro-organisms 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 ww test mat. (nominal) based on: Mean number of live juvenile earthworms (offspring)	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**).

		Reference **Johnson I., Weeks J.M. & Kille P. 2005**
Eisenia sp. [*Annelida*] (*annelids*) toxicity to soil macro-organisms 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**
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) 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**
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. A total of 10	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**

Copyright protected – No copying / use allowed

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		**Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017**
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** 2-nonylphenol / 25154-52-3 / 246-672-0, (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: 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** 4-nonylphenol / 104-40-5 / 203-199-4, (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: soil toxicity to terrestrial arthropods: long-term (laboratory study) no guideline available	EC10 (21d): 27 mg/kg soil ww test mat. (not specified) based on: reproduction	4 (not assignable) supporting study experimental study **Test material** 4-nonylphenol / 104-40-5 / 203-199-4,

No Data		(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 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 (Inhibition of Reproduction of Collembola by Soil Pollutants)	NOEC (64d): 32 mg/kg soil dw test mat. (nominal) based on: Survival	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full 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: 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**

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:

 Copyright protected – No copying / use allowed

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)50 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, 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 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 andrei*) 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 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 EC10of 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:

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 sort-term study by Kwak et al (2017) also reported that exposure of *Lobella 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 Scott-Fordsmand et al (2004) and Domene et al (2009) study. The long-term data for *Collembola* species ranged from 23 to 63.2 mg nonylphenol/kg with test duration 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 88mg 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 [VR1], 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. Scott-Fordsmand study reported *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 14. 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** 2-nonylphenol / 25154-52-3 / 246-672-0, (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
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**
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**
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	*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	2 (reliable with restrictions) supporting study experimental study **Test material** Nonylphenol, branched, technical

Forschungsanstalt) according to OECD Guideline 208 (Terrestrial Plants Test: Seedling Emergence and Seedling Growth Test) [before 19 July 2006]	growth inhibition	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) 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**
Lactuca sativa (*Dicotyledonae* (dicots)) toxicity to terrestrial plants: long-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 (14d): 625 mg/kg soil dw test mat. (nominal) based on: growth	2 (reliable with restrictions) supporting study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (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**

Copyright protected – No copying / use allowed

Discussion

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

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 fresh weight of 574.8 mg nonylphenol/kg.

Value used for CSA:
Short-term EC50 or LC50 for terrestrial plants: 559 mg/kg soil dw
Long-term EC10/LC10 or NOEC for terrestrial plants: 574.8 mg/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 soil (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 ranging from 559 mg nonylphenol/kg for *L. sativa* (7-day) to >2000 mg nonylphenol/kg for *V. radiata* (14 days). Both studies also reported long-term data for the same species, where NOEC and EC10 for 21 days of exposure were 1500 and 1433 mg nonylphenol/kg for *O. sativa* and >2000, respectively and 1822 mg/kg for *V. radiata* (Kwak et al, 2017). Long-term exposure (14 days) of *L. sativa* determined, instead, an EC50 of 625 mg/kg is reported (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 0.5g/kg level or more. Based on the arguments of data reliability, adequacy and sensitivity of test species, the key value 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 15. 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	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,

description of test conditions: Test well plates were maintained in the incubator at 24 °C, 100 rpm, 16:8 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		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, 16:8 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 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 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: 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**

Discussion

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

Two studies are available for the soil micro-organism 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: 108 mg/kg soil dw

Long-term EC10/LC10 or NOEC for soil micro-organisms: 100 mg/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 6-day period. The reported EC50 for growth inhibition measured as a change in concentration of chlorophyll-a was 108 mg/kg dw soil. NOEC estimated value was 100 mg/kg dw soil. The study by Trocme et al (1989) presents a long-term carbon transformation test by soil micro-organisms 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, *Chlamydomonas reinhardtii*, over 6-days 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

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

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) study. 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 88mg 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, 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. Scott-Fordsmand study reported *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.

7.3. Atmospheric compartment

No relevant information available.

7.4. Microbiological activity in sewage treatment systems

The results are summarised in the following table:

Table 16. Effects on micro-organisms

Method	Results	Remarks
activated sludge of a predominantly domestic sewage freshwater static according to OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test [before 22 July 2010]	EC50 (3h): 950 mg/L test mat. (nominal) based on: inhibition of total respiration - respiration rate	2 (reliable with restrictions) key study experimental study **Test material** 2-nonylphenol / 25154-52-3 / 246-672-0, (full information in **Annex II**). **Reference** **Diefenbach R 1999**

Discussion

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

Diefenbach (1999) provided an EC50 (respiration) of 950 mg/L in a reliable study.

Value used for CSA:
EC50/LC50 for aquatic micro-organisms: 950mg/L EC10/LC10 or NOEC for aquatic micro-organisms:

Additional information:
A reliable study of common sewage activated sludge micro-organism exposed to nonylphenol was reported by Diefenbach (1999). The test organisms represented a mixture of microorganisms contained in common activated sludge treatment of wastewater and effects concentration reported as EC50 was based on percent inhibition of respiration. The mixture of microorganisms was exposed to nominal concentrations 125, 251.6, 500, 1000, and 2002 mg nonylphenol/L under static conditions. An EC50 was estimated at 950 mg nonylphenol/L as the maximum percent inhibition after 3 hrs exposure was 44% and a 50% inhibition level was not attained. The authors concluded total inhibition of activated sludge respiration could not be expected due to the limited water solubility of nonylphenol.

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 17. 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)	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 JR, Craig-Veit CB, Quaglino AE, Erichson AL, Famula TR and Fry DM. 2001**
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)	2 (reliable with restrictions) key study read-across from supporting substance (structural analogue or surrogate) **Test material** 4-octylphenol / 1806-26-4 / 217-302-5, (full information in **Annex II**). **Reference** **Millam JR, Craig-Veit CB, Quaglino AE, Erichson AL, Famula TR and Fry DM. 2001**
Justification for type of information: The read-across justification is provided in a separate report in Section 13 of the CSR.		
Coturnix japonica long-term toxicity to birds: reproduction test (drinking water)	NOEC (18wk): 0.01 mg/L drinking water test mat. based on: body weight - female NOEC (18wk): 0.001 mg/L drinking water	2 (reliable with restrictions) supporting study

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	test mat. based on: body weight - male NOEC (18wk): 0.001 mg/L drinking water test mat. 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 set X 100; 14 d survival rate= number of 14 d survivors/Number of the embryos that liberate themselves from the eggs X 100 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 - female (Highest concentration tested) NOEC (18wk): >0.1 mg/L drinking water test mat. based on: egg shell thickness (Highest concentration tested) not applicable	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		

<u>**Discussion**</u>

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

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. The methodology does deviate from standard test guidelines, particularly in relation to the duration of the study which was reduced because of the smaller bird species (a non-standard species). However, the study is deemed to be reliable with restriction for REACH assessment as it is indicative of avian toxicity.

The read-across justification is provided in a separate report in Section 13 of the CSR.

Value used for CSA:
Short-term EC50 or LC50 for birds: Long-term EC10/LC10 or NOEC for birds: 70.8 mg/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 supporting long-term study exposed the *Japanese quail* and *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.

 Copyright protected – No copying / use allowed

7.6. PNEC derivation and other hazard conclusions

7.6.1. PNEC derivation and other hazard conclusions

Table 18. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater	PNEC aqua (freshwater): 0.1µg/L Intermittent releases:	Assessment factor: 50 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 Aldenberg & Jaworska (2000) Method. For the PNEC aquatic (freshwater) a total of 34 geometric mean NOEC or EC10 were available for species representing salmonid and cyprinid fish, aquatic invertebrates (crustacea) and insects, algae, aquatic plants, nematodes, molluscs and amphibia. These nine groups of organisms and >15 species exceed the criteria for the SSD approach. The HC5 value from the SSD is 5.27 µg/L. An assessment factor of 5 was applied to the HC5 to derive the PNEC aquatic of 1.05 µg/L. In parallel a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, Section 13). The precautionary approach was taken to lower the PNEC aquatic to be protective of endocrine effects and uncertainties and an additional factor of 10 is applied (in total, an Assessment Factor of 50 is applied to the HC5). PNEC aquatic (freshwater) = 0.00105 mg/L or 1.05 µg/L (based on apical endpoints and an AF of 5), then PNEC aquatic (freshwater) = 1.05 µg/L with AF of 10 = 0.1 µg/L (protective of apical and endocrine effects)
Marine water	PNEC aqua (marine water): 0.42µg/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 Aldenberg & Jaworska (2000) Method. For the PNEC aquatic (saltwater) a total of 38 geometric mean NOEC or EC10 were available for species representing salmonid and cyprinid fish, aquatic invertebrates (crustacea) and insects, algae, aquatic plants, nematodes, molluscs and amphibia. These nine groups of organisms and >15 species exceed the criteria for the SSD approach. The HC5 value from the SSD is 4.22 µg/L. An assessment factor of 10 was applied to the HC5 to derive the PNEC aquatic of 0.42 µg/L. ECHA guidance advises an AF of 1 to 5 for application to an HC5 to derive a PNEC. However, in parallel a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, Section 13). The precautionary approach was taken to lower the PNEC aquatic to be protective of endocrine effects and uncertainties by using an AF of 10 applied to the HCs.

 Copyright protected – No copying / use allowed

		HC5 of 4.22 µg/L is divided by an AF of 10 to derive the PNEC aquatic (marine) of 0.42 µg/L.
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). However, in parallel a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, Section 13). 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/kg dw (Zulkosky et al 2002) marine test with benthic crustacean, *Leptocheirus plumulosus*. However, in parallel a review of potential endocrine-mediated adverse effects was undertaken (Adverse Outcomes Report, Section 13). 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: 9.5mg/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 (Huls-Diefenbach 1999) test with activated sludge measuring growth inhibition where the EC50 = 950 mg/L.
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 and soil microbes). Scott-Fordsmand (2004) provided a long-term study with *Folsomia fimetaria* where the EC10 was 23 mg/kg nonylphenol.
Air	no hazard identified:	The substance is not considered to be volatile and no hazard has been identified for the potential effects of nonylphenol to the air compartment.
Secondary poisoning	PNEC oral: 2.36 mg/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). Read-across was applied as the test result is for octylphenol. **PNEC oral** The PNEC oral was derived by converting the NOEL to a NOEC in accordance with ECHA Guidance. $NOEC_{oral, predator} = NOAEL_{oral, predator} \times CONV_{predator}$ - Conversion factor = body weight/ daily food intake. For *Gallus domesticus* (chicken) $CONV_{predator}$ is 8. -For Zebra Finch this is calculated as 12 g/ 3.5 g per day = 3.429 $NOEC_{oral, predator} = NOAEL_{oral, predator} \times CONV_{predator}$ $NOEC_{oral, predator}$= 20.632 mg/kg x 3.429 = 70.747 mg/kg $PNEC_{oral, bird}$= chronic NOEC/ AF of 30 = 2.36 mg/kg

Conclusion on environmental classification
Nonylphenol does not fulfil the screening criteria for persistence (P-criterion) and bioaccumulation (B-criterion). Although the T-criterion is fulfilled for aquatic organisms, the overall conclusion is that nonylphenol does not meet the PBT or vPvB criteria. No further testing or an emission characterisation and risk characterization for PBT/vPvB substances in accordance with REACH Article 14(4) is required.

General discussion

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

	Upper 95% CL (µg/L)	Lower 95% CL (µg/L)
PNEC aquatic freshwater	1.58	0.31
PNEC aquatic marine	1.79	0.30

The effects assessment builds on the original EU Risk Assessment 4-Nonylphenol (Branched) and Nonylphenol (EURAR 2002), the UK Environment Agency risk assessment report for nonylphenol (EA, 2009) and the Lead Registrant's dossier for nonylphenol 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 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 effect assessment relate to apical endpoints such as survival, growth and reproduction. This is in accordance with ECHA Guidance (Guidance on information

 Copyright protected – No copying / use allowed

requirements and chemical safety assessment Chapter R.10: Characterisation of dose [concentration]-response for environment, ECHA 2008). The preceding risk assessments indicate that nonylphenol can exhibit oestrogenic effects on aquatic organisms. A literature search for potential endocrine effects was also undertaken as part of this hazard assessment that similarly builds 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 section 13 of this CSR. A brief summary is provided below.

Conclusion:
EURAR 2002 found that reliable data indicate oestrogenic mediated effects of nonylphenol can occur around 10-20 µg/L. The calculated PNEC $_{\text{fresh water}}$ and PNEC $_{\text{marine}}$ as presented in this CSR Report are 0.1 µg/L and 0.42 µg/L and protective of potential oestrogenic effects.

A separate review of endocrine-mediated adverse effects was undertaken using an Adverse Outcome Pathways (AOP) approach and is reported in section 13 of this CSR. 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 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 NP. NP is a widely studied substance, 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 mean species-endpoint toxicity values for nonylphenol 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 NP at sensitive life stages of fish, invertebrates and amphibia development. They include exposure to adults, juveniles and eggs and 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 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 rely 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 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). These PNECs were PNEC fresh water NP = 0.64 µg/L and PNEC saltwater NP = 0.55 µg/L.

The literature search undertaken for this CSR has revealed new chronic toxicity data that increased these PNEC values, particularly the PNEC fresh water for nonylphenol, which rose from 0.64 µg/L to 1.05 µg/L 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 more precautionary than the PNEC aqua for 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 factor 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	Nonylphenol	1.05 µg/L	Yes Additional AF of 10; total AF of 50 applied to HC5 from SSD[1]	0.1 µg/L
Saltwater	Nonylphenol	0.84 µg/L	Yes AF of 10 increased from 5 applied to HC5 from SSD	0.42 µg/L
Sediment, freshwater	Nonylphenol	4.62 mg/kg dw	Yes Additional AF of 10 applied to previous PNEC	0.46 mg/kg dw
Sediment, marine	Nonylphenol	1.23 mg/kg dw	Yes Additional AF of 2 applied to previous PNEC	0.61 mg/kg dw
Soil	Nonylphenol	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).
[2]HC5 is the hazardous concentration affecting 5% of species in a species sensitivity distribution of chronic ecotoxicity data.

 Copyright protected – No copying / use allowed

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.

Copyright protected – No copying / use allowed

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 Chemetall under EU REACH was transitioned into UK REACH on 4th November 2021[1] under Authorisation Number UKREACH/21/03/0.

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 nonylphenol ethoxylate (NPE). Nonylphenol ethoxylates (NPEs) have been listed as entry 43 of Annex XIV to Regulation (EC) No 1907/2006. NPEs are listed "because through their degradation, they are substances for which there is scientific evidence of probable serious effects to the environment"[2]. Substance identification is provided in Section 1.1 of this document. This is consistent with the Annex XV dossier, which does not include specific substance identifiers other than name. Indeed, various identifiers for this substance, including several commonly used names and CAS Numbers (e.g., 68412-54-5, etc.) are possible. NPEs are known to degrade to nonylphenol itself in the environmental compartment. The Annex XIV listing is limited to the effects on the environment. Chemetall and Airbus have worked to develop and submit applications for authorisation (AfAs) and subsequently this Review Report for use of NPEs in these two-component polysulfide sealant formulations by the aerospace industry, and this is submitted by Chemetall to support continued use of the sealants by its customers, including Airbus and its suppliers who account for approximately 95% of the downstream use. A six-year review period is being applied for. This document addresses use of NPE in two-component polysulfide sealant formulations. Due to the UK leaving the EU a Review Report for the use applied for here and the formulation use has been submitted to ECHA in May 2023. The conditions of use for the mixing use are the same within the EU and the UK.

NPE is present in a surfactant substance (NPE-Phosphate) used in formulation of the hardener.

NPE is only present in concentrations of between 2.5 and 10 % in the surfactant. When formulated into the hardener component of the polysulfide sealant, the maximum level of NPE present is 0.6% w/w. When the hardener is mixed with the base component to form the final sealant, the NPE 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], such that handling and use of the mixed sealant is not subject to authorisation under REACH, and is outside of the scope of this Review Report.

This means only activities relating to the initial formulation of the NPE containing hardener component and the subsequent mixing of the hardener with the base component would be subject to authorisation. As formulation takes place in the EU only the subsequent mixing of the hardener with the base component is covered by this CSR. The subsequent use of the mixed polysulfide sealant in aerospace applications 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.

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1033353/uk-reach-chemetall-decision-ref-ID-0207-02.pdf

[2] NPE: https://echa.europa.eu/documents/10162/964d8d93-cca5-4e24-a691-c22dc9420971

[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);

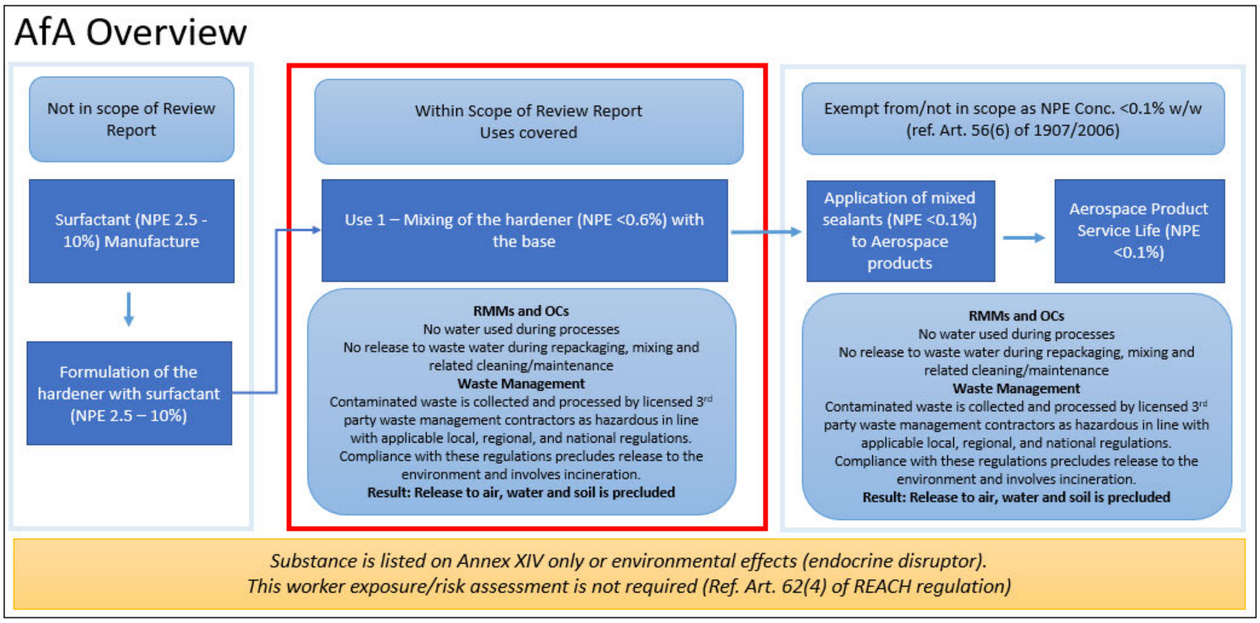


Figure 1: Overview of the scope of the Original AfA and Review Report.

The red bordered activities are covered by this Review Report.

Ultimately, the tonnage of NPE placed on the market within polysulfide sealants used by the aerospace industry is low, with only between 40 and 70 kg of the substance being used per annum, all of which is provided to aerospace companies.

The polysulfide sealants within the scope of this NPE 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., adherence, 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 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 Original Equipment Manufacturers (OEMs) for use in production, and in maintenance, repair and overhaul (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 components, sub-assemblies and assemblies are assembled. Examples of production are provided in the SEA and AoA reports, which form part of this submission. As noted in the SEA, the polysulfide sealants are used widely throughout the manufacture of aerospace products at specific aerospace 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.

The activity of mixing the NPE containing hardener with the sealant base prior to use takes place across approximately 30 – 40 sites in the UK. Specific process controls ensure complete mixing by downstream users, so all final mixed sealant materials contain below 0.1% NPE. Use in the aerospace sector 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 a multiple constituents in the sealants. Adherence to the appropriate RMMs and OCs, including specific procedures for waste management, described within this document, results in no potential release to the environment of NPE.

 Copyright protected – No copying / use allowed

In discussing the appropriate RMMs and OCs employed for use of the NPE containing hardener and the resulting mixed sealant, it is relevant and important to note that other ingredients comprise approximately 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 that prevent release to the aquatic environment are important for constituents of the sealant other than NPE. Therefore, the overall level of control exerted to prevent potential release to the environment of NPE 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 NPE 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 tonnage per annum usage of NPE covered by this authorisation is very low (40 – 70 Kg). The concentration of NPE in the hardener after formulation is low (below 0.6 %), although above the 0.1% limit requiring authorisation. This document specifically details the handling processes of mixing of the hardener with its partner base by downstream users.

The concentration of NPE in the final sealant after mixing is 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 NPE substance to the environment throughout the sealant lifecycle. In doing so, it demonstrates that the ongoing use of the polysulfide sealants containing NPE according to the RMMs and OCs implemented by industry and prescribed within the Exposure Scenarios poses no risk to the environment.

This Review Report CSR concerns the use of NPE within the specialist family of polysulfide sealants. The uses are defined as such:

Use 1: Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE 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 NPE 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 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 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 focusses 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 and NPE 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 demonstrates within this CSR that, considering measures in place, emissions of NPE to the environment during the two uses applied for (as discussed within section 9.0.1) are not only minimised but effectively precluded.

Additionally, consideration is given to the lifecycle of the sealant after mixing, including use of the mixed

[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).

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

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 use of these does not result in release of NPE to the environment across the lifecycle of the sealant.

Airbus and their associated supply chains require good manufacturing practices, including compliance with standard operating procedures, and Exposure Scenarios communicated by the formulator, in place at all Downstream User sites carrying out the activities associated with the exposure scenarios covered within this CSR. This is necessary to ensure aerospace equipment is safe to use and delivers environmental protection. Adherence to these requirements means that release of NPE to the environment during use is precluded.

The term ‘downstream user’ encompasses all possible actors in the supply chain provided with the initial two component sealant from the formulator. It covers a range of actors who will handle and use 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:

- **Formulator [Chemetall]** that purchases the raw materials (including NPE containing mixtures) from manufacturers or importers. The formulator develops mixtures (which are proprietary, such that formulation composition is highly confidential) to meet the requirements of its clients in each market and supply formulations containing NPE to meet performance specifications and industrial approvals. Its customers are generally component manufacturers, OEMs, and MRO operations. As noted, earlier formulation takes place within the EU and is thus out of scope of this Review Report.

- **Component manufacturers** that ‘build-to-print’ 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)** that define the performance requirements of the components and the materials and processes used in manufacturing and maintenance. OEMs are responsible for the integration and certification of the final product. OEMs use NPE-containing sealants in a similar manner to component manufacturers.

- **Maintenance repair and overhaul (MRO) shops** that carry out aerospace product maintenance, repair and overhaul activities using polysulfide sealants during their daily activities.

9.0.1 Overview of uses and Exposure Scenarios

9.0.1.1 Overview of the processes

9.0.1.1.1 Use 1: Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing < 0.1% w/w of NPE for Aerospace 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 specifications of polysulfide sealants in any day.

Two-component polysulfide sealants require that the base and the NPE-containing hardener be systematically and thoroughly mixed by the downstream user in the correct ratio (base:hardener ratio is between 100:9 and 100:12 by weight), communicated through the technical data sheet by the formulator (see example in Annex 3), before being applied to the component. This may be completed in three ways:

i) Mixing within a two-compartment kit (i.e. a Techkit); 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 3 to 7. Figure 2 below shows the base and hardener containers for each type of mixing

Figure 2: Examples of the containers for each type of mixing. The red outline shows the hardener component, the yellow outline 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, and communicates this through the technical data sheet for the sealant. Mixing to the correct ratio achieves, on mixing, a final sealant with the necessary properties to match the particular set of specifications for that sealant formulation, 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 known and would not have demonstrably met the specification requirements. This further illustrates the rigorous level of control associated with successful completion of the mixing process and precision of formulation 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.

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 safety of the final assembly. 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 NPE 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., Techkit), 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 ’Techkit’. Figure 3 provides an illustration of the use of a Techkit. The Techkit 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.

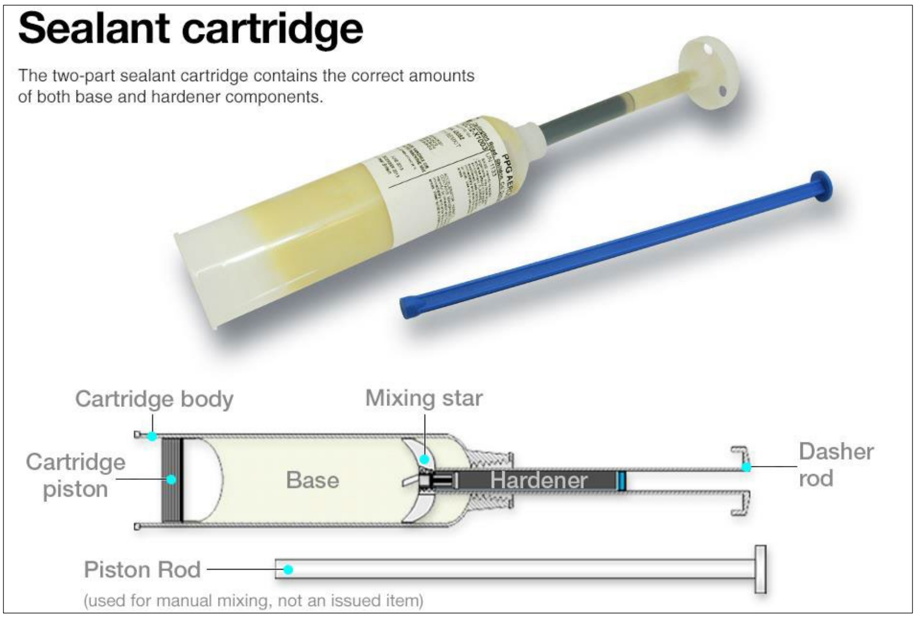


Figure 3: A two-compartment cartridge kit

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 NPE-containing hardener 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 potential release to the environment of NPE, is described in Section 9.1.

ii) <u>Mixing in small scale batches by hand</u>

Small 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 component 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 ratio of base:hardener is between 100:9 and 100:12 by weight, with the accurate ratio communicated through the technical data sheet by the formulator (see example in Annex 3)). 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 appropriate 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 4 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 potential release to the environment of NPE. These are discussed in Section 9.1.

Figure 4: Small scale hand mixing of hardener with base

iii) Bulk mixing by machine

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 (base: hardener ratio is between 100:9 and 100:12 by weight, with the accurate ratio communicated through the technical data sheet provided by the formulator (see example in Annex 3)) will be achieved on mixing the full contents of both. The larger container (a 200 L drum, fill quantity 162 L) holds the base component and the smaller container (a 21 L hobbock, fill quantity 18 L) holds the hardener component. These two drums are typically delivered 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 5 to 7 below.

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

Figure 5: Bulk mixing machine

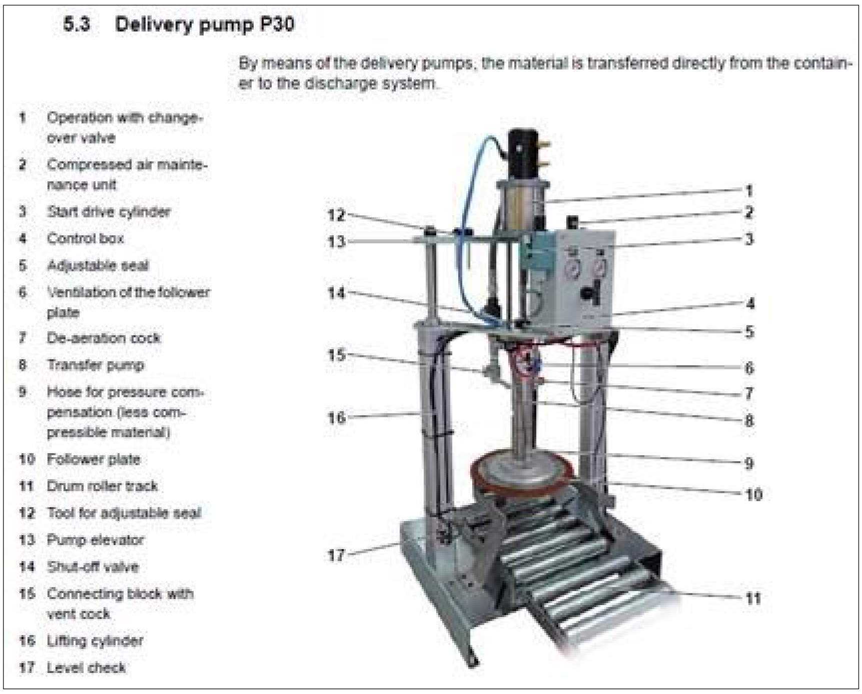


Figure 6: Annotated bulk mixing machine

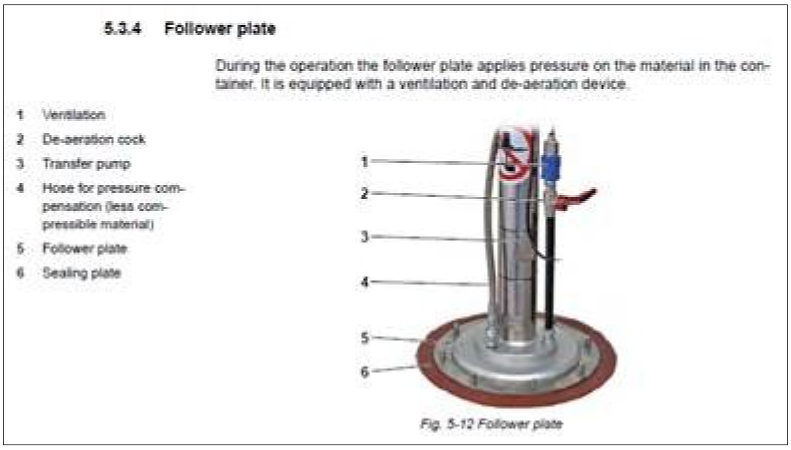


Figure 7: Annotated Follower Plate from the bulk mixing machinery

9.0.1.1.2 Post-Mixing, Service Life and End of Life

Following mixing, the concentration of NPE in the sealant is below 0.1% w/w. Skilled workers apply the mixed sealant to aerospace 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.
- 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 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. This allows end users to access sealant without the need to mix a new batch.

Once applied, the sealant is allowed to cure at either ambient temperatures or elevated temperatures. Elevated temperatures can be used to decrease the curing time. Curing can take between 3 hours and 90 days.

Once applied to aerospace hardware, 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 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 NPE. 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 Sections 9.2 of this CSR.

All wastes containing or contaminated with uncured or cured polysulfide sealant will be managed, consigned as hazardous waste and collected by licensed third party waste contractors. The discharge of cured or uncured sealant to wastewater systems is not allowed under any circumstances. These prevent potential release to the environment of NPE through the life cycle. A summary of the waste management processes is provided in Figure 8 below.

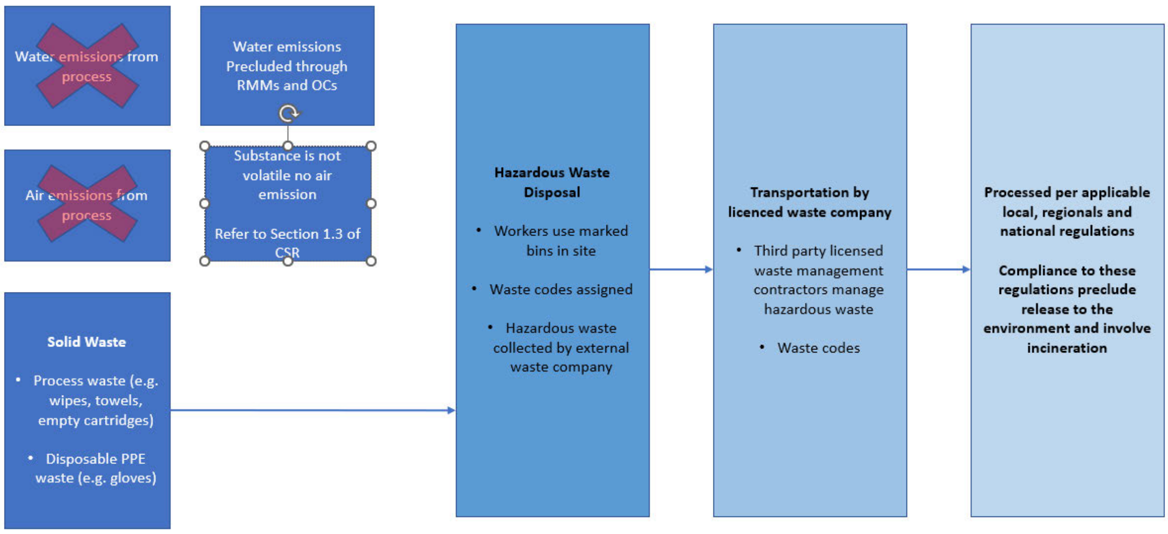


Figure 8: Flow diagram showing the waste management processes in place on site

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 section 9.1.

9.0.1.1.3 Tonnage information

Assessed tonnage: 40-70 kg/year based on:

40 – 70 kg/year used in manufacture of polysulfide sealant hardener, and subsequently handled during mixing of polysulfide sealants by Aerospace companies

Tonnage supplied per market sector:

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

Table 19. 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)
IW-1	IW	Mixing, by Aerospace companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE containing hardener, resulting in mixtures containing <0.1% w/w of NPE 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))	≤ 0.07
*** 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 NPE (on their own, or in mixtures) to the environment following a survey of relevant operations and with reference to the physical-chemical properties of NPE and its degradation product NP, 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 thirteen Downstream User sites. This information was verified by observation of operations during site visits. Three site visits were carried out:

- A site visit to a Downstream User site in the UK. Operations observed included bulk mixing by machine, use of a Techkit, and mixing by hand, and included production and MRO activities within designated facilities.
- A site visit to an MRO site in Germany, 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 NPE 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 NPE is the aquatic environment. Degradation of NPE to the respective alkylphenol (NP) is expected to occur in wastewater treatment plants, surface water and soils, and more slowly in sediments.

Thus, the qualitative assessment focused on use of water and/or discharge of wastewater and/or generation of waste materials in the 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 Section 9.1, are effective in preventing release of NPE 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 is that release to the environment is effectively prevented.

- 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 potential release to the environment is prevented. 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 in the vicinity of the process). As such, sampling is not logical or meaningful.

- Background concentration of NPE or NP in intake water to the site may produce a false positive in any wastewater from sites, leading to erroneous conclusions. The background level of NP in the environment is often similar to the achievable method detection limit[6]. Additionally, NP present in the environment may be from sources other than polysulfide sealant or even NPE degradation, therefore making reading of this nature potentially irrelevant given the alternative sources from which NP could reach the environment.

- Achievable method detection limits for NPE and NP in water/wastewater are in the order of 0.1 µg/l[7]. Lower method detection limits are difficult to achieve. There is also no approved method available for measuring the levels of NPE or NP in the environment, so providing justified measurement results is not feasible.

- Thus, the outcome of analysis could not be interpreted in any meaningful way.

- There is no standard method for measuring the air emission of NPE, or NP, from the uses covered within this Review Report. Additionally, as NPE, and NP, are not volatile substances, measurements in air are not relevant. This is supported by the Annex XV dossier published on the ECHA website, which states that 'due to the low vapour pressure of the ethoxylates evaporation into the atmosphere is expected to be negligible. For example, short chain 4-NP1EO has a vapour pressure of $2.38*10^{-5}$ Pa, the vapour pressure is expected to decrease with increasing length of the ethoxylate chain'. 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

[6] https://www.echa.europa.eu/documents/10162/f28b5c79-11e0-4ce2-91db-e53f7daa4d5a Section B9.7
[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.

 Copyright protected – No copying / use allowed

in the section below.

The findings of the 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 20. 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 0.1µg/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	

To support the conclusion of the qualitative assessment that no release of the substance to the environment means no exposure to the environment, EUSES modelling has been undertaken based on 0% release to water, soil, and air. The substance specific inputs used for this modelling are summarised in the below table.

Table 21. Substance specific inputs for the EUSES modelling

Substance Property	
Molecular weight	220.351 g/mol
Molecular weight used for the assessment	220.351 g/mol
Vapour pressure	0.3 Pa
Partition coefficient (Log Kow)	5.4
Water solubility	5.7 mg/L
Melting point	7 °
Boiling point	302 °C
Biodegradation in water	Inherently biodegradable
BCF (aquatic specific)	7760
Adsorption/Desorption: Koc at 20 °C	6730 L/kg

The results of the EUSES modelling confirm that, if there is no release to the environment, there is no exposure to the environment, thus confirming that there is no risk to the environment through these uses of NPE when handled in the way detailed throughout this CSR.

9.0.2.2 Humans via environment

Scope and type of assessment:

There is no potential release to the environment from the uses covered in this Review Report. Therefore, there is no potential for exposure to NPE 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 NPE 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 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 NPE-containing hardener or of the mixed sealant described within this CSR.

 Copyright protected – No copying / use allowed

9.1 Exposure scenario 1: Mixing, by Aerospace Companies and their associated supply chains, including the Applicant, of base polysulfide sealant components with NPE-containing hardener, resulting in mixtures containing <0.1% w/w of NPE 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 Techkit); 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 3 to 7.

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 NPE 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 Section 9.2.0.3. Compliance to these regulations precludes release to the environment and involves incineration.

9.1.1 Downstream Use Sites

9.1.1.1 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 30 -40.

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

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

9.1.1.2 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'[8], 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

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

highlighted within the ECHA guidance document as relating to an industrial use. Furthermore, and as outlined below (9.1.0.3), 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 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.

9.1.1.3 Regulatory Requirements

The downstream user of the sealant is subject to UK national and local laws, including any other relevant applicable local, regional, and national transposed acts/regulations, governing environmental protection, including but not limited to:

- Directive 2008/98/EC on waste (Waste Framework Directive) and implementing legislation[9] – 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.
- 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.

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.

9.1.1.4 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.

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

Workers also undergo regular re-certification/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 NPE in hardener and the final sealant, during mixing and use on site.

Sealants using NPE 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, tooling, 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 site size.

Workers are skilled, and receive regular training and recertification/refresher training with regards to chemical risk management and how to wear properly 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:

- **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 Fig. 1 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 in relation to the use of the relevant PPE during mixing and use of the sealant and how to manage such equipment should it, despite precautions, become contaminated with the hardener or base component or the final 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 personal protective equipment, 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.** In order 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.

- **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 sealants, 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 and determination of each type of waste made by the waste producer. This classification is based on the type and nature of the waste. Waste hardener and sealant are considered as hazardous waste and are assigned the relevant waste code

  – labelling and often colour-coding of designated waste storage bins to which hardener or final sealant should be disposed on the shop floor, an example of which is shown in Figure 18 below:

Figure 9: A colour coded hazardous waste bin

  – collection of hazardous waste by trained staff

  – storage of hazardous waste in an appropriately designed, secure and contained waste disposal facility

  – consignment of the material as hazardous waste and processing by licensed third party waste contractors

  – compliance with all relevant 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 the NPE 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 release of NPE.
- **Housekeeping**. The highest level of housekeeping is maintained in both internal and external assembly and repair areas. This is necessary to ensure manufacturing meets the requirements of aerospace companies. These specifications are upheld via a rigorous system of internal checks.

  Various Foreign Object Damage (FOD) controls also require aerospace 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 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 the 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

9.1.2 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 NPE 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 is 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

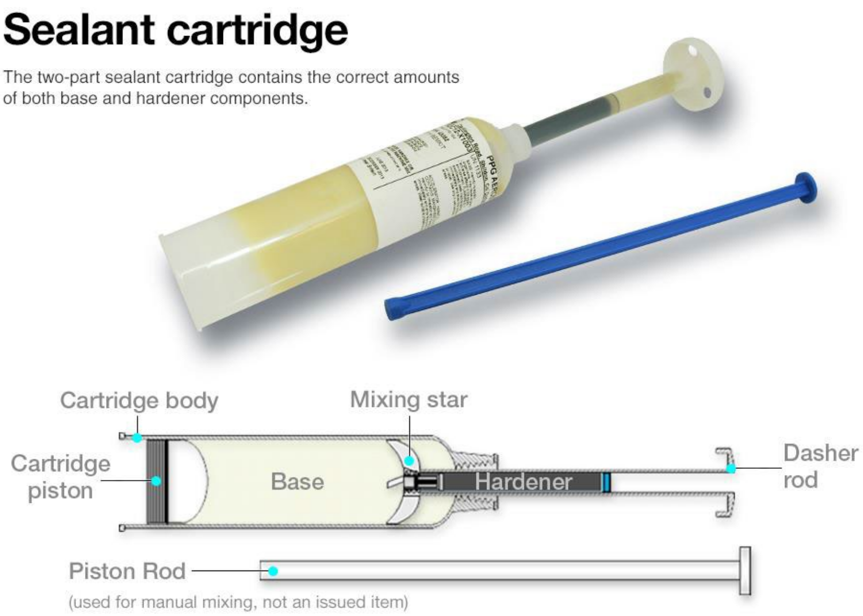


Figure 11: A two-compartment kit for mixing of the base and hardener components and subsequent extrusion

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.

Figure 12: Insertion of the piston rod into the cartridge body by a worker

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

NPE 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 13 shows an example of the machine used for mixing. Figures 23 to 25 demonstrate operation of the machine.

Figure 13: Machine used for mixing of Techkits

Figure 14: A worker places the Techkit into the machine for mixing

Figure 15: The mixing machine door is closed, fully containing the Techkit during mixing

Figure 16: A worker holding a fully mixed Techkit

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 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 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, as demonstrated in Figure 17 below. As such, it is disposed of as hazardous waste in a marked bin on site.

Figure 17: 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. The final sealant contains NPE at levels below 0.1%. Even though levels of NPE are very low and there is typically minimal sealant residue, the empty cartridge is still handled as hazardous waste.

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.

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 impregnated 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 to all workers using the sealant, and 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.

Given the above RMMs and OCs in place, when mixing is undertaken within a two-compartment kit it does not result in potential release of NPE to the environment.

9.1.2.1 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 NPE 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 NPE 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 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 NPE 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 user 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 NPE material at the site
Other conditions affecting environmental exposure
▪ Not applicable

9.1.2.2 Releases

There are no releases to the environment of the NPE 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 22. 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 to prevent any potential release to the environment of the NPE containing hardener or sealant. An exposure-based model (EUSES) is included in Annex 5 of this CSR using the above inputs, and this shows there is no release to the environment. The substance specific EUSES inputs have been summarised in section 9.0.2.1.

 Copyright protected – No copying / use allowed

Releases to waste

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.

9.1.2.3 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 NPE contained within the hardener component.

9.1.3 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 NPE to the environment.

The product is delivered to site in two separate containers, a larger container (100 ml – 1000 ml) holding a base component and a smaller container (10 ml - 100 ml) holding a hardener component (Figure 18). 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 10 ml up to 100 ml. The kit also comprises the sealant base component that has been batch tested to match the NPE 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 NPE 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 18: 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 NPE is below 0.1% w/w. The mixture is applied to the surface which requires sealing. 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, provisions of training to all workers using the sealant, and 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.

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

The 2-compartment kit mixing machinery is cleaned with a pre-impregnated wipe, by a worker wearing PPE. The PPE used is a combination of the previously mentioned equipment, namely, disposable gloves, reusable overalls, googles, and a disposable apron if appropriate. 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. The only appropriate cleaning material(s) are the wipes pre-impregnated with solvent. Therefore, no water is used during the cleaning operations.

Any contaminated reusable PPE is cleaned after use with a rag soaked in solvent, to remove any contamination by NPE, the formulated hardener, or the final sealant product. Workers are instructed, through the training processes previously detailed within these responses, to ensure their reusable PPE is clean before returning it to storage for future use. 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. These risk assessments are written documents which are maintained on file for workers to access and reference. Given the self-contained nature of the 2-compartment kits, where the mixtures and mixing processes are fully contained, and 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 of the hardener component, workers will wear disposable gloves, along with reusable protective overalls and goggles. A disposable protective apron may be worn to further protect the reusable overalls from exposure to the materials. Disposable PPE is disposed of to the marked hazardous waste containers in the production area, in line with the detail offered in previous responses above, while reusable PPE is cleaned as noted earlier within this question response

 Copyright protected – No copying / use allowed

9.1.3.1 Conditions of use

Amount used, frequency and duration of use (or from service life)
▪ Daily use at site: Up to 24hours 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 NPE 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 NPE 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 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 NPE 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 user 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 NPE material at the site
Other conditions affecting environmental exposure
▪ Not applicable

9.1.3.2 Releases

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

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:** There is no release to wastewater on site. RMMs and OCs in place on site prevent any potential release to the environment of the NPE containing hardener or sealant.

Release	Release factor estimation method	Explanation / Justification
		An exposure-based model (EUSES) is included in Annex 5 of this CSR using the above inputs, and this shows there is no release to the environment. The substance specific EUSES inputs have been summarised in section 9.0.2.1.

Releases to waste

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.

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

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

9.1.4 Environmental contributing scenario: Use and handling of the hardener component during bulk scale mixing

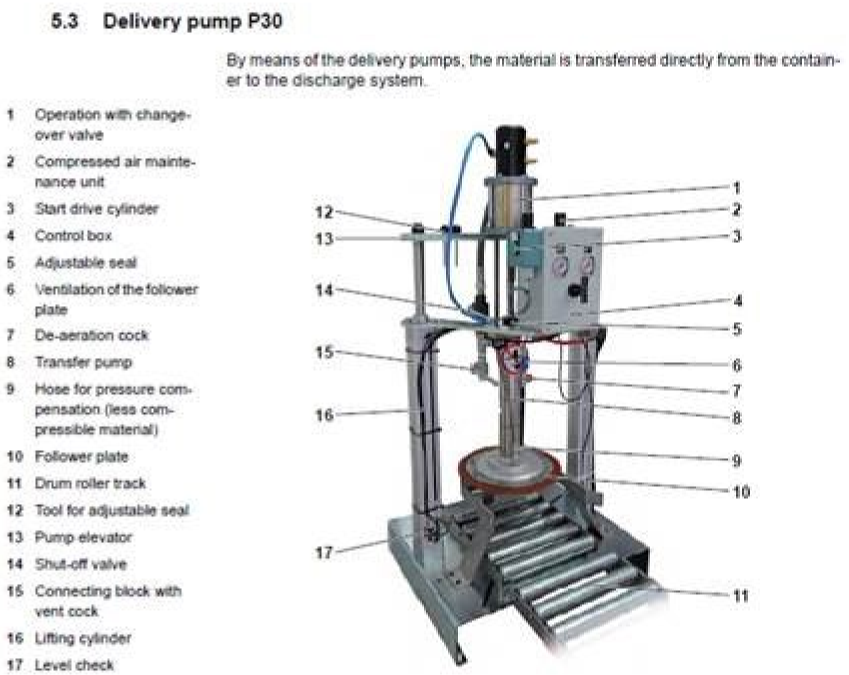
Delivery of the two-drum kit is by road, paired on a pallet, to a contained area. This is necessary so the relevant hardener component is stored and used with the correct base component to provide a final sealant that meets the specification for any particular use (e.g., capping a fastener versus a fillet seal versus a faying surface). Examples of the two drum kits are pictured (Figure 19).

Figure 19: 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 22, which move the contents of the drum down and minimise any residual material on the walls. In doing this, the company minimise material and financial loss due to wastage. As can be seen in Figure 20, 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 component and the 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 20, Figure 21, Figure 22).

Figure 20: Example of a bulk scale mixing machine

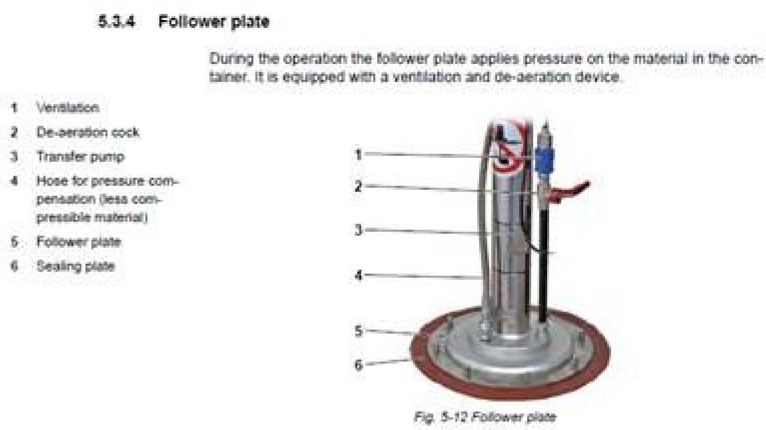


5.3 Delivery pump P30

By means of the delivery pumps, the material is transferred directly from the container to the discharge system.

1 Operation with change-over valve
2 Compressed air maintenance unit
3 Start drive cylinder
4 Control box
5 Adjustable seal
6 Ventilation of the follower plate
7 De-aeration cock
8 Transfer pump
9 Hose for pressure compensation (less compressible material)
10 Follower plate
11 Drum roller track
12 Tool for adjustable seal
13 Pump elevator
14 Shut-off valve
15 Connecting block with vent cock
16 Lifting cylinder
17 Level check

Figure 21: Annotated bulk mixing machine



5.3.4 Follower plate

During the operation the follower plate applies pressure on the material in the container. It is equipped with a ventilation and de-aeration device.

1 Ventilation
2 De-aeration cock
3 Transfer pump
4 Hose for pressure compensation (less compressible material)
5 Follower plate
6 Sealing plate

Fig. 5-12 Follower plate

Figure 22: Annotated Follower Plate from the bulk mixing machinery

Workers wear the relevant PPE. After mixing, any disposable PPE are disposed of as hazardous 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. 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.

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 NPE 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, provisions of training to all workers using the sealant, and 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.

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

Given the viscous nature of the NPE-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 exposure of the material to soil. Prior to being used for mixing, all materials, including the NPE-containing sealant hardener, are held 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, with the waste subsequently incinerated.

Mixing processes utilise specialised machinery in order to ensure a full mixing process is completed with minimal loss of product.

The follower plate 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 if appropriate. 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 is then handled as hazardous waste, placed in the relevant marked bin, and sent for incineration off-site by a third-party waste management contractor.

Any contaminated reusable PPE is cleaned after use with a rag soaked in solvent, to remove any contamination by NPE, the formulated hardener, or the final sealant product. Workers are instructed, through the training processes previously detailed within these responses, to ensure their reusable PPE is clean before returning it to storage for future use. 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. These risk assessments are written documents which are maintained on file for workers to access and reference. Given the self-contained nature of the 2-compartment kits, where the mixtures and mixing processes are fully contained, and 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 of the hardener component, workers will wear disposable gloves, along with reusable protective overalls and goggles. A disposable protective apron may be worn to further protect the reusable overalls from exposure to the materials. Disposable PPE is disposed of to the marked hazardous waste containers in the production area, in line with the detail offered in previous responses above, while reusable PPE is cleaned as noted earlier within this question response.

9.1.4.1 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 NPE 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 NPE 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 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 NPE 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 user 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 NPE material at the site
Other conditions affecting environmental exposure
▪ Not applicable

9.1.4.2 Releases

There are no releases to the environment of the NPE containing hardener component of the two-part sealant when bulk mixing by 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

Copyright protected – No copying / use allowed

Release	Release factor estimation method	Explanation / Justification
		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 NPE containing hardener or sealant. An exposure-based model (EUSES) is included in Annex 5 of this CSR using the above inputs, and this shows there is no release to the environment. The substance specific EUSES inputs have been summarised in section 9.0.2.1.

Releases to waste

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.

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

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

9.1.5 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 NPE, 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 adequately manage 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 NPE.

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 NPE 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.

Waste that may be generated during 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. The rags are handled and disposed as hazardous waste.

 Copyright protected – No copying / use allowed

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

9.1.5.1 Exposure and risks for workers

A worker risk assessment is not required.

 Copyright protected – No copying / use allowed

9.2 Service Life of Polysulfide Sealants

Following mixing, the concentration of NPE 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.

9.2.1 Downstream Use Sites

9.2.1.1 Site Locations

See Section 9.1.0.1.

9.2.1.2 Nature of Downstream Use Sites

See Section 9.1.0.2.

9.2.1.3 Regulatory Requirements

See Section 9.1.0.3.

9.2.1.4 Management Systems

See Section 9.1.0.4.

The highest level of housekeeping is maintained in assembly and repair areas. This is necessary to ensure manufacturing meets the requirements of aerospace companies. 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.

9.2.1.5 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.
- 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 and facilitate in service draining.

Occasionally two-compartment kits or caps 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 NPE) during production (assembly) and MRO respectively. They represent the use and handling of the overall sealant.

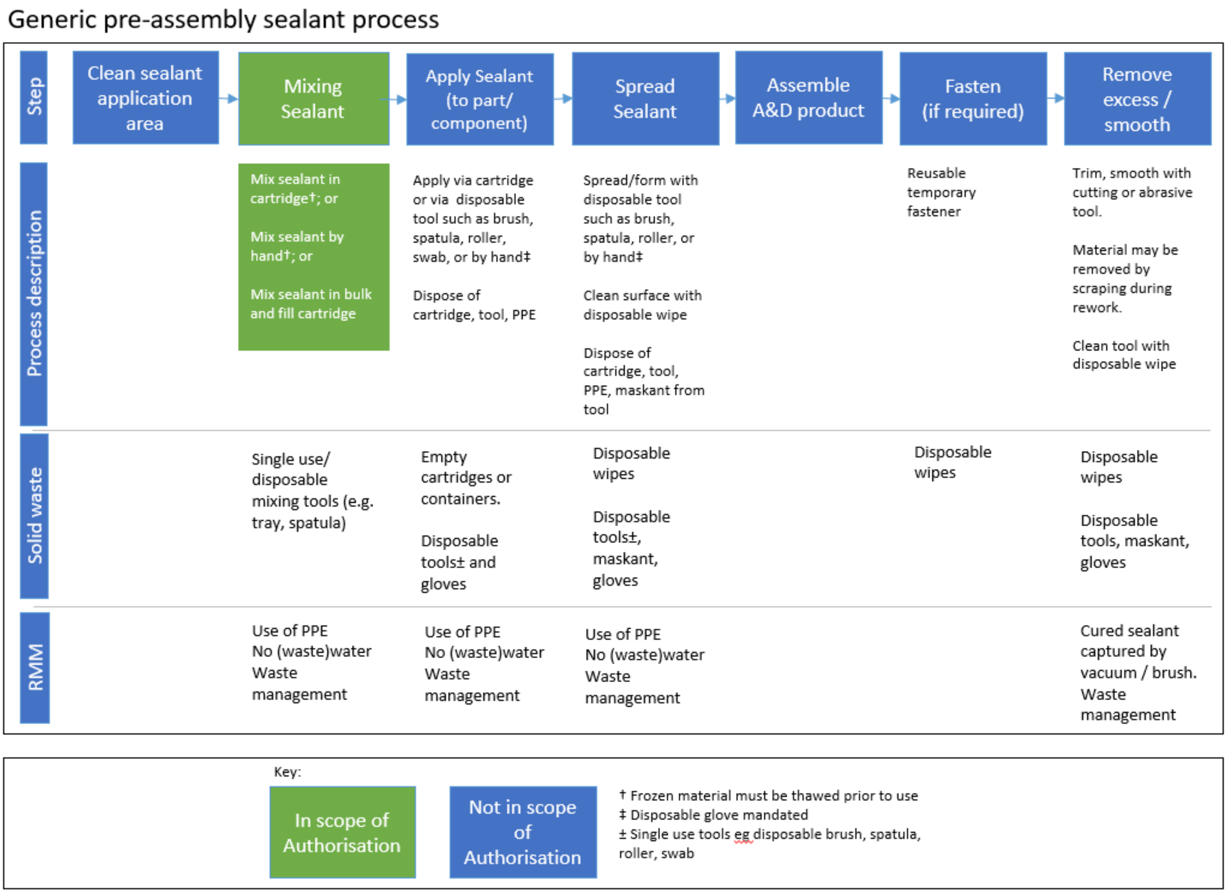


Figure 23: Generic pre-assembly processes of sealant use

The process for post-assembly sealant use is the same as in Figure 23 above, except cured sealant is removed as part of the cleaning sealant application area activities. The below chart shows the various mixing processes undertaken for NPE containing polysulfide sealants which are considered within this Review Report.

The sealant is manually applied using disposable tools such as a Techkit 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 manner and accurately to avoid waste. Disposable tools are also used to spread or smooth. The tools may be wiped clean with a rag or paper towel. All waste tools, rags, and towels contaminated with sealant is collected and disposed to waste bins marked for hazardous waste. Alternatively, to disposable tools, a gloved finger may be used to smooth sealant after it has been applied. When a gloved finger is used, the glove will subsequently be carefully removed, 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 impregnated rag/paper towel, which would then be disposed to waste bins marked for hazardous waste.

 Copyright protected – No copying / use allowed

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. 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. There is no release to wastewater during production or MRO processes involving polysulfide sealant. Workers wear the same personal protective equipment (PPE) as for mixing. Any disposable PPE are disposed of as hazardous waste in a bin on site whether contaminated or not.

If a Techkit is used, the valved dasher rod identified in Figure 3 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 Techkits, 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 8.

The collection of NPE 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.

9.2.1.6 Releases

There are no releases to the environment of the NPE containing sealant when applying the sealant to the equipment, 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. RMMs and OCs in place on site to prevent any potential release to the environment of the NPE containing hardener or sealant. An exposure-based model (EUSES) is included in Annex 5 of this CSR using the above inputs, and this shows there is no release to the environment. The substance specific EUSES inputs have been summarised in section 9.0.2.1.

Releases to waste

All NPE 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.

9.2.1.6 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 NPE is below 0.1 %, as shown in Figure 24. They are discussed here only to the extent necessary to provide detail on release of NPE over the lifecycle of the sealant.

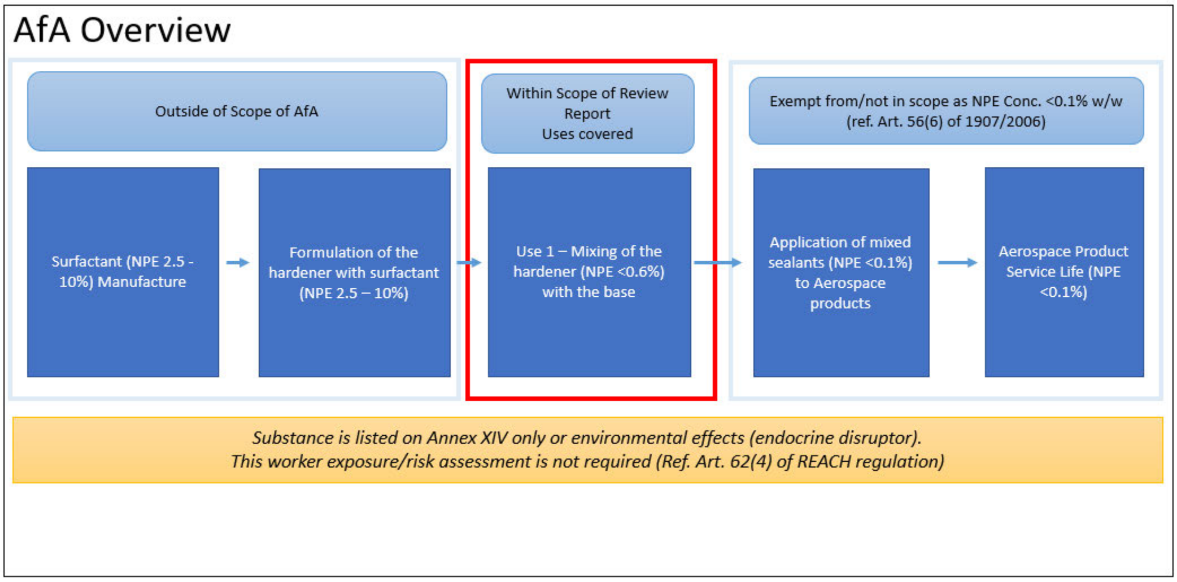


Figure 24: Overview of the scope of the Review Report

When repair is needed, the old sealant is removed by cutting it away with a sharp, 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 NPE 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 NPE is present in very low concentrations (below 0.1 % w/w) in the 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 NPE was to migrate from the sealant to the fuel, 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 NPE from the sealant to water is expected to be limited, as only a small fraction of the sealant will be exposed at the surface. The potential for migration of NPE depends on the surface area of the sealant in each application will be present. Transport of NPE from within the polysulfide to the surface will be by diffusion. This implies that the NPE (below 0.1% 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 ethoxylate 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 NPE 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 NPE 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 face of the aircraft and not protected by paint or primer). It also considers that a fraction of the NPE 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 NPE 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 NPE released to the environment would be very low. In case NPE 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 NP in the environment.

Considering UK-wide release NPE from polysulfide sealant to water			
	Value		**Comment**
	Reasonable Case	Worst Case Hypothetical Example	
Concentration of NPE in Sealant on Aircraft	<0.1%	<0.1%	0.001
Volume sealant used in aerospace industry in UK per year	[redacted] t/a	[redacted] t/a	Provided by applicant
% Released to the environment during production and DU use	0%	0%	No release to environment
Tonnage of NPE in sealant on aerospace equipment	[redacted] kg/year	70 kg/year	Provided by applicant
% of Sealant used in applications that have contact to surface water	0%	5%	There are no known instances in the scope of this application where sealants are used in applications that have contact to surface water. The hypothetical worst-case situation assumes 95% applications are internal or coated with primer so no release to surface water possible.
Tonnage of NPE in sealant in applications that could be exposed to surface water	0 kg	3.5 kg	UK wide
% of total NPE 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%	10%	Approximation total exposed surface area. Assumes e.g. only 10% ethoxylate in surface facing edge of sealant

CBI 1

			available for release to the environment and all of that released in first year. 90% remains in sealant at end of life.
Tonnage of NPE in sealant in scope of this Review Report released to surface water UK-wide	0 kg/year	0.35 kg/year	Released globally across all flight paths. Assumes all exposed NPE is released to water. However, the major fraction of any material released would be retained in soil, where it would eventually degrade.
UK area	0.25m km^2	0.25m km^2	
Tonnage of NPE in sealant in scope of this Review Report released to surface water UK-wide	0 $\mu g/m^2$/year	~14$\mu g/m^2$/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 NPE released to the environment (should there be exposure of cured sealants to the environment and any leaching at all) in one year is 0.35 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.

9.2.2 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 suspect unapproved parts, be destroyed to avoid reuse. 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 specialist waste contractors familiar with these requirements.

 Copyright protected – No copying / use allowed

9.3 Conclusion of the Hazard Assessment

The potential impact of the mixing of this hardener with a base as part of a two-component kit, has been assessed within this CSR.

The NPE substance has been listed for authorisation due to endocrine disrupting potential of its degradation product, nonylphenol, 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 (and subsequent 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 35 below:

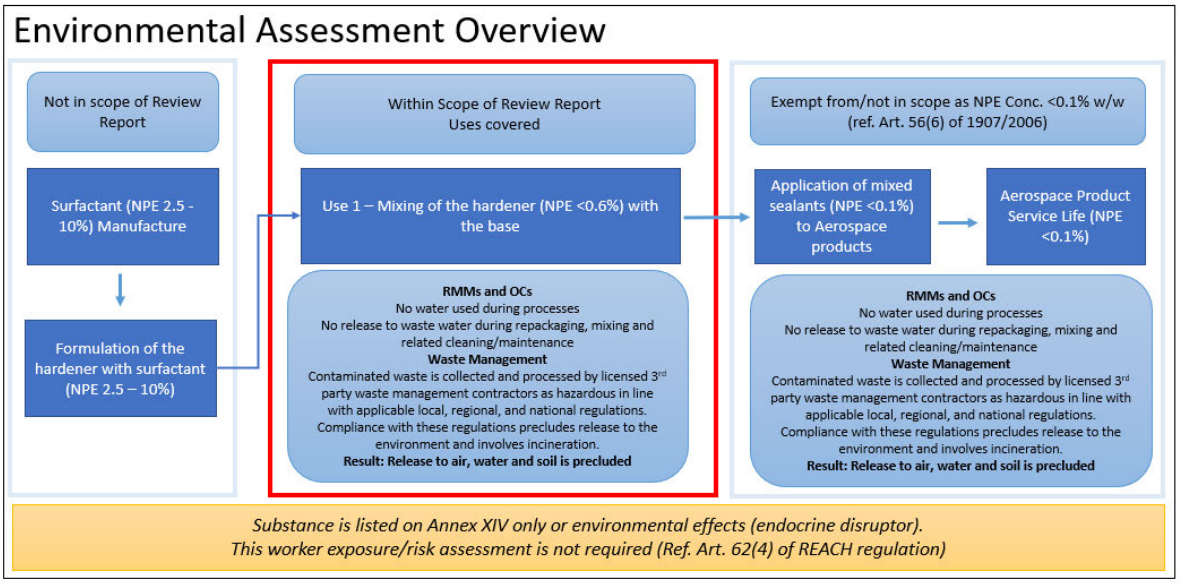


Figure 25: Overview of the Environmental Risk Assessment

A number of stringent RMMs and OCs are in place during the mixing processes involving this hardener that preclude the release of the NPE to the environment during handling and use. As such, there is no anticipated risk to the environment during mixing of the hardener with the base by Aerospace companies, and continuation of these activities can be considered safe for the purpose of this Review Report. NPE is also present at low concentrations during the mixing steps.

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 hardener component containing NPE within it, stringent RMMs and OCs are in place to prevent release of material to the environment. These include workforce training, waste management, and location design, which work together to preclude release of the NPE substance 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, exposure to the environment is precluded throughout use of NPE 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 NPE containing 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 exposure scenario occurs at separate downstream user sites within the UK. As such, an assessment of the local exposure due to combined uses at a single site is not relevant.

 Copyright protected – No copying / use allowed

Annexes

Annex 1: References

Brooke, L.T. 1993: Acute and Chronic Toxicity of Nonylphenol to Ten Species of Aquatic Organisms (study report), U.S. EPA. Testing laboratory: Environmental Health Laboratory at Univ. of Wisconsin-Superior, Report no: Contract No. 68-C1-0034. Owner company; NA, Study number: NA, Report date:

Dwyer, F.J., F.L. Mayer, L.C. Sappington, D.R. Buckler, C.M. Bridges, I.E. Greer, D.K. Hardesty, C.E. Henke, C.G. Ingersoll, J.L. Kunz, D.W. Whites, T. Augspurger, D.R. Mount, K. Hattala, G.N. Neuderfer 2005: Assessing Contaminant Sensitivity of Endangered and Threatened Aquatic Species: Part I Acute Toxicity of Five Chemicals (publication), Arch. Environ. Contam. Toxicol. 48, 143-154. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Kelly SA & Di Giulio RT 2000: Developmental toxicity of estrogenic alkylphenols in killifish (Fundulus heteroclitus) (publication), Environmental Toxicology and Chemistry. 19(10): 2564-2570. Report date:

TenEyck MC & Markee TP 2007: Toxicity of Nonylphenol, Nonylphenol Monoethoxylate and Nonylphenol Diethoxylate and Mixtures of these Compounds to Pimephales promelas (Fathead Minnow) and Ceriodaphnia dubia (publication), Archives of Environmental Contaminant Toxicology 53: 599 - 606. Report date:

Lussier SM, Champlin D, LiVolsi J, Pouncher S & Pruell RJ 2000: Acute toxicity of para-nonylphenol to saltwater animals (publication), Environmental toxicology and chemistry 19(3): 617-621. Report date:

Bhattacharya H, Xiao Q & Lun L 2008: Toxicity studies of nonylphenol on rosy barb (Puntius conchonious): A biochemical and histopathological evaluation (publication), Tissue and Cell 40: 243 - 249. Report date:

Ward TJ & Boeri RL 1990: Acute flow through toxicity of nonylphenol to the Sheepshead Minnow, Cyprinodon variegatus. Test Standard 40 CFR 797.1400 (study report), Testing laboratory: Envirosystems Division, Resource Analysts, Incorporated, PO Box 778, One Lafayette Road, Hampton, New Hampshire 03842, Report no: 8972-CMA. Owner company; NA, Report date: Nov 19, 1990

Spehar, R. L., Brooke, L. T., Markee, T. P., Kahl, M. D. 2010: Comparative Toxicity and Bioconcentration of Nonylphenol in Freshwater Organisms (publication), Environmental Toxicology and Chemistry. Testing laboratory: Lake Superior Research Institute, Report date: Apr 28, 2010

Yoshifumi Horie, Takahiro Yamagishi, Hiroko Takahashi, Youko Shintaku, Taisen Iguchi, Norihisa Tatarazako 2017: Assessment of the lethal and sublethal effects of 20 environmental chemicals in zebrafish embryos and larvae by using OECD TG 212 (publication), J. Appl. Toxicol. 2017; 37: 1245–1253. Report date: May 29, 2017

Daniel Stengel, Florian Zindler, Thomas Braunbeck 2017: An optimized method to assess ototoxic effects in the lateral line of zebrafish (Danio rerio) embryos (publication), Comparative Biochemistry and Physiology, Part C 193 (2017) 18–29. Report date: Nov 12, 2016

Watanabe h, Yoshifumi H, Hitomi T, Masaaki K, Taisen I and Norihisa T 2017: Medaka extended one-generation reproduction test (MEOGRT) evaluation 4-nonylphenol (publication), Environmental Toxicology and Chemistry. Testing laboratory: Center for Health and Environmental Risk Research, National Institute for Environmental Studies, Report date:

Brooke, L.T. 1993: Accumulation and Lethality for Two Freshwater Fishes (Fathead Minnow and Bluegill) to Nonylphenol (study report), USEPA. Testing laboratory: Environmental Health Laboratory at Univ. of Wisconsin-Superior, Report no: Contract # 68-C1-0034. Owner company; NA, Study number: NA, Report date: Sep 30, 1993

Yokota, H., Seki, M., Maeda, M., Oshima, Y., Tadokoro, H., Honjo, T., Kobayashi, K. 2001: Life-cycle Toxicity of 4-Nonylphenol to Medaka (Oryzias latipes) (publication), Environmental Toxicology and Chemistry Vol 20:11 2552-2560. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Ackermann,G.E., Schwaiger, J., Negele, R.D., Fent, K. 2002: Effects of long-term nonylphenol exposure on gonadal development and biomarkers of estrogenicity in juvenile rainbow trout (Oncorhynchus mykiss) (publication), Aquatic Toxicity Vol 60: 203-221. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Moore, A., Scott, A.P., Lower, N., Katsiadiki, I., Greenwood, L. 2003: The effects of 4-nonylphenol and atrazine on Atlantic salmon (salmo salar L) smolts (publication), Aquaculture 222 p253-263. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Zha, J., Sun, L., Spear, P., Wang, Z. 2008: Comparison of ethinylestradiol and nonylphenol effects on reproduction of Chinese rare minnows (Gobiocypris rarus) (publication), Ecotoxicology and Environmental Safety Vol 71: 390-399. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Kang, I.J.,Yokota, H., Oshima, Y., Tsurday, Y., Hano, T., Maeda, M., Imada, N., Tadokoro, H., Honjo, T. 2003: Effects of 4-Nonylphenol on Reproduction of Japanese Madaka, Oryzias latipes (publication), Environmental Toxicology and Chemistry Vol 22:10 2438-2445. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Nimrod, A.C., and Benson, W. H. 1998: Reproduction and development of Japanese medaka following an early life stage exposure to xenoestrogens (publication), Aquatic Toxicology vol 44: 141-156. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

Brooke, L.T. 1993: Acute and Chronic Toxicity of Nonylphenol to Ten Species of Aquatic Organisms (study report), USEPA. Testing laboratory: Environmental Health Laboratory at Univ. of Wisconsin-Superior, Report no: Contract # 68-C1-0034. Owner company; NA, Study number: NA, Report date: May 24, 1993

Afonso, L., Smith, J., Ikonomou, M., Devlin, R. 2002: Y-Chromosomal DNA Markers for Discrimination of Chemical Substance and Effluent Effects on Sexual Differentiation in Salmon (publication), Environmental Health Perspectives 110:9 pp881-887. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Iman Shirdel, Mohammad Reza Kalbassi 2016: Effects of nonylphenol on key hormonal balances and histopathology of the endangered Caspian brown trout (Salmo trutta caspius) (publication), Comparative Biochemistry and Physiology, Part C 183–184 (2016) 28–35. Report date: Jan 23, 2016

E. Puy-Azurmendi, A. Olivares, A. Vallejo, M. Ortiz-Zarragoitia, B. Piña, O. Zuloaga, M.P. Cajaraville 2014: Estrogenic effects of nonylphenol and octylphenol isomers in vitro by recombinant yeast assay (RYA) and in vivo with early life stages of zebrafish (publication), Science of the Total Environment 466–467 (2014) 1–10. Report date: Jul 25, 2013

Brooke, L.T. 1993: Acute and Chronic Toxicity of Nonylphenol to Ten Species of Aquatic Organisms (study report), U.S. EPA. Testing laboratory: Environmental Health Laboratory at University of Wisconsin-Superior, Report no: Contract No. 68-C1-0034. Owner company; NA, Study number: NA, Report date:

Scholz N 1992: Bestimmung der Auswirkungen von Nonylphenol auf das Schwimmverhalten von Daphnia magna (study report), Testing laboratory: Huels AG, Report no: DK-522. Owner company; Sasol Germany GmbH, Study number: 2469, Report date: Jul 1, 1992

Lussier SM, Champlin D, LiVolsi J, Poucher S & Pruell RJ 2000: Acute toxicity of para-nonylphenol to saltwater animals (publication), Environmental toxicology and chemistry 19(3):617-621. Report date:

Ward TJ & Boeri RL 1990: Acute flow through toxicity of nonylphenol to the mysid, Mysidopsis bahia. Test Standard 40 CFR 797-1930 (study report), Testing laboratory: Envirosystems Division, Resource Analysts, Incorporated, PO Box 778, One Lafayette Road, Hampton, New Hampshire 03842, Report no: 8974-CMA. Owner company; NA, Report date: Nov 16, 1990

Comber MHI, Williams TD & Stewart KM 1993: The effects of nonylphenol on Daphnia magna (study report), Wat. Res. 27 (2): 273-276. Report date:

 Copyright protected – No copying / use allowed

Ankley GT, Peterson GS, Lukasewycz MT & Jensen DA 1990: Characteristics of surfactants in toxicity identification evaluations (publication), Chemosphere 21: 3 - 12. Report date:

Hong L & Li MH 2007: Acute toxicity of 4-Nonylphenol to aquatic invertebrates (publication), Bull Environ Contam Toxicol 78:445-449. Report date:

Hirano M, Ishibashi H, Matsumura N, Nagao Y, Watanabe N, Watanabe A, Onikura N, Kishi K & Arizono K 2004: Acute toxicity responses of two crustaceans, Americamysis bahia and Daphnia magna, to endocrine disrupters (publication), Journal of Health Science. 50 (1): 97-100. Report date:

Brennan S, Brougham CA, Roche JJ & Fogarty AM 2006: Multi-generational effects of four selected environmental oestrogens on Daphnia magna (publication), Chemosphere 64: 49 - 55. Report date:

Isidori M, Lavorgna M, Nardelli A & Parrella A 2006: Toxicity on crustaceans and endocrine disrupting activity on Saccharomyses cerevisiae of eight alkylphenols (publication), Chemosphere 64: 135-143. Report date:

Matteo Oliva, Elvira Mennillo, Martina Barbaglia, Gianfranca Monni, Federica Tardelli, Valentina Casu, Carlo Pretti 2018: The serpulid Ficopomatus enigmaticus (Fauvel,1923) as candidate organisms for ecotoxicological assays in brackish and marine waters (publication), Ecotoxicology and Environmental Safety 148 (2018) 1096–1103. Report date: Nov 17, 2015

Comber, M.H. I., Williams, T.D., and Stewart, K. M. 1993: The Effects of Nonylphenol on Daphnia Magna (publication), Water Research Vol 27:2 273-276pp. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

England, D.E. 1995: Chronic Toxicity of Nonylphenol to Ceriodaphnia dubia (study report), Testing laboratory: ABC Laboratories, Report no: 41509. Owner company; Chemical Manufacturers Association, Report date: Apr 5, 1995

Brooke, L.T. 1993: Acute and Chronic Toxicity of Nonylphenol to Ten Species of Aquatic Organisms (study report), Testing laboratory: Environmental Health Laboratory University of Wisconsin-Superior, Report no: EPA Contract No. 68-C1-0034. Report date:

Brennan, S., Brougham, C., Roche, J., Fogarty, A. 2006: Multi-generational effects of four selected environmental oestrogens on Daphnia magna (publication), Chemosphere Vol 64:49-55. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Marcial, H., Hagiwara, A., Snell, T.W. 2003: Estrogenic Compounds Affect Development of Harpacticoid Copepod Tigriopus japonicus (publication), Environ. Tox. & Chem. 22:12 3025-3030. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

Baldwin, W., Graham, S., Shea, D., LeBlanc, G. 1997: Metabolic Androgenization of Female Daphnia magna by the Xenoestrogen 4-Nonylphenol (publication), Environ. Tox. Chem. 16:9 1905-1911. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Kahl, Michael, Makynen, E., Kosian, P., Ankley, G. 1997: Toxicity of 4-Nonylphenol in a Life-Cycle Test with the Midge Chironomus tentans (publication), Ecotoxicology and Environmental Safety 38 155-160. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

Sun, H. and Gu, X. 2005: Comprehensive Toxicity Study of Nonylphenol and Short-Chain Nonylphenol Polyethoxylates on Daphnia magna (publication), Bull. Environ. contam. Toxicol. 75:677-683. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Isidori, M., Lavorgna, M.,Nardelli, A., Parrella, A. 2006: Toxicity on crustaceans and endocrine disrupting activity on Saccharomyces cerevisiae of eight alkylphenols (publication), Chemosphere vol 64: 135-143. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Kuhn, A., Munns Jr., W.R., Champlin, D., McKinney, R., Tagliabue, M., Serbst, J., Gleason, T. 2001: Evaluation of the Efficacy of Extrapolation Population Modelling to Predict the Dynamics of Americamysis bahia Populations in the Laboratory (publication), Environ. Tox. Chem. 20:1 213-221. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Tanaka, Y., and Nakanishi, J. 2002: Chronic Effects of p-Nonylphenol on Survival and Reproduction of Daphnia galeata: Multigenerational Life Table Experiment (publication), Environmental Toxicology 17(5), 487-492.. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Bechmann, R. 2005: Effect of the endocrine disrupter nonylphenol on the marine copepod Tisbe battagliai (publication), Science of the Total Environment 23:33-46. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Hoss, S., Juttner, I., Traunspurger, W., Pfister, G., Schramm, K.W., Steinberg, C. 2002: Enhanced growth and reproduction of Caenorhabditis elegans (Nematoda) in the presence of 4-nonylphenol (publication), Environmental Pollution 120 169-172. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

Scholz N 1992: Bestimmung der Auswirkungen von Nonylphenol auf die Reproduktion von Daphnia magna (study report), Testing laboratory: Huels AG, Report no: DL-143. Owner company; Sasol Germany GmbH, Study number: 2468, Report date: Oct 12, 1992

Masashi Hirano, Hiroshi Ishibashi, Joon-Woo Kim, Naomi Matsumura, Koji Arizono 2009: Effects of environmentally relevant concentrations of nonylphenol on growth and 20-hydroxyecdysone levels in mysid crustacean, Americamysis bahia (study report), Comparative Biochemistry and Physiology, Part C 149 (2009) 368–373. Report date: Sep 18, 2008

Olivier Geffard, Benoit Xuereb, Arnaud Chaumot, Alain Geffard, Sylvie Biagianti, Claire Noel, Khedidja Abbaci, Jeanne Garric, Guy Charmantier, Mireille Charmantier-Daures 2010: Ovarian cycle and embryonic development in Gammarus fossarum: Application for reproductive toxicity assessment (publication), Environmental Toxicology and Chemistry, Vol. 29, No. 10, pp. 2249–2259,. Report date: Apr 30, 2010

Masaya Uchida, Masashi Hirano, Hiroshi Ishibashi, Jun Kobayashi, Yoshihiro Kagami, Akiko Koyanagi, Teruhiko Kusano, Minoru Koga, Koji Arizono 2016: Transcriptional response of mysid crustacean, Americamysis bahia, is affected by subchronic exposure to nonylphenol (publication), EcotoxicologyandEnvironmentalSafety133(2016)360–365. Report date: Aug 4, 2016

Scholz N 1989: Bestimmung der Auswirkungen von Nonylphenol auf das Wachstum von Scenedesmus subspicatus 86.81.SAG (study report), Testing laboratory: Huels AG, Germany, Report no: AW-185. Owner company; Sasol Germany GmbH, Study number: 3896, Report date: Mar 1, 1996

Ward TJ & Boeri RL 1990: Acute static toxicity of nonylphenol to the marine alga Skeletonema costatum (study report), Testing laboratory: EnviroSystems Division Resource Analysts, Incorporated, PO Box 778, One Lafayette Road, Hampton, New Hampshire 0.3842, Report no: 8970-CMA. Owner company; NA, Report date: Nov 19, 1990

Ward, T.J. and R.L. Boeri 1990: Acute Static Toxicity of Nonylphenol to the Freshwater Alga Selenastrum capricornutum (study report), Testing laboratory: Envirosystems Division Resource Analysts, Inc, Owner company; Chemical Manufacturers Association, Study number: 8969-CMA, Report date: Nov 19, 1990

Nadezda Medvedeva, Tatyana Zaytseva, Irina Kuzikova 2017: Cellular responses and bioremoval of nonylphenol by the bloom-forming cyanobacterium Planktothrix agardhii 1113 (publication), Journal of Marine Systems 171 (2017) 120–128. Report date: Jan 16, 2017

T. B. Zaytseva, N. G. Medvedeva, V. N. Mamontova 2015: Peculiarities of the Effect of Octyl and Nonylphenols on the Growth and Development of Microalgae (publication), ISSN 19950829, Inland Water Biology, 2015, Vol. 8, No. 4, pp. 406–413. Report date: Mar 28, 2014

Guang-Jie Zhou, Fu-Qiang Peng, Bin Yang, Guang-Guo Ying 2013: Cellular responses and bioremoval of nonylphenol and octylphenol in the freshwater green microalga Scenedesmus obliquus (publication), Ecotoxicology and Environmental Safety 87 (2013) 10–16. Report date: Oct 30, 2012

Q.T. Gao, N.F.Y. Tam 2011: Growth, photosynthesis and antioxidant responses of two microalgal species, Chlorella vulgaris and Selenastrum capricornutum, to nonylphenol stress (publication), Chemosphere 82 (2011) 346–354. Report date: Oct 28, 2010

Graff L, Isnard P, Cellier P, Bastide J, Cambon J-P, Narbonne J-F, Budzinski H & Vasseur P 2003: Toxicity of Chemicals to Microalgae in River and Standard Waters (publication), Environmental Toxicology and Chemistry V22(6): 1368-1379. Report date:

Brooke LT 1993: Acute and chronic toxicity of nonylphenol to ten species of aquatic organisms (study report), Testing laboratory: Environmental Health Laboratory, Lake Superior Research Institute, University of Wisconsin-Superior, Superior, WI 54880, Report no: 68-C1-0034. Owner company; NA, Report date: Mar 24, 1993

Brooke LT 1993: Acute and chronic toxicity of nonylphenol to ten species of aquatic organisms (study report), Testing laboratory: Environmental Health Laboratory, Lake Superior Research Institute, University of Wisconsin-Superior, Superior, WI 54880, Report no: 68-C1-0034. Owner company; NA, Report date: Mar 24, 1993

Bettinetti, R. and Provini, A. 2002: Toxicity of 4-Nonylphenol to Tubifex and Chironomus riparius in 28-day Whole-Sediment Tests (publication), Ecotox. Environ. Saf. Vol 53 113-121. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

Zulkosky, A.M., Ferguson, P.L., McElroy, A.E. 2002: Effects of sewage-impacted sediment on reproduction i the benthic crustacean Leptocheirus plumulosus (publication), Marine Environmental Research 54 615-619. Testing laboratory: NA, Owner company; NA, Study number: NA, Report date:

Quinn, B., Gagne, F., Blaise, C., Costello, M., Wilson, J.G., Mothersill, C. 2006: Evaluation of the lethal and sub-lethal toxicity and potential endocrine disrupting effect of nonlyphenol on the zebra mussel (Dressena polymorpha) (publication), Comparative Biochemistry and Physiology, Part C 142 pp118-127. Testing laboratory: NA, Report no: NA. Owner company; NA, Study number: NA, Report date:

Chan Jin Park, Han Seung Kang, Myung Chan Gye 2010: Effects of nonylphenol on early embryonic development, pigmentation and 3,5,30-triiodothyronine-induced metamorphosis in Bombina orientalis (Amphibia: Anura) (publication), Chemosphere 81 (2010) 1292–1300. Report date: Sep 25, 2010

Johnson I., Weeks J.M. & Kille P. 2005: Endocrine disruption in aquatic and terrestrial invertebrates - Final Report (publication), WRc-NSF Limited. Testing laboratory: WRc-NSF Limited, Report no: UC 4906/6. Owner company; Department of Environment, Food and Rural Affairs (UK Government), Study number: CDEP 84/5/317, Report date:

Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009: Soil pollution by nonylphenol and nonylphenol ethoxylates and their effects to plants and invertebrates (publication), Journal of Soils and Sediments, Vol. 9: 555-567. Testing laboratory: Universitat Autonoma de Barcelona, Report no: No data. Owner company; No data, Study number: No data, Report date:

Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008: Soil pollution by nonylphenol and nonylphenol ethoxylates and their effects to plants and invertebrates (publication), Journal of Soils and Sediments, Vol. 9: 555-567. Testing laboratory: Universitat Autonoma de Barcelona, Report no: No data. Owner company; No data, Study number: No data, Report date:

Jin Il Kwak, Jongmin Moon, Dokyung Kim, Rongxue Cui, and Youn-Joo An 2017: Species Sensitivity Distributions for Nonylphenol to Estimate Soil Hazardous Concentration (publication), Environ. Sci. Technol. 2017, 51, 13957−13966. Report date: Nov 8, 2017

Dorthe Jensen, Mark Bayley, Martin Holmstrup 2009: Synergistic interaction between 4-nonylphenol and high but not low temperatures in Dendrobaena octaedra (publication), Ecotoxicology and Environmental Safety 72 (2009) 10–16. Report date: May 2, 2008

Debra Teixeira 2002: Nonylphenol - Chronic Toxicity and Reproductive Effects to Earthworms (Eisenia fetida) Following Exposure to Dosed Sludge in Artificial Soil (study report), Testing laboratory: Springborn Smithers Laboratories 790 Main Street Wareham, Massachusetts 02571-1075, Report no: Study No. 13752.6100. Owner company; Alkylphenol & Ethoxylates Research Council, Report date: Jun 21, 2002

Scott-Fordsmand J.J., Henning Krogh P. 2004: The influence of application form on the toxicity of nonylphenol to Folsomia fimetaria (Collembola: Isotomidae) (publication), Ecotoxicology and Environmental Safety 58 (2005) pp 294-299. Testing laboratory: Department of Terrestrial Ecology, National Environmental Research Institute, Denmark, Report no: No Data. Owner company; No Data, Study number: No Data, Report date:

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: European Union Risk Assessment Report-4-nonylphenol (branched) and nonylphenol, Volume 10 (study report), Office for Official Publications of the European Communities, 2002. Testing laboratory: No Data, Report no: EUR 20387 EN. Owner company; European Commission, Study number: No Data, Report date:

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: European Union Risk Assessment Report - 4-nonylphenol (branched) and nonylphenol, Volume 10 (study report), Office for Official Publications of the European Communities, 2002. Testing laboratory: No Data, Report no: EUR 20387 EN. Owner company; European Commission, Study number: No Data, Report date:

Widarto T.H., Krogh P.H., Forbes V.E. 2007: Nonylphenol stimulates fecundity but not population growth rate of Folsomia candida (publication), Ecotoxicology and Environmental Safety 67 (2007) pp 369-377. Testing laboratory: Department of Life Sciences and Chemistry, Roskilde University, Denmark and Department of Terrestrial Ecology (TERI), National Environmental Research Institute, Denmark, Report no: No Data. Owner company; No Data, Study number: No Data, Report date:

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: Phytotoxicity Studies with Lactuca sativa in Soil and Nutrient Solution (publication), Environmental Toxicology and Chemistry, Vol. 12, pp. 1079-1094. Testing laboratory: National Institute of Public Health and Environmental Protection (RIVM), The Netherlands, Report no: No Data. Owner company; Dutch Ministry for Housing, Physical Planning and the Environment, Study number: No Data, Report date:

Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2009: Soil pollution by nonylphenol ethoxylates and their effects to plants and invertebrates (publication), Journal of Soils and Sediments, Vol. 9: 555-567. Testing laboratory: Universitat Autonoma de Barcelona, Report no: No data. Owner company; No data, Study number: No data, Report date:

Domene X, Ramirez W, Sola L, Alcaniz J & Andres P. 2008: Soil pollution by nonylphenol ethoxylates and their effects to plants and invertebrates (publication), Journal of Soils and Sediments, Vol. 9: 555-567. Testing laboratory: Universitat Autonoma de Barcelona, Report no: No data. Owner company; No data, Study number: No data, Report date:

Domene X., Ramirez W., Sola L., Alcaniz J. & Andres P. 2008: Soil pollution by nonylphenol ethoxylates and their effects to plants and invertebrates (publication), Journal of Soils and Sediments, Vol. 9: 555-567. Testing laboratory: Universitat Autonoma de Barcelona, Report no: No data. Owner company; No data, Study number: No data, Report date:

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: Phytotoxicity Studies with Lactuca sativa in Soil and Nutrient Solution (publication), Environmental Toxicology and Chemistry, Vol. 12, pp. 1079-1094. Testing laboratory: National Institute of Public Health and Environmental Protection (RIVM), The Netherlands., Report no: No Data. Owner company; Dutch Ministry for Housing, Physical Planning and the Environment, Study number: No Data, Report date:

Trocme M., Tarradellas J. and Vedy J-C. 1988: Biotoxicity and persistence of nonylphenol during incubation in a compost-sandstone mixture (publication), Bio Fertil Soils 5: 299-303. Testing laboratory: Institut de Genie de l'Environnement et Institut de Genie Rural-Pedologie, Report no: No data. Owner company; No data, Study number: No data, Report date:

Diefenbach R 1999: NONYLPHENOL Determination of the inhibition of activated sludge respiration (OECD

209) (study report), Testing laboratory: Hüls Infracor GmbH, Germany, Report no: BH-99/02. Owner company; Sasol Germany GmbH, Study number: 2470, Report date: Sep 10, 1999

Millam JR, Craig-Veit CB, Quaglino AE, Erichson AL, Famula TR and Fry DM. 2001: Posthatch Oral Estrogen Exposure Impairs Adult Reproductive Performance of Zebra Finch in a Sex-Specific Manner (publication), Hormones and Behavior 40, 542-549. Testing laboratory: University of California, Report no: No data. Owner company; No data, Study number: No data, Report date:

Yan Cheng, Zhengjun Shan, Junying Zhou, Yuanqing Bu, Pengfu Li, Shan Lu 2017: Effects of 4-nonylphenol in drinking water on the reproductive capacity of Japanese quails (Coturnix japonica) (publication), Chemosphere 175 (2017) 219e227. Report date: Feb 8, 2017

Annex 2: Information on Test Material

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

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: **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: - Name of test material (as cited in study report): nonylphenol - Analytical purity: technical grade 85-90% - Source: Chem Service (West Chester, PA, USA)

Test material: **para-nonylphenol**
Form:

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

Details on test material: - Name of test material (as cited in study report): para-nonylphenol - Analytical purity: >95% - Lot/batch No.: 103762 - Other: Sourced from Schenectady International (Schenectady, NY)

Test material: **4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5; 4-nonylphenol / 104-40-5 / 203-199-4; para-nonylphenol (4-nonylphenol, PNP)**
Form:

Composition type: Constituent	**Reference substance:** para-nonylphenol (4-nonylphenol, PNP) EC no.: CAS no: IUPAC name: para-nonylphenol (4-nonylphenol, PNP)	**Concentration range:**
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:**
Composition type: Constituent	**Reference substance:** p-nonylphenol EC no.: 203-199-4	**Concentration range:**

	CAS no: 104-40-5 IUPAC name: 4-nonylphenol	

Details on test material: - Name of test material (as cited in study report): para-C9 phenols (CAS 84852-15-3), 4-nonlyphenol, para-nonylphenol, PNP - Analytical purity: 90% para-C9 phenols (CAS 84852-15-3)

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 - Other: obtained from Sigma-Aldrich (USA)

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0; 4-(7-methyloctyl)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:**
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 / para-nonylphenol - CAS: 84852-15-3 - Substance type: para-branched c9-alkylphenols - Analytical purity: >95% - Lot/batch No.: batch IP890218 sample 2380E - Storage condition of test material: in dark at room temperature - Other: Manufacture date Nov 28th, 1989

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 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: **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	**Concentration range:**

	IUPAC name: 4-nonylphenol	

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-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: **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-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: - 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-(7-methyloctyl)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	**Concentration range:**

	CAS no: 104-40-5 IUPAC name: 4-nonylphenol	

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: - 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: - CAS 25154-52-3 - 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: - Name of test material (as cited in study report): Nonylphenol - Substance type: pure active substance - Physical state: liquid - Stability under test conditions: 6 month - Storage condition of test material: not mentioned - Other: none

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

Composition type: Constituent	**Reference substance:** para-nonylphenol EC no.: CAS no: IUPAC name: para-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:**
Composition type: Constituent	**Reference substance:** PNP EC no.: CAS no: IUPAC name: PNP	**Concentration range:**

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol, para-nonylphenol, PNP - Purity: 90% para-C9 phenols (CAS 84852-15-3) used for all tests

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0; 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5**
Form:

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

Composition type:	Reference substance:	Concentration range:
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 - CAS: 84852-15-3 - Purity: >95% - Lot/batch No.: IP890218 - Date of manufacture: November 28, 1989

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: - Name of test material (as cited in study report): nonylphenol - Physical state: dissolved in solvent for test solution - Composition of test material, percentage of components: Characterised as 91.8% nonylphenol, 86.1% 4-nonylphenol. - Isomers composition: mixture of ring isomers and homologues, typical of industrial feedstock - Source: ICI Surfactants, Wilton, Middlesbrough

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: - Name of test material (as cited in study report): nonylphenol

Test material: **4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5; 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:**
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): 4-nonylphenol - CAS 84852-15-3 - Purity: 94% - Source: Riedel-de Haen (Sigma-Aldrich, USA)

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: - Name of test material (as cited in study report): nonylphenol - Physical state: dissolved in solvent - Source: Aldrich Chemical Company Inc. (Tokyo, Japan)

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	**Concentration range:**

	IUPAC name: 4-nonylphenol	

Details on test material: - Name of test material (as cited in study report): 4-nonylphenol - Supplied by Lancaster ltd. Germany.

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

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: - 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: **4-(7-methyloctyl)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**
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: Aldrich Chemical Company Milwaukee, WI - Name of test material (as cited in study report): 4-nonylphenol - Analytical purity:90%

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: **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): 4-Nonylphenol -Source: Fluka Chemical, Ronkonkoma, NY -Purity: not provided

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

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: - 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 - Analytical purity: at least 97% -Source of test material was Sigma Chemical, St. Louis, MO USA

Test material: **2-nonylphenol / 25154-52-3 / 246-672-0; 4-(7-methyloctyl)phenol / 84852-15-3 / 284-325-5**
Form:

Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0 CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	**Concentration range:**
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): para-C9-Nonylphenol -Source: Schenectady International Inc. -Purity: 90%

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

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: - 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-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: - 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; 4-(7-methyloctyl)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:**
Composition type: Constituent	**Reference substance:** nonylphenol EC no.: 246-672-0	**Concentration range:**

	CAS no: 25154-52-3 IUPAC name: 2-nonylphenol	

Details on test material: - Name of test material (as cited in study report): Nonylphenol/para-nonylphenol - CAS: 84852-15-3 - Purity: >95% active ingredient - Lot/batch No.: batch IP890218 sample 2380E - Source: Schenectady Chemicals Inc, Schenectady, New York - Manufacture date: Nov 28, 1989

Test material: **4-(7-methyloctyl)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): para-nonylphenol - Analytical purity: >95% -- Lot/batch No.:IP890218 -Source: Schenectady Chemicals, Inc -Chemical storage: in the dark at room temperature

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: Sigma (Saint Quentin Fallavier, France - Adsorption properties: organic carbon partition (Koc): 3x10^4 or 6 x 10^4 - Analytical purity: 85%

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: - 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: - Read-across: both, CAS 104-40-5 and CAS 84852-15-3 refer to Nonylphenol - Source: Sigma (Saint Quentin Fallavier, France - Adsorption properties: organic carbon partition (Koc): 3x10^4 or 6 x 10^4 - Analytical purity: 85%

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: - Name of test material (as cited in study report): nonylphenol - CAS: 25154-52-3 - Read-across: both, CAS 25154-52-3 and CAS 84852-15-3 refer to Nonylphenol - 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:	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: Sigma-Aldrich, UK -Purity:99% mixture of ring and chain isomers

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: Sigma-Aldrich, UK -Purity: 99% mixed isomers mixture of ring and chain isomers

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

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

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

Test material: **Nonylphenol - Technical Grade**
Form:

Composition type:	Reference substance: Nonylphenol - Technical Grade	Concentration range:
Constituent	EC no.: CAS no: IUPAC name: Nonylphenol - Technical Grade	

Details on test material: - Technical Grade nonylphenol - Supplier: Sigma-Aldrich Company Ltd, Fancy Road, Poole, Dorset, BH17 7NH, UK

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

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

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

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

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

Details on test material: - Technical Grade nonylphenol - Supplier: Sigma-Aldrich Company Ltd., Fancy Road, Poole, Dorset, BH17 7NH, UK.

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

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

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: **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: No Data

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

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

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

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

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: **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: - Name of test material (as cited in study report): Nonylphenol, CAS 25154-52-3 - Substance type: pure active substance - Physical state: liquid - Stability under test conditions: no data - Storage condition of test material: no data - Other: none

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

 Copyright protected – No copying / use allowed

Annex 3: Example technical data sheet from Chemetall

 Copyright protected – No copying / use allowed

Naftoseal® MC-770 Class B Grey

FUSELAGE SEALANT

1 Description

Naftoseal® MC-770 B Grey is a two-component, manganese-dioxide cured polysulfide polymer system with low density providing excellent fuselage seals. It has outstanding resistance to aviation gasoline and jet fuel, as well as resistance to the chemicals and petroleum products used in the aircraft industry.

Naftoseal® MC-770 Class B Grey maintains its flexibility and bond strength on most metal substrates like aluminum, stainless steel, steel, titanium, composite and many coatings under extremes of temperature, weathering and stress.

The mixed compound is a thixotropic paste easily applied by extrusion, injection gun or spatula. It has excellent tooling properties.

Naftoseal® MC-770 Class B Grey can be mixed by MCI-Mixer or by appropriate 2-component mixing and dosing systems.

The curing time may be reduced considerably by increasing the temperature (up to 60 °C / 140 °F max)

2 Field of application

- Sealing fuselages

3 Specifications

Naftoseal® MC-770 Class B Grey fulfills the requirements of the Airbus Specification AIMS 04-05-001.

Application life and cure time at 23°C (73°F) / 50% r.H.			
Type	**Min. Application Time**	**Tack Free Time**	**Time to Shore A 30**
Naftoseal® MC-770 B-2 Grey	2,0 hours	≤ 14 hours	≤ 48 hours

 Copyright protected – No copying / use allowed

BASF We create chemistry | Chemetall expect more

Typical Physical and Application Properties		
	Base	**Hardener**
Colour	Grey	Brown
Viscosity at 23 °C, Brookfield RV, Spindel 7	1.400 ± 300 Pa.s (2 rpm)	200 Pa.s max. (10 rpm)
Mixing ratio by weight	100	10
Mixing ratio by volume	100	6,9
Non-volatile content	≥ 97%	

Typical Values of MC-770 Class B after 14 days at 23 °C (73 °F) / 50 % r.h.	
Colour	Grey
Specific gravitiy	1,1 g/ccm
Ultimate Shore A Hardness	Ca. 50
Service temperature	-55 °C (-67 °F)/ +130 °C (+266 °F)
Tensile Strength	≥ 1,8 N/mm²
Elongation	Ca. 300 %
Peel Strength on Aluminum, Epoxy Primer, Top Coat and other Substrates	≥ 140 N/25mm

Mixing Instruction for Techkits			
Naftoseal® MC-770 B	Motor revolution in rpm	Strokes up and down	Mixing Time
	110 ± 10	90	2 Min ± 1 Min

4 Surface preparation

To obtain good adhesion, clean surfaces with appropriate cleaners (e.g. Chemetall's Ardrox® products like Ardrox® 5529 or Ardrox® 5575) to remove dirt, grease and processing oils just prior to sealant application. Use lint-free rags or paper towels that are free of oil. Always pour cleaner on the cloth to avoid contamination of the cleaner supply. Clean one small area at a time, quickly wiping it dry before the cleaner's solvent evaporates to prevent redeposition of oil, wax or other contaminants. PUR and EP topcoats as well as composite components should be pre-treated by the Naftoseal® MC-110 Adhesion Promoter.

 Copyright protected – No copying / use allowed

5 Packaging

Designation	Base Compund Content/Pierce	No. / Case
Techkit 55	58 ccm	24
Techkit 130	137 ccm	24
Kit 25	263 ccm	12
Kit 100	1050 ccm	4

6 Storage

The shelf life of Naftoseal® MC-770 Class B Grey is 6 months from date of manufacture, when stored at temperatures below 26 °C in its original unopened container. Storage at lower temperatures increases shelf life.

7 Health and safety precautions

See Safety Data Sheet.

The above details have been compiled to the best of our knowledge on the basis of tests and research work and with regard to the current state of our practical experience. This technical product information is non-binding. No liabilities or guarantees deriving from or in connection with this leaflet can be imputed to us. Statements relating to possible uses of the product do not constitute a guarantee that such uses are appropriate in a particular user's case or that such uses do not infringe the patents or proprietary rights of any third party. The reproduction of any or all of the information contained in this leaflet is expressly forbidden without Chemetall's prior written consent.

Headquarters and Regional Head Office
Europe, Middle East, Africa, South America
Chemetall GmbH
Trakehner Straße 3
60487 Frankfurt am Main, Germany
Tel: +49 (0) 69 7165-0

Regional Head Office
North America
Chemetall US, Inc.
675 Central Avenue
New Providence, NJ 07974, USA
Tel: +1-908-464-6900

Regional Head Office
Asia-Pacific
Chemetall Asia Pte Ltd.
12 Loyang Crescent
Singapore 508980
Tel: +65 6885 7900

www.chemetall.com | surfacetreatment@basf.com

© 2018 Chemetall GmbH, Frankfurt am Main, Germany

Annex 4: Retraining Certification from Chemetall

BASF We create chemistry / Chemetall expect more	**Ausbildungs-/ Schulungsnachweis Teilnehmerliste**	

Art der Veranstaltung:	**Jährliche Unterweisung Gefahrstoffe und Betriebsanweisungen §14 GefStoffV Produktion Aerospace – Stand 10.10.2022**
angesprochener Personenkreis / Betrieb / Ressort:	**Alle Mitarbeiter LOA**
Tag der Veranstaltung:	**22.11.2022**
Zeit:/ Zeitdauer:	10^{00} – 11^{50} / 110 min
Referent:	**S. Niitväli**

Inhalte: **Gefahrstoffunterweisung (Präsentation vom 10.10.2022)**

Im Rahmen der Schulung wurde die Wirksamkeit mit 10 **Fragen geprüft.**

Ergebnis:
- [x] **positiv**
- [ ] **negativ**
- [ ] **Nachschulungen erforderlich**

Ich habe den Inhalt der Schulung verstanden und werde die Regelungen beachten und den Inhalt entsprechend anwenden.

Nr.	Teilnehmer, Name	Unterschrift	Pers. Nr.	Abteilung
1	Schlein		963089	G-ECT/LOAF
2	Könnemund		963170	G-ECT/LOAF
3	Hildebrandt		963145	G-ECT/LOAF
4	Seferovic		963172	G-ECT/LOAF
5	Ahrends		840214	G-ECT/LOAF
6	Arnecke		963063	G-ECT/LOAL
7	Basgüner		963027	G-ECT/LOAL
8	Chromik		963114	G-ECT/LOAL
9	Hoim		963115	G-ECT/LOAL
10	Neumann		794345	G-ECT/LOAL
11	Uffel		963071	G-ECT/LOAL
12				

Dokumenten-Nr.: FFM_C-00_00007, Version: 7, Gültig ab: 17.02.20

Internal

Annex 5: EUSES Modelling Outputs

DEFAULTS

DEFAULT IDENTIFICATION

General name	Standard Euses 2.1		D
Description	According to TGDs		D

CHARACTERISTICS OF COMPARTMENTS

GENERAL

Density of solid phase	2.5	[kg.l-1]	D
Density of water phase	1	[kg.l-1]	D
Density of air phase	1.3E-03	[kg.l-1]	D
Environmental temperature	12	[oC]	D
Standard temperature for Vp and Sol	25	[oC]	D
Temperature correction method distribution	Temperature correction for local D		
Constant of Junge equation	0.01	[Pa.m]	D
Surface area of aerosol particles	0.01	[m2.m-3]	D
Gas constant (8.314)	8.314 [Pa.m3.mol-1.K-1]	D	

SUSPENDED MATTER

Volume fraction solids in suspended matter	0.1	[m3.m-3]	D
Volume fraction water in suspended matter	0.9	[m3.m-3]	D
Weight fraction of organic carbon in suspended matter	0.1	[kg.kg-1]	D
Bulk density of suspended matter 3]	1.15E+03 O	[kgwwt.m-	
Conversion factor wet-dry suspened matter	4.6 [kgwwt.kgdwt-1]	O	

SEDIMENT

Volume fraction solids in sediment	0.2	[m3.m-3]	D
Volume fraction water in sediment	0.8	[m3.m-3]	D
Weight fraction of organic carbon in sediment	0.05	[kg.kg-1]	D

 Copyright protected – No copying / use allowed

SOIL

Volume fraction solids in soil	0.6	[m3.m-3] D
Volume fraction water in soil	0.2	[m3.m-3] D
Volume fraction air in soil	0.2	[m3.m-3] D
Weight fraction of organic carbon in soil	0.02	[kg.kg-1] D
Weight fraction of organic matter in soil	0.034	[kg.kg-1] O
Bulk density of soil 3]	1.7E+03 O	[kgwwt.m-
Conversion factor wet-dry soil	1.13 [kgwwt.kgdwt-1]	O

STP SLUDGE

Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1] D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1] D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1] D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1] D

DEGRADATION AND TRANSFORMATION RATES

Rate constant for abiotic degradation in STP	0	[d-1] D
Rate constant for abiotic degradation in bulk sediment (12[oC])	0 D	[d-1]
Rate constant for anaerobic biodegradation in sediment (12[oC])	0 D	[d-1]
Fraction of sediment compartment that is aerated	0.1	[m3.m-3] D
Concentration of OH-radicals in atmosphere 3]	5E+05 D	[molec.cm-
Rate constant for abiotic degradation in bulk soil (12[oC])	0 D	[d-1]

RELEASE ESTIMATION

Fraction of EU production volume for region	100	[%] D
Fraction of EU tonnage for region (private use)	10	[%] D
Fraction connected to sewer systems	80	[%] D

SEWAGE TREATMENT

GENERAL

Number of inhabitants feeding one STP	1E+04	[eq]	D
Sewage flow	200 D	[l.eq-1.d-1]	
Effluent discharge rate of local STP	2E+06	[l.d-1]	O
Temperature correction for STP degradation	No		D
Temperature of air above aeration tank	15	[oC]	D
Temperature of water in aeration tank	15	[oC]	D
Height of air column above STP	10	[m]	D
Number of inhabitants of region	2E+07	[eq]	D
Number of inhabitants of continental system	3.5E+08	[eq]	O
Windspeed in the system	3	[m.s-1]	D

RAW SEWAGE

Mass of O2 binding material per person per day 1]	54 D	[g.eq-1.d-	
Dry weight solids produced per person per day 1]	0.09 D	[kg.eq-1.d-	
Density solids in raw sewage	1.5	[kg.l-1]	D
Fraction of organic carbon in raw sewage sludge	0.3	[kg.kg-1]	D

PRIMARY SETTLER

Depth of primary settler	4	[m]	D
Hydraulic retention time of primary settler	2	[hr]	D
Density suspended and settled solids in primary settler	1.5	[kg.l-1]	D
Fraction of organic carbon in settled sewage sludge	0.3	[kg.kg-1]	D

 Copyright protected – No copying / use allowed

ACTIVATED SLUDGE TANK

Depth of aeration tank	3	[m]	D
Density solids of activated sludge	1.3	[kg.l-1]	D
Concentration solids of activated sludge	4	[kg.m-3]	D
Steady state O2 concentration in activated sludge	2E-03	[kg.m-3]	D
Mode of aeration	Surface		D
Aeration rate of bubble aeration	1.31E-05	[m3.s-1.eq-1]	D
Fraction of organic carbon in activated sewage sludge	0.37	[kg.kg-1]	D
Sludge loading rate	0.15	[kg.kg-1.d-1]	D
Hydraulic retention time in aerator (9-box STP)	6.9	[hr]	O
Hydraulic retention time in aerator (6-box STP)	10.8	[hr]	O
Sludge retention time of aeration tank	9.2	[d]	O

SOLIDS-LIQUIDS SEPARATOR

Depth of solids-liquid separator	3	[m]	D
Density suspended and settled solids in solids-liquid separator	1.3	[kg.l-1]	D
Concentration solids in effluent	30	[mg.l-1]	D
Hydraulic retention time of solids-liquid separator	6	[hr]	D
Fraction of organic carbon in effluent sewage sludge	0.37	[kg.kg-1]	D

LOCAL DISTRIBUTION

AIR AND SURFACE WATER

Concentration in air at source strength 1 [kg.d-1]	2.78E-04	[mg.m-3]	D
Standard deposition flux of aerosol-bound compounds	0.01	[mg.m-2.d-1]	D
Standard deposition flux of gaseous compounds	4E-04	[mg.m-2.d-1]	O
Suspended solids concentration in STP effluent water	15	[mg.l-1]	D
Dilution factor (rivers)	10	[-]	D
Flow rate of the river	1.8E+04	[m3.d-1]	D
Calculate dilution from river flow rate	No		D
Dilution factor (coastal areas)	100	[-]	D

SOIL

Mixing depth of grassland soil	0.1	[m]	D
Dry sludge application rate on agricultural soil 1.yr-1]	5E+03 D	[kg.ha-	
Dry sludge application rate on grassland 1.yr-1]	1000 D	[kg.ha-	
Averaging time soil (for terrestrial ecosystem)	30	[d]	D
Averaging time agricultural soil	180	[d]	D
Averaging time grassland	180	[d]	D
PMTC, air side of air-soil interface	1.05E-03	[m.s-1]	O
Soil-air PMTC (air-soil interface)	5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)	5.56E-10	[m.s-1]	D
Mixing depth agricultural soil	0.2	[m]	D
Fraction of rain water infiltrating soil	0.25	[-]	D
Average annual precipitation	700	[mm.yr-1]	D

REGIONAL AND CONTINENTAL DISTRIBUTION

CONFIGURATION

Fraction of direct regional emissions to seawater	1	[%]	D
Fraction of direct continental emissions to seawater	0	[%]	D
Fraction of regional STP effluent to seawater	0	[%]	D
Fraction of continental STP effluent to seawater	0	[%]	D
Fraction of flow from continental rivers to regional rivers	0.034	[-]	D
Fraction of flow from continental rivers to regional sea	0	[-]	D
Fraction of flow from continental rivers to continental sea	0.966	[-]	O
Number of inhabitants of region	2E+07	[eq]	D
Number of inhabitants in the EU	3.7E+08	[eq]	D
Number of inhabitants of continental system	3.5E+08	[eq]	O

 Copyright protected – No copying / use allowed

AREAS

REGIONAL

Area (land+rivers) of regional system	4E+04	[km2]	D
Area fraction of freshwater, region (excl. sea)	0.03	[-]	D
Area fraction of natural soil, region (excl. sea)	0.27	[-]	D
Area fraction of agricultural soil, region (excl. sea)	0.6	[-]	D
Area fraction of industrial/urban soil, region (excl. sea)	0.1	[-]	D
Length of regional seawater	40	[km]	D
Width of regional seawater	10	[km]	D
Area of regional seawater	400	[km2]	O
Area (land+rivers+sea) of regional system	4.04E+04	[km2]	O
Area fraction of freshwater, region (total)	0.0297	[-]	O
Area fraction of seawater, region (total)	9.9E-03	[-]	O
Area fraction of natural soil, region (total)	0.267	[-]	O
Area fraction of agricultural soil, region (total)	0.594	[-]	O
Area fraction of industrial/urban soil, region (total)	0.099	[-]	O

CONTINENTAL

Total area of EU (continent+region, incl. sea)	7.04E+06	[km2]	D
Area (land+rivers+sea) of continental system	7E+06	[km2]	O
Area (land+rivers) of continental system	3.5E+06	[km2]	O
Area fraction of freshwater, continent (excl. sea)	0.03	[-]	D
Area fraction of natural soil, continent (excl. sea)	0.27	[-]	D
Area fraction of agricultural soil, continent (excl. sea)	0.6	[-]	D
Area fraction of industrial/urban soil, continent (excl. sea)	0.1	[-]	D
Area fraction of freshwater, continent (total)	0.015	[-]	O
Area fraction of seawater, continent (total)	0.5	[-]	D
Area fraction of natural soil, continent (total)	0.135	[-]	O
Area fraction of agricultural soil, continent (total)	0.3	[-]	O
Area fraction of industrial/urban soil, continent (total)	0.05	[-]	O

MODERATE

Area of moderate system (incl.continent,region)	8.5E+07	[km2]	D
Area of moderate system (excl.continent, region)	7.8E+07	[km2]	O
Area fraction of water, moderate system	0.5	[-]	D

 Copyright protected – No copying / use allowed

ARCTIC

Area of arctic system	4.25E+07	[km2]	D
Area fraction of water, arctic system	0.6	[-]	D

TROPIC

Area of tropic system	1.275E+08	[km2]	D
Area fraction of water, tropic system	0.7	[-]	D

TEMPERATURE

Environmental temperature, regional scale	12	[oC]	D
Environmental temperature, continental scale	12	[oC]	D
Environmental temperature, moderate scale	12	[oC]	D
Environmental temperature, arctic scale	-10	[oC]	D
Environmental temperature, tropic scale	25	[oC]	D
Enthalpy of vaporisation	50 D	[kJ.mol-1]	
Enthalpy of solution	10 D	[kJ.mol-1]	

MASS TRANSFER

Air-film PMTC (air-water interface)	3.89E-03	[m.s-1]	O
Water-film PMTC (air-water interface)	4.69E-06	[m.s-1]	O
PMTC, air side of air-soil interface	1.05E-03	[m.s-1]	O
PMTC, soil side of air-soil interface	2.43E-10	[m.s-1]	O
Soil-air PMTC (air-soil interface)	5.56E-06	[m.s-1]	D
Soil-water film PMTC (air-soil interface)	5.56E-10	[m.s-1]	D
Water-film PMTC (sediment-water interface)	2.78E-06	[m.s-1]	D
Pore water PMTC (sediment-water interface)	2.78E-08	[m.s-1]	D

AIR

GENERAL

Atmospheric mixing height	1000	[m]	D
Windspeed in the system	3	[m.s-1]	D
Aerosol deposition velocity	1E-03	[m.s-1]	D
Aerosol collection efficiency	2E+05	[-]	D

 Copyright protected – No copying / use allowed

RAIN			
Average precipitation, regional system	700	[mm.yr-1]D	
Average precipitation, continental system	700	[mm.yr-1]D	
Average precipitation, moderate system	700	[mm.yr-1]D	
Average precipitation, arctic system	250	[mm.yr-1]D	
Average precipitation, tropic system	1.3E+03	[mm.yr-1]D	
RESIDENCE TIMES			
Residence time of air, regional	0.687	[d]	O
Residence time of air, continental	9.05	[d]	O
Residence time of air, moderate	30.2	[d]	O
Residence time of air, arctic	22.3	[d]	O
Residence time of air, tropic	38.6	[d]	O
WATER			
DEPTH			
Water depth of freshwater, regional system	3	[m]	D
Water depth of seawater, regional system	10	[m]	D
Water depth of freshwater, continental system	3	[m]	D
Water depth of seawater, continental system	200	[m]	D
Water depth, moderate system	1000	[m]	D
Water depth, arctic system	1000	[m]	D
Water depth, tropic system	1000	[m]	D
SUSPENDED SOLIDS			
Suspended solids conc. freshwater, regional	15	[mg.l-1]	D
Suspended solids conc. seawater, regional	5	[mg.l-1]	D
Suspended solids conc. freshwater, continental	15	[mg.l-1]	D
Suspended solids conc. seawater, continental	5	[mg.l-1]	D
Suspended solids conc. seawater, moderate	5	[mg.l-1]	D
Suspended solids conc. seawater, arctic	5	[mg.l-1]	D
Suspended solids conc. seawater, tropic	5	[mg.l-1]	D
Concentration solids in effluent, regional	30	[mg.l-1]	D
Concentration solids in effluent, continental	30	[mg.l-1]	D
Concentration biota 1]	1 D	[mgwwt.l-	

 Copyright protected – No copying / use allowed

RESIDENCE TIMES

Residence time of freshwater, regional	43.3	[d]	O
Residence time of seawater, regional	4.64	[d]	O
Residence time of freshwater, continental	172	[d]	O
Residence time of seawater, continental	365	[d]	O
Residence time of water, moderate	2.69E+03	[d]	O
Residence time of water, arctic	5.84E+03	[d]	O
Residence time of water, tropic	1.09E+04	[d]	O

SEDIMENT

DEPTH

Sediment mixing depth	0.03	[m]	D

SUSPENDED SOLIDS

(Biogenic) prod. susp. solids in freshwater, reg	10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in seawater, reg	10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in freshwater, cont	10	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in seawater, cont	5	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, moderate	1	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, arctic	1	[g.m-2.yr-1]	D
(Biogenic) prod. susp. solids in water, tropic	1	[g.m-2.yr-1]	D

SEDIMENTATION RATES

Settling velocity of suspended solids	2.5	[m.d-1]	D
Net sedimentation rate, freshwater, regional	2.8	[mm.yr-1]	O
Net sedimentation rate, seawater, regional	1.53	[mm.yr-1]	O
Net sedimentation rate, freshwater, continental	2.75	[mm.yr-1]	O
Net sedimentation rate, seawater, continental	6.69E-03	[mm.yr-1]	O
Net sedimentation rate, moderate	2.8E-03	[mm.yr-1]	O
Net sedimentation rate, arctic	2E-03	[mm.yr-1]	O
Net sedimentation rate, tropic	2E-03	[mm.yr-1]	O

SOIL

GENERAL

Fraction of rain water infiltrating soil	0.25	[-]	D
Fraction of rain water running off soil	0.25	[-]	D

DEPTH

Chemical-dependent soil depth	No		D
Mixing depth natural soil	0.05	[m]	D
Mixing depth agricultural soil	0.2	[m]	D
Mixing depth industrial/urban soil	0.05	[m]	D
Mixing depth of soil, moderate system	0.05	[m]	D
Mixing depth of soil, arctic system	0.05	[m]	D
Mixing depth of soil, tropic system	0.05	[m]	D

EROSION

Soil erosion rate, regional system	0.03	[mm.yr-1]	D
Soil erosion rate, continental system	0.03	[mm.yr-1]	D
Soil erosion rate, moderate system	0.03	[mm.yr-1]	D
Soil erosion rate, arctic system	0.03	[mm.yr-1]	D
Soil erosion rate, tropic system	0.03	[mm.yr-1]	D

CHARACTERISTICS OF PLANTS, WORMS AND CATTLE

PLANTS

Volume fraction of water in plant tissue	0.65	[m3.m-3]	D
Volume fraction of lipids in plant tissue	0.01	[m3.m-3]	D
Volume fraction of air in plant tissue	0.3	[m3.m-3]	D
Correction for differences between plant lipids and octanol	0.95	[-]	D
Bulk density of plant tissue (wet weight)	0.7	[kg.l-1]	D
Rate constant for metabolism in plants	0	[d-1]	D
Rate constant for photolysis in plants	0	[d-1]	D
Leaf surface area	5	[m2]	D
Conductance	1E-03	[m.s-1]	D
Shoot volume	2	[l]	D
Rate constant for dilution by growth	0.035	[d-1]	D
Transpiration stream	1	[l.d-1]	D

 Copyright protected – No copying / use allowed

WORMS

Volume fraction of water inside a worm	0.84	[m3.m-3]	D
Volume fraction of lipids inside a worm	0.012	[m3.m-3]	D
Density of earthworms	1	[kgwwt.l-1]	D
Fraction of gut loading in worm	0.1	[kg.kg-1]	D

CATTLE

Daily intake for cattle of grass (dryweight)	16.9	[kg.d-1]	D
Conversion factor grass from dryweight to wetweight	4	[kg.kg-1]	D
Daily intake of soil (dryweight)	0.41	[kg.d-1]	D
Daily inhalation rate for cattle	122	[m3.d-1]	D
Daily intake of drinking water for cattle	55	[l.d-1]	D

CHARACTERISTICS OF HUMANS

Daily intake of drinking water	2	[l.d-1]	D
Daily intake of fish	0.115	[kg.d-1]	D
Daily intake of leaf crops (incl. fruit and cereals)	1.2	[kg.d-1]	D
Daily intake of root crops	0.384	[kg.d-1]	D
Daily intake of meat	0.301	[kg.d-1]	D
Daily intake of dairy products	0.561	[kg.d-1]	D
Inhalation rate for humans (consumers, environment)	0.833333	[m3.hr-1]	D
Inhalation rate for humans (worker exposure)	1.5	[m3.hr-1]	D
Bodyweight of the human considered	70	[kg]	D
Correction factor for duration and frequency of exposure	2.8	[-]	D

SUBSTANCE

SUBSTANCE IDENTIFICATION

General name	NPE		S
Description	Nonylphenol Ethoxylates		S
CAS-No			D
EC-notification no.			D
EINECS no.			D

PHYSICO-CHEMICAL PROPERTIES

Molecular weight	220.351	[g.mol-1]	S
Melting point	7	[oC]	S
Boiling point	302	[oC]	S
Vapour pressure at test temperature	0.3	[Pa]	S
Temperature at which vapour pressure was measured	25	[oC]	S
Vapour pressure at 25 [oC]	0.3	[Pa]	O
Octanol-water partition coefficient	5.4	[log10]	S
Water solubility at test temperature	5.7	[mg.l-1]	S
Temperature at which solubility was measured	25	[oC]	D
Water solubility at 25 [oC]	5.7	[mg.l-1]	O

PARTITION COEFFICIENTS AND BIOCONCENTRATION FACTORS

SOLIDS-WATER

Chemical class for Koc-QSAR	Non-hydrophobics (default QSAR)		D
Organic carbon-water partition coefficient	6.73E+03	[l.kg-1]	O
Solids-water partition coefficient in soil	135	[l.kg-1]	O
Solids-water partition coefficient in sediment	336	[l.kg-1]	O
Solids-water partition coefficient suspended matter	673	[l.kg-1]	O
Solids-water partition coefficient in raw sewage sludge	2.02E+03	[l.kg-1]	O
Solids-water partition coefficient in settled sewage sludge	2.02E+03	[l.kg-1]	O
Solids-water partition coefficient in activated sewage sludge	2.49E+03	[l.kg-1]	O
Solids-water partition coefficient in effluent sewage sludge	2.49E+03	[l.kg-1]	O
Soil-water partition coefficient	202	[m3.m-3]	O
Suspended matter-water partition coefficient	169	[m3.m-3]	O
Sediment-water partition coefficient	169	[m3.m-3]	O

 Copyright protected – No copying / use allowed

AIR-WATER

Environmental temperature	12	[oC]	D
Water solubility at environmental temperature	4.74	[mg.l-1]	O
Vapour pressure at environmental temperature	0.119	[Pa]	O
Sub-cooled liquid vapour pressure	0.119	[Pa]	O
Fraction of chemical associated with aerosol particles	8.36E-04	[-]	O
Henry's law constant at test temparature	?? [Pa.m3.mol-1]	D	
Temperature at which Henry's law constant was measured	25	[oC]	D
Henry's law constant at 25 [oC]	11.6 [Pa.m3.mol-1]	O	
Henry's law constant at enviromental temparature	5.55 [Pa.m3.mol-1]	O	
Air-water partitioning coefficient	2.34E-03	[m3.m-3]	O

BIOCONCENTRATION FACTORS

PREDATOR EXPOSURE

Bioconcentration factor for earthworms	3.02E+03 O	[l.kgwwt-1]	

HUMAN AND PREDATOR EXPOSURE

Bioconcentration factor for fish	7.76E+03 O	[l.kgwwt-1]	
QSAR valid for calculation of BCF-Fish	Yes		O
Biomagnification factor in fish	10	[-]	O
Biomagnification factor in predator	10	[-]	O

HUMAN EXPOSURE

Partition coefficient between leaves and air	5.76E+05	[m3.m-3]	O
Partition coefficient between plant tissue and water	1.35E+03	[m3.m-3]	O
Transpiration-stream concentration factor	0.0378	[-]	O
Bioaccumulation factor for meat	6.31E-03	[d.kg-1]	O
Bioaccumulation factor for milk	2E-03	[d.kg-1]	O
Purification factor for surface water	0.25	[-]	O

BIOTA-WATER

FOR REGIONAL/CONTINENTAL DISTRIBUTION

Bioconcentration factor for aquatic biota	7.76E+03 O	[l.kgwwt-1]	

 Copyright protected – No copying / use allowed

DEGRADATION AND TRANSFORMATION RATES

CHARACTARIZATION

Characterization of biodegradability	Inherently biodegr., fulfilling criteria		S

STP

Degradation calculation method in STP	First order, standard OECD/EU tests		D
Rate constant for biodegradation in STP	2.4	[d-1]	O
Total rate constant for degradation in STP	2.4	[d-1]	O
Maximum growth rate of specific microorganisms	2	[d-1]	D
Half saturation concentration	0.5	[g.m-3]	D

WATER/SEDIMENT

WATER

Rate constant for hydrolysis in surface water (12[oC])	6.93E-07 O	[d-1]	
Rate constant for photolysis in surface water	6.93E-07	[d-1]	O
Rate constant for biodegradation in surface water (12[oC])	4.62E-03 O	[d-1]	
Total rate constant for degradation in bulk surface water (12[oC])	4.62E-03 O	[d-1]	
Rate constant for biodegradation in saltwater (12[oC])	0 O	[d-1]	
Total rate constant for degradation in bulk saltwater (12[oC])	1.39E-06 O	[d-1]	

SEDIMENT

Rate constant for biodegradation in aerated sediment (12[oC])	2.31E-04 O	[d-1]	
Total rate constant for degradation in bulk sediment (12[oC])	2.31E-05 O	[d-1]	

AIR

Specific degradation rate constant with OH-radicals	0 [cm3.molec-1.s-1]	D	
Rate constant for degradation in air	0	[d-1]	O

SOIL

Rate constant for biodegradation in bu k soil (12[oC])	2.31E-04 O	[d-1]	
Total rate constant for degradation in bulk soil (12[oC])	2.31E-04 O	[d-1]	

Copyright protected – No copying / use allowed

REMOVAL RATE CONSTANTS SOIL

Total rate constant for degradation in bulk soil (12[oC])	2.31E-04 O	[d-1]	
Rate constant for volatilisation from agricultural soil	1.03E-04	[d-1]	O
Rate constant for leaching from agricultural soil	1.19E-05	[d-1]	O
Total rate constant for removal from agricultural top soil	3.46E-04	[d-1]	O
Rate constant for volatilisation from grassland soil	2.05E-04	[d-1]	O
Rate constant for leaching from grassland soil	2.37E-05	[d-1]	O
Total rate constant for removal from grassland top soil	4.6E-04	[d-1]	O
Rate constant for volatilisation from industrial soil	4.11E-04	[d-1]	O
Rate constant for leaching from industrial soil	4.75E-05	[d-1]	O
Total rate constant for removal from industrial soil	6.89E-04	[d-1]	O

 Copyright protected – No copying / use allowed

RELEASE ESTIMATION

CHARACTERIZATION AND TONNAGE

High Production Volume Chemical	No		D
Production volume of chemical in EU	350	[tonnes.yr-1]	S
Fraction of EU production volume for region	100	[%]	D
Regional production volume of substance	350	[tonnes.yr-1]	O
Continental production volume of substance	0	[tonnes.yr-1]	O
Volume of chemical imported to EU	0	[tonnes.yr-1]	D
Volume of chemical exported from EU	0	[tonnes.yr-1]	D
Tonnage of substance in Europe	350	[tonnes.yr-1]	O

USE PATTERNS

PRODUCTION STEPS

EMISSION INPUT DATA

Usage/production title	Formulation of NPE containing sealant hardener		S
Industry category	2 Chemical industry: basic chemicals		S
Use category	55/0 Others		S
Extra details on use category	No extra details necessary		D
Extra details on use category	No extra details necessary		D
Main category production	III Multi-purpose equipment		S
Use specific emission scenario	No		D
Emission scenario	no special scenario selected/available		S
Fraction of tonnage for application	1	[-]	O
Total of fractions for all production steps	1	[-]	O
Relevant production volume for usage	350	[tonnes.yr-1]	O
Regional production volume of substance	350	[tonnes.yr-1]	O
Regional production volume for usage	350	[tonnes.yr-1]	O

OTHER LIFE CYCLE STEPS

Total of fractions for all applications	1	[-]	O

INTERMEDIATE RESULTS

INTERMEDIATE

RELEASE FRACTIONS AND EMISSION DAYS

PRODUCTION

Emission tables table)	A1.1 (general table), B1.1 (general S		

RELEASE FRACTIONS

Fraction of tonnage released to air	0	[-]	S
Fraction of tonnage released to wastewater	0	[-]	S
Fraction of tonnage released to surface water	0	[-]	O
Fraction of tonnage released to industrial soil	0	[-]	S
Fraction of tonnage released to agricultural soil	0	[-]	O
Emission fractions determined by special scenario	No		O

EMISSION DAYS

Fraction of the main local source	1	[-]	O
Number of emission days per year	264	[-]	S
Release to wastewater only	No		D
Emission days determined by special scenario	No		O

REGIONAL AND CONTINENTAL RELEASES

PRODUCTION

REGIONAL

Regional release to air	0	[kg.d-1]	O
Regional release to wastewater	0	[kg.d-1]	O
Regional release to surface water	0	[kg.d-1]	O
Regional release to industrial soil	0	[kg.d-1]	O
Regional release to agricultural soil	0	[kg.d-1]	O

CONTINENTAL

Continental release to air	0	[kg.d-1]	O
Continental release to wastewater	0	[kg.d-1]	O
Continental release to surface water	0	[kg.d-1]	O
Continental release to industrial soil	0	[kg.d-1]	O
Continental release to agricultural soil	0	[kg.d-1]	O

 Copyright protected – No copying / use allowed

REGIONAL AND CONTINENTAL TOTAL EMISSIONS

Total regional emission to air	0	[kg.d-1]	O
Total regional emission to wastewater	0	[kg.d-1]	O
Total regional emission to surface water	0	[kg.d-1]	O
Total regional emission to industrial soil	0	[kg.d-1]	O
Total regional emission to agricultural soil	0	[kg.d-1]	O
Total continental emission to air	0	[kg.d-1]	O
Total continental emission to wastewater	0	[kg.d-1]	O
Total continental emission to surface water	0	[kg.d-1]	O
Total continental emission to industrial soil	0	[kg.d-1]	O
Total continental emission to agricultural soil	0	[kg.d-1]	O

LOCAL

[PRODUCTION]

Local emission to air during episode	0	[kg.d-1]	O
Emission to air calculated by special scenario	No		O
Local emission to wastewater during episode	0	[kg.d-1]	O
Emission to water calculated by special scenario	No		O
Show this step in further calculations	Yes		O
Intermittent release	No		D

 Copyright protected – No copying / use allowed

DISTRIBUTION

SEWAGE TREATMENT

CONTINENTAL

Fraction of emission directed to air	0	[%]	O
Fraction of emission directed to water	0	[%]	O
Fraction of emission directed to sludge	0	[%]	O
Fraction of the emission degraded	0	[%]	O
Total of fractions	0	[%]	O
Indirect emission to air	0	[kg.d-1]	O
Indirect emission to surface water	0	[kg.d-1]	O
Indirect emission to agricultural soil	0	[kg.d-1]	O

REGIONAL

Fraction of emission directed to air	0	[%]	O
Fraction of emission directed to water	0	[%]	O
Fraction of emission directed to sludge	0	[%]	O
Fraction of the emission degraded	0	[%]	O
Total of fractions	0	[%]	O
Indirect emission to air	0	[kg.d-1]	O
Indirect emission to surface water	0	[kg.d-1]	O
Indirect emission to agricultural soil	0	[kg.d-1]	O

LOCAL

[PRODUCTION]

INPUT AND CONFIGURATION [PRODUCTION]

INPUT

Use or bypass STP (local freshwater assessment)	Use STP		D
Use or bypass STP (local marine assessment)	Bypass STP		D
Local emission to wastewater during episode	0	[kg.d-1]	O
Concentration in untreated wastewater	0	[mg.l-1]	O
Local emission entering the STP	0	[kg.d-1]	O

 Copyright protected – No copying / use allowed

CONFIGURATION

Type of local STP	With primary settler (9-box)		D
Number of inhabitants feeding this STP	1E+04	[eq]	O
Effluent discharge rate of this STP	2E+06	[l.d-1]	O
Calculate dilution from river flow rate	No		O
Flow rate of the river	1.8E+04	[m3.d-1]	O
Dilution factor (rivers)	10	[-]	O
Dilution factor (coastal areas)	100	[-]	O

OUTPUT [PRODUCTION]

Fraction of emission directed to air by STP	0	[%]	O
Fraction of emission directed to water by STP	0	[%]	O
Fraction of emission directed to sludge by STP	0	[%]	O
Fraction of the emission degraded in STP	0	[%]	O
Total of fractions	0	[%]	O
Local indirect emission to air from STP during episode	0	[kg.d-1]	O
Concentration in untreated wastewater	0	[mg.l-1]	O
Concentration of chemical (total) in the STP-effluent	0	[mg.l-1]	O
Concentration in effluent exceeds solubility	No		O
Concentration in dry sewage sludge	0	[mg.kg-1]	O
PEC for micro-organisms in the STP	0	[mg.l-1]	O

 Copyright protected – No copying / use allowed

REGIONAL, CONTINENTAL AND GLOBAL DISTRIBUTION

PECS

REGIONAL

Regional PEC in surface water (total)	0	[mg.l-1]	O
Regional PEC in seawater (total)	0	[mg.l-1]	O
Regional PEC in surface water (dissolved)	0	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Regional PEC in seawater (dissolved)	0	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Regional PEC in air (total)	0	[mg.m-3]	O
Regional PEC in agricultural soil (total)	0 [mg.kgwwt-1]	O	
Regional PEC in pore water of agricultural soils	0	[mg.l-1]	O
Regional PEC in natural soil (total)	0 [mg.kgwwt-1]	O	
Regional PEC in industrial soil (total)	0 [mg.kgwwt-1]	O	
Regional PEC in sediment (total)	0 [mg.kgwwt-1]	O	
Regional PEC in seawater sediment (total)	0 [mg.kgwwt-1]	O	

CONTINENTAL

Continental PEC in surface water (total)	0	[mg.l-1]	O
Continental PEC in seawater (total)	0	[mg.l-1]	O
Continental PEC in surface water (dissolved)	0	[mg.l-1]	O
Continental PEC in seawater (dissolved)	0	[mg.l-1]	O
Continental PEC in air (total)	0	[mg.m-3]	O
Continental PEC in agricultural soil (total)	0 [mg.kgwwt-1]	O	
Continental PEC in pore water of agricultural soils	0	[mg.l-1]	O
Continental PEC in natural soil (total)	0 [mg.kgwwt-1]	O	
Continental PEC in industrial soil (total)	0 [mg.kgwwt-1]	O	
Continental PEC in sediment (total)	0 [mg.kgwwt-1]	O	
Continental PEC in seawater sediment (total)	0 [mg.kgwwt-1]	O	

GLOBAL: MODERATE

Moderate PEC in water (total)	0	[mg.l-1]	O
Moderate PEC in water (dissolved)	0	[mg.l-1]	O
Moderate PEC in air (total)	0	[mg.m-3]	O
Moderate PEC in soil (total)	0 [mg.kgwwt-1]		O
Moderate PEC in sediment (total)	0 [mg.kgwwt-1]		O

GLOBAL: ARCTIC

Arctic PEC in water (total)	0	[mg.l-1]	O
Arctic PEC in water (dissolved)	0	[mg.l-1]	O
Arctic PEC in air (total)	0	[mg.m-3]	O
Arctic PEC in soil (total)	0 [mg.kgwwt-1]		O
Arctic PEC in sediment (total)	0 [mg.kgwwt-1]		O

GLOBAL: TROPIC

Tropic PEC in water (total)	0	[mg.l-1]	O
Tropic PEC in water (dissolved)	0	[mg.l-1]	O
Tropic PEC in air (total)	0	[mg.m-3]	O
Tropic PEC in soil (total)	0 [mg.kgwwt-1]		O
Tropic PEC in sediment (total)	0 [mg.kgwwt-1]		O

STEADY-STATE FRACTIONS

REGIONAL

Steady-state mass fraction in regional freshwater	??	[%]	O
Steady-state mass fraction in regional seawater	??	[%]	O
Steady-state mass fraction in regional air	??	[%]	O
Steady-state mass fraction in regional agricultural soil	??	[%]	O
Steady-state mass fraction in regional natural soil	??	[%]	O
Steady-state mass fraction in regional industrial soil	??	[%]	O
Steady-state mass fraction in regional freshwater sediment	??	[%]	O
Steady-state mass fraction in regional seawater sediment	??	[%]	O

Copyright protected – No copying / use allowed

CONTINENTAL

Steady-state mass fraction in continental freshwater	??	[%]	O
Steady-state mass fraction in continental seawater	??	[%]	O
Steady-state mass fraction in continental air	??	[%]	O
Steady-state mass fraction in continental agricultural soil	??	[%]	O
Steady-state mass fraction in continental natural soil	??	[%]	O
Steady-state mass fraction in continental industrial soil	??	[%]	O
Steady-state mass fraction in continental freshwater sediment	??	[%]	O
Steady-state mass fraction in continental seawater sediment	??	[%]	O

GLOBAL: MODERATE

Steady-state mass fraction in moderate water	??	[%]	O
Steady-state mass fraction in moderate air	??	[%]	O
Steady-state mass fraction in moderate soil	??	[%]	O
Steady-state mass fraction in moderate sediment	??	[%]	O

GLOBAL: ARCTIC

Steady-state mass fraction in arctic water	??	[%]	O
Steady-state mass fraction in arctic air	??	[%]	O
Steady-state mass fraction in arctic soil	??	[%]	O
Steady-state mass fraction in arctic sediment	??	[%]	O

GLOBAL: TROPIC

Steady-state mass fraction in tropic water	??	[%]	O
Steady-state mass fraction in tropic air	??	[%]	O
Steady-state mass fraction in tropic soil	??	[%]	O
Steady-state mass fraction in tropic sediment	??	[%]	O

STEADY-STATE MASSES

REGIONAL

Steady-state mass in regional freshwater	0	[kg]	O
Steady-state mass in regional seawater	0	[kg]	O
Steady-state mass in regional air	0	[kg]	O
Steady-state mass in regional agricultural soil	0	[kg]	O
Steady-state mass in regional natural soil	0	[kg]	O
Steady-state mass in regional industrial soil	0	[kg]	O
Steady-state mass in regional freshwater sediment	0	[kg]	O
Steady-state mass in regional seawater sediment	0	[kg]	O

CONTINENTAL

Steady-state mass in continental freshwater	0	[kg]	O
Steady-state mass in continental seawater	0	[kg]	O
Steady-state mass in continental air	0	[kg]	O
Steady-state mass in continental agricultural soil	0	[kg]	O
Steady-state mass in continental natural soil	0	[kg]	O
Steady-state mass in continental industrial soil	0	[kg]	O
Steady-state mass in continental freshwater sediment	0	[kg]	O
Steady-state mass in continental seawater sediment	0	[kg]	O

GLOBAL: MODERATE

Steady-state mass in moderate water	0	[kg]	O
Steady-state mass in moderate air	0	[kg]	O
Steady-state mass in moderate soil	0	[kg]	O
Steady-state mass in moderate sediment	0	[kg]	O

GLOBAL: ARCTIC

Steady-state mass in arctic water	0	[kg]	O
Steady-state mass in arctic air	0	[kg]	O
Steady-state mass in arctic soil	0	[kg]	O
Steady-state mass in arctic sediment	0	[kg]	O

GLOBAL: TROPIC

Steady-state mass in tropic water	0	[kg]	O
Steady-state mass in tropic air	0	[kg]	O
Steady-state mass in tropic soil	0	[kg]	O
Steady-state mass in tropic sediment	0	[kg]	O

LOCAL

[PRODUCTION]

LOCAL CONCENTRATIONS AND DEPOSITIONS [PRODUCTION]

AIR

Concentration in air during emission episode	0	[mg.m-3]	O
Annual average concentration in air, 100 m from point source	0	[mg.m-3]	O
Total deposition flux during emission episode	0	[mg.m-2.d-1]	O
Annual average total deposition flux	0	[mg.m-2.d-1]	O

WATER, SEDIMENT

Concentration in surface water during emission episode (dissolved)	0	[mg.l-1]	O
Concentration in surface water exceeds solubility	No		O
Annual average concentration in surface water (dissolved)	0	[mg.l-1]	O
Concentration in seawater during emission episode (dissolved)	0	[mg.l-1]	O
Annual average concentration in seawater (dissolved)	0	[mg.l-1]	O

SOIL, GROUNDWATER

Concentration in agric. soil averaged over 30 days	0 [mg.kgwwt-1]	O	
Concentration in agric. soil averaged over 180 days	0 [mg.kgwwt-1]	O	
Concentration in grassland averaged over 180 days	0 [mg.kgwwt-1]	O	
Fraction of steady-state (agricultural soil)	??	[-]	O
Fraction of steady-state (grassland soil)	??	[-]	O

LOCAL PECS [PRODUCTION]

AIR

Annual average local PEC in air (total)	0	[mg.m-3]	O

WATER, SEDIMENT

Local PEC in surface water during emission episode (dissolved)	0	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in surface water (dissolved)	0	[mg.l-1]	O
Local PEC in fresh-water sediment during emission episode	0 [mg.kgwwt-1]	O	
Local PEC in seawater during emission episode (dissolved)	0	[mg.l-1]	O
Qualitative assessment might be needed (TGD Part II, 5.6)	No		O
Annual average local PEC in seawater (dissolved)	0	[mg.l-1]	O
Local PEC in marine sediment during emission episode	0 [mg.kgwwt-1]	O	

 Copyright protected – No copying / use allowed

SOIL, GROUNDWATER

Local PEC in agric. soil (total) averaged over 30 days	0 [mg.kgwwt-1]	O	
Local PEC in agric. soil (total) averaged over 180 days	0 [mg.kgwwt-1]	O	
Local PEC in grassland (total) averaged over 180 days	0 [mg.kgwwt-1]	O	
Local PEC in pore water of agricultural soil	0	[mg.l-1]	O
Local PEC in pore water of grassland	0	[mg.l-1]	O
Local PEC in groundwater under agricultural soil	0	[mg.l-1]	O

 Copyright protected – No copying / use allowed

EXPOSURE

SECONDARY POISONING

SECONDARY POISONING [PRODUCTION]

Concentration in fish for secondary poisoning (freshwater)	0	[mg.kgwwt-1]	O
Concentration in earthworms from agricultural soil	0	[mg.kg-1]	O
Concentration in fish for secondary poisoning (marine)	0	[mg.kgwwt-1]	O
Concentration in fish-eating marine top-predators	0	[mg.kgwwt-1]	O

HUMANS EXPOSED TO OR VIA THE ENVIRONMENT

LOCAL

[PRODUCTION]

CONCENTRATIONS IN FISH, PLANTS AND DRINKING WATER [PRODUCTION]

Local concentration in wet fish	0	[mg.kg-1]	O
Local concentration in root tissue of plant	0	[mg.kg-1]	O
Local concentration in leaves of plant	0	[mg.kg-1]	O
Local concentration in grass (wet weight)	0	[mg.kg-1]	O
Fraction of total uptake by crops from pore water	??	[-]	O
Fraction of total uptake by crops from air	??	[-]	O
Fraction of total uptake by grass from pore water	??	[-]	O
Fraction of total uptake by grass from air	??	[-]	O
Local concentration in drinking water	0	[mg.l-1]	O
Annual average local PEC in air (total)	0	[mg.m-3]	O

CONCENTRATIONS IN MEAT AND MILK [PRODUCTION]

Local concentration in meat (wet weight)	0	[mg.kg-1]	O
Local concentration in mi k (wet weight)	0	[mg.kg-1]	O
Fraction of total intake by cattle through grass	??	[-]	O
Fraction of total intake by cattle through drinking water	??	[-]	O
Fraction of total intake by cattle through air	??	[-]	O
Fraction of total intake by cattle through soil	??	[-]	O

DAILY HUMAN DOSES [PRODUCTION]

Daily dose through intake of drinking water	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of drinking water	??	[-]	O
Daily dose through intake of fish	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of fish	??	[-]	O
Daily dose through intake of leaf crops	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of leaf crops	??	[-]	O
Daily dose through intake of root crops	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of root crops	??	[-]	O
Daily dose through intake of meat	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of meat	??	[-]	O
Daily dose through intake of milk	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of milk	??	[-]	O
Daily dose through intake of air	0	[mg.kg-1.d-1]	O
Fraction of total dose through intake of air	??	[-]	O
Local total daily intake for humans	0	[mg.kg-1.d-1]	O

 Copyright protected – No copying / use allowed

EFFECTS

INPUT OF EFFECTS DATA

MICRO-ORGANISMS

Test system C.11, OECD 209	Respiration inhibition, EU Annex V		D
EC50 for micro-organisms in a STP	950	[mg.l-1]	S
EC10 for micro-organisms in a STP	??	[mg.l-1]	D
NOEC for micro-organisms in a STP	??	[mg.l-1]	D

AQUATIC ORGANISMS

FRESH WATER

L(E)C50 SHORT-TERM TESTS

LC50 for fish	0.096	[mg.l-1]	S
L(E)C50 for Daphnia	0.085	[mg.l-1]	S
EC50 for algae	0.41	[mg.l-1]	S
LC50 for additional taxonomic group	??	[mg.l-1]	D
Aquatic species	other		D

NOEC LONG-TERM TESTS

NOEC for fish	1.27E-04	[mg.l-1]	S
NOEC for Daphnia	0.024	[mg.l-1]	S
NOEC for algae	0.5	[mg.l-1]	S
NOEC for additional taxonomic group	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D
NOEC for additional taxonomic group	??	[mg.l-1]	D

MARINE

L(E)C50 SHORT-TERM TESTS

LC50 for fish (marine)	0.017	[mg.l-1]	S
L(E)C50 for crustaceans (marine)	0.03	[mg.l-1]	S
EC50 for algae (marine)	0.027	[mg.l-1]	S
LC50 for additional taxonomic group (marine)	??	[mg.l-1]	D
Marine species	other		D
LC50 for additional taxonomic group (marine)	??	[mg.l-1]	D
Marine species	other		D

 Copyright protected – No copying / use allowed

NOEC LONG-TERM TESTS

NOEC for fish (marine)	1.27E-04	[mg.l-1]	S
NOEC for crustaceans (marine)	9.46E-03	[mg.l-1]	S
NOEC for algae (marine)	0.5	[mg.l-1]	S
NOEC for additional taxonomic group (marine)	??	[mg.l-1]	D
NOEC for additional taxonomic group (marine)	??	[mg.l-1]	D

FRESH WATER SEDIMENT

L(E)C50 SHORT-TERM TESTS

LC50 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

EC10/NOEC LONG-TERM TESTS

EC10 for fresh-water sediment organism	231	[mg.kgwwt-1]	S
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for fresh-water sediment organism	231	[mg.kgwwt-1]	S
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for fresh-water sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

MARINE SEDIMENT

L(E)C50 SHORT-TERM TESTS

LC50 for marine sediment organism	??	[mg.kgwwt-1]	D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

EC10/NOEC LONG-TERM TESTS

EC10 for marine sediment organism	61.5 [mg.kgwwt-1]		S
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for marine sediment organism	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
EC10 for marine sediment organism	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for marine sediment organism	61.5 [mg.kgwwt-1]		S
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for marine sediment organism	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D
NOEC for marine sediment organism	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested sediment	0.05	[kg.kg-1]	D

TERRESTRIAL ORGANISMS

L(E)C50 SHORT-TERM TESTS

LC50 for plants	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
LC50 for earthworms	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
EC50 for microorganisms	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
LC50 for other terrestrial species	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D

NOEC LONG-TERM TESTS

NOEC for plants	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for earthworms	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for microorganisms	?? [mg.kgwwt-1]		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for additional taxonomic group	?? [mg.kgwwt-1]		D
Terrestrial species	other		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D
NOEC for additional taxonomic group	?? [mg.kgwwt-1]		D
Terrestrial species	other		D
Weight fraction of organic carbon in tested soil	0.02	[kg.kg-1]	D

BIRDS

LC50 in avian dietary study (5 days)	??	[mg.kg-1]	D
NOEC via food (birds)	??	[mg.kg-1]	D
NOAEL (birds)	??	[mg.kg-1.d-1]	D
Conversion factor NOAEL to NOEC (birds)	8	[kg.d.kg-1]	D

MAMMALS

REPEATED DOSE

ORAL

Oral NOAEL (repdose)	??	[mg.kg-1.d-1]	D
Oral LOAEL (repdose)	??	[mg.kg-1.d-1]	D
Oral CED (repdose)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (repdose)	??	[mg.kg-1]	D
LOEC via food (repdose)	??	[mg.kg-1]	D
CED via food (repdose)	?? [mg.kgfood-1]		D

 Copyright protected – No copying / use allowed

INHALATORY

Inhalatory NOAEL (repdose)	??	[mg.m-3]	D
Inhalatory LOAEL (repdose)	??	[mg.m-3]	D
Inhalatory CED (repdose)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D

DERMAL

Dermal NOAEL (repdose)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (repdose)	??	[mg.kg-1.d-1]	D
Dermal CED (repdose)	??	[mg.kg-1.d-1]	D

FERTILITY

ORAL

Oral NOAEL (fert)	??	[mg.kg-1.d-1]	D
Oral LOAEL (fert)	??	[mg.kg-1.d-1]	D
Oral CED (fert)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (fert)	??	[mg.kg-1]	D
LOEC via food (fert)	??	[mg.kg-1]	D
CED via food (fert)	??	[mg.kgfood-1]	D

INHALATORY

Inhalatory NOAEL (fert)	??	[mg.m-3]	D
Inhalatory LOAEL (fert)	??	[mg.m-3]	D
Inhalatory CED (fert)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D

DERMAL

Dermal NOAEL (fert)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (fert)	??	[mg.kg-1.d-1]	D
Dermal CED (fert)	??	[mg.kg-1.d-1]	D

 Copyright protected – No copying / use allowed

MATERNAL-TOX

ORAL

Oral NOAEL (mattox)	??	[mg.kg-1.d-1]	D
Oral LOAEL (mattox)	??	[mg.kg-1.d-1]	D
Oral CED (mattox)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (mattox)	??	[mg.kg-1]	D
LOEC via food (mattox)	??	[mg.kg-1]	D
CED via food (mattox)	??	[mg.kgfood-1]	D

INHALATORY

Inhalatory NOAEL (mattox)	??	[mg.m-3]	D
Inhalatory LOAEL (mattox)	??	[mg.m-3]	D
Inhalatory CED (mattox)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D

DERMAL

Dermal NOAEL (mattox)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (mattox)	??	[mg.kg-1.d-1]	D
Dermal CED (mattox)	??	[mg.kg-1.d-1]	D

DEVELOPMENT-TOX

ORAL

Oral NOAEL (devtox)	??	[mg.kg-1.d-1]	D
Oral LOAEL (devtox)	??	[mg.kg-1.d-1]	D
Oral CED (devtox)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (devtox)	??	[mg.kg-1]	D
LOEC via food (devtox)	??	[mg.kg-1]	D
CED via food (devtox)	??	[mg.kgfood-1]	D

INHALATORY

Inhalatory NOAEL (devtox)	??	[mg.m-3]	D
Inhalatory LOAEL (devtox)	??	[mg.m-3]	D
Inhalatory CED (devtox)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D

DERMAL

Dermal NOAEL (devtox)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (devtox)	??	[mg.kg-1.d-1]	D
Dermal CED (devtox)	??	[mg.kg-1.d-1]	D

CARC (THRESHOLD)

ORAL

Oral NOAEL (carc)	??	[mg.kg-1.d-1]	D
Oral LOAEL (carc)	??	[mg.kg-1.d-1]	D
Oral CED (carc)	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
NOEC via food (carc)	??	[mg.kg-1]	D
LOEC via food (carc)	??	[mg.kg-1]	D
CED via food (carc)	??	[mg.kgfood-1]	D

INHALATORY

Inhalatory NOAEL (carc)	??	[mg.m-3]	D
Inhalatory LOAEL (carc)	??	[mg.m-3]	D
Inhalatory CED (carc)	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D

DERMAL

Dermal NOAEL (carc)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (carc)	??	[mg.kg-1.d-1]	D
Dermal CED (carc)	??	[mg.kg-1.d-1]	D

CARC (NON-THRESHOLD)

ORAL

Oral T25 for non-threshold effects	??	[mg.kg-1.d-1]	D
Oral CED for non-threshold effects	??	[mg.kg-1.d-1]	D
Species for conversion of NOAEL to NOEC	Rattus norvegicus (<=6 weeks)		D
Conversion factor NOAEL to NOEC	10	[kg.d.kg-1]	O
T25 via food for non-threshold effects	??	[mg.kgfood-1]	D
CED via food for non-threshold effects	??	[mg.kgfood-1]	D

INHALATORY

Inhalatory T25 for non-threshold effects	??	[mg.m-3]	D
Inhalatory CED for non-threshold effects	??	[mg.m-3]	D
Correction factor for allometric scaling	1	[-]	D

DERMAL

Dermal T25 for non-threshold effects	??	[mg.kg-1.d-1]	D
Dermal CED for non-threshold effects	??	[mg.kg-1.d-1]	D

ACUTE

Oral LD50	??	[mg.kg-1]	D
Oral Discriminatory Dose	??	[mg.kg-1]	D
Inhalatory LC50	??	[mg.m-3]	D
Dermal LD50	??	[mg.kg-1]	D

PREDATOR

Duration of (sub-)chronic oral test	28 days		D
NOEC via food for secondary poisoning	??	[mg.kg-1]	O
Source for NOEC-via-food data	No data available, enter manually		S

BIO-AVAILIBILITY

Bioavailability for oral uptake (oral to inhalation)	0.5	[-]	D
Bioavailability for oral uptake (oral to dermal)	1	[-]	D
Bioavailability for oral uptake (route to oral)	1	[-]	D
Bioavailability for inhalation (route from inhalation)	1	[-]	D
Bioavailability for inhalation (route to inhalation)	1	[-]	D
Bioavailability for dermal uptake (route from dermal)	0.1	[-]	O
Bioavailability for dermal uptake (route to dermal)	0.1	[-]	O

HUMANS

REPEATED DOSE

ORAL

Oral NOAEL (repdose)	??	[mg.kg-1.d-1]	D
Oral LOAEL (repdose)	??	[mg.kg-1.d-1]	D

INHALATORY

Inhalatory NOAEL (repdose)	??	[mg.m-3] D
Inhalatory LOAEL (repdose)	??	[mg.m-3] D

DERMAL

Dermal NOAEL (repdose) 1.d-1]	?? D	[mg.kg-
Dermal LOAEL (repdose) 1.d-1]	?? D	[mg.kg-
Dermal NOEC in a medium (repdose)	?? D	[mg.cm-3]
Dermal LOEC in a medium (repdose)	?? D	[mg.cm-3]

FERTILITY

ORAL

Oral NOAEL (fert) 1.d-1]	?? D	[mg.kg-
Oral LOAEL (fert) 1.d-1]	?? D	[mg.kg-

INHALATORY

Inhalatory NOAEL (fert)	??	[mg.m-3] D
Inhalatory LOAEL (fert)	??	[mg.m-3] D

DERMAL

Dermal NOAEL (fert) 1.d-1]	?? D	[mg.kg-
Dermal LOAEL (fert) 1.d-1]	?? D	[mg.kg-
Dermal NOEC in a medium (fert)	?? D	[mg.cm-3]
Dermal LOEC in a medium (fert)	?? D	[mg.cm-3]

MATERNAL-TOX

ORAL

Oral NOAEL (mattox) 1.d-1]	?? D	[mg.kg-
Oral LOAEL (mattox) 1.d-1]	?? D	[mg.kg-

INHALATORY

Inhalatory NOAEL (mattox)	??	[mg.m-3] D
Inhalatory LOAEL (mattox)	??	[mg.m-3] D

DERMAL

Dermal NOAEL (mattox) 1.d-1]	?? D	[mg.kg-
Dermal LOAEL (mattox) 1.d-1]	?? D	[mg.kg-
Dermal NOEC in a medium (mattox)	?? D	[mg.cm-3]
Dermal LOEC in a medium (mattox)	?? D	[mg.cm-3]

DEVELOPMENT-TOX

ORAL

Oral NOAEL (devtox) 1.d-1]	?? D	[mg.kg-
Oral LOAEL (devtox) 1.d-1]	?? D	[mg.kg-

INHALATORY

Inhalatory NOAEL (devtox)	??	[mg.m-3] D
Inhalatory LOAEL (devtox)	??	[mg.m-3] D

DERMAL

Dermal NOAEL (devtox) 1.d-1]	?? D	[mg.kg-
Dermal LOAEL (devtox) 1.d-1]	?? D	[mg.kg-
Dermal NOEC in a medium (devtox)	?? D	[mg.cm-3]
Dermal LOEC in a medium (devtox)	?? D	[mg.cm-3]

CARC (THRESHOLD)

ORAL

Oral NOAEL (carc) 1.d-1]	?? D	[mg.kg-
Oral LOAEL (carc) 1.d-1]	?? D	[mg.kg-

 Copyright protected – No copying / use allowed

INHALATORY

Inhalatory NOAEL (carc)	??	[mg.m-3]	D
Inhalatory LOAEL (carc)	??	[mg.m-3]	D

DERMAL

Dermal NOAEL (carc)	??	[mg.kg-1.d-1]	D
Dermal LOAEL (carc)	??	[mg.kg-1.d-1]	D
Dermal NOEC in a medium (carc)	??	[mg.cm-3]	D
Dermal LOEC in a medium (carc)	??	[mg.cm-3]	D

CURRENT CLASSIFICATION

Corrosive (C, R34 or R35)	No		D
Irritating to skin (Xi, R38)	No		D
Irritating to eyes (Xi, R36)	No		D
Risk of serious damage to eyes (Xi, R41)	No		D
Irritating to respiratory system (Xi, R37)	No		D
May cause sensitisation by inhalation (Xn, R42)	No		D
May cause sensitisation by skin contact (Xi, R43)	No		D
May cause cancer (T, R45)	No		D
May cause cancer by inhalation (T, R49)	No		D
Possible risk of irreversible effects (Xn, R40)	No		D

ENVIRONMENTAL EFFECTS ASSESSMENT

ENVIRONMENTAL PNECS

FRESH WATER

Same taxonomic group for LC50 and NOEC	Yes		O
Toxicological data used for extrapolation to PNEC Aqua	1.27E-04	[mg.l-1]	O
Assessment factor applied in extrapolation to PNEC Aqua	5	[-]	S
PNEC for aquatic organisms	0.0254	[ug.l-1]	O

INTERMITTENT RELEASES

Toxicological data used for extrapolation to PNEC Aqua	0.085	[mg.l-1]	O
Assessment factor applied in extrapolation to PNEC Aqua	100	[-]	O
PNEC for aquatic organisms, intermittent releases	8.5E-04	[mg.l-1]	O

Copyright protected – No copying / use allowed

STATISTICAL

PNEC for aquatic organisms with statistical method	0.1	[ug.l-1]	S

MARINE

Same taxonomic group for marine LC50 and NOEC	Yes		O
Toxicological data used for extrapolation to PNEC Marine	1.27E-04	[mg.l-1]	O
Assessment factor applied in extrapolation to PNEC Marine	5	[-]	S
PNEC for marine organisms	2.54E-05	[mg.l-1]	O

STATISTICAL

PNEC for marine organisms with statistical method	0.42	[ug.l-1]	S

FRESH WATER SEDIMENT

Toxicological data used for extrapolation to PNEC sediment (fresh)	231 [mg.kgwwt-1]	O	
Assessment factor applied in extrapolation to PNEC sediment (fresh)	1000	[-]	S
PNEC for fresh-water sediment organisms (from toxicological data)	0.231 [mg.kgwwt-1]	O	
PNEC for fresh-water sediment organisms (equilibrium partitioning)	3.74E-03 [mg.kgwwt-1]	O	
Equilibrium partitioning used for PNEC in fresh-water sediment?	No		O
PNEC for fresh-water sediment, normalised to 10% o.c. (local)	0.462 [mg.kgwwt-1]	O	
PNEC for fresh-water sediment, normalised to 5% o.c. (regional)	0.231 [mg.kgwwt-1]	O	

MARINE SEDIMENT

Toxicological data used for extrapolation to PNEC sediment (marine)	61.5 [mg.kgwwt-1]	O	
Assessment factor applied in extrapolation to PNEC sediment (marine)	200	[-]	S
PNEC for marine sediment organisms (from toxicological data)	0.307 [mg.kgwwt-1]	O	
PNEC for marine sediment organisms (equilibrium partitioning)	3.74E-03 [mg.kgwwt-1]	O	
Equilibrium partitioning used for PNEC in marine sediment?	No		O
PNEC for marine sediment, normalised to 10% o.c. (local)	0.615 [mg.kgwwt-1]	O	
PNEC for marine sediment, normalised to 5% o.c. (regional)	0.307 [mg.kgwwt-1]	O	

 Copyright protected – No copying / use allowed

TERRESTRIAL

Same taxonomic group for LC50 and NOEC	No		O
Toxicological data used for extrapolation to PNEC Terr	?? [mg.kgwwt-1]	O	
Assessment factor applied in extrapolation to PNEC Terr	??	[-]	O
PNEC for terrestrial organisms (from toxicological data)	?? [mg.kgwwt-1]	O	
PNEC for terrestrial organisms (equilibrium partitioning)	3.02E-03 [mg.kgwwt-1]	O	
Equilibrium partitioning used for PNEC in soil?	Yes		O
PNEC for terrestrial organisms	3.02E-03 [mg.kgwwt-1]	O	

STATISTICAL

PNEC for terrestrial organisms with statistical method	?? [mg.kgwwt-1]	D	

SECONDARY POISONING

Toxicological data used for extrapolation to PNEC oral	??	[mg.kg-1]	O
Assessment factor applied in extrapolation to PNEC oral	??	[-]	O
PNEC for secondary poisoning of birds and mammals	??	[mg.kg-1]	O

STP

Toxicological data used for extrapolation to PNEC micro	950	[mg.l-1]	O
Assessment factor applied in extrapolation to PNEC micro	100	[-]	O
PNEC for micro-organisms in a STP	9.5	[mg.l-1]	O

Copyright protected – No copying / use allowed

RISK CHARACTERIZATION

REFERENCE MOS

HUMANS EXPOSED TO OR VIA THE ENVIRONMENT

REPEATED DOSE

ORAL

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, oral (repdose)	1	[-]	O

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, inhalatory (repdose)	1	[-]	O

FERTILITY

ORAL

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, oral (fert)	1	[-]	O

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, inhalatory (fert)	1	[-]	O

MATERNAL-TOX

ORAL

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, oral (mattox)	1	[-]	O

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, inhalatory (mattox)	1	[-]	O

DEVELOPMENT-TOX

ORAL

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, oral (devtox)	1	[-]	O

 Copyright protected – No copying / use allowed

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, inhalatory (devtox)	1	[-]	O

CARC (THRESHOLD)

ORAL

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, oral (carc)	1	[-]	O

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for intraspecies differences	1	[-]	D
Assessment factor for differences in exposure duration	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Reference-MOS, human environmental, inhalatory (carc)	1	[-]	O

CARC (NON-THRESHOLD)

ORAL

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Assessment factor for extrapolation to a low-risk level	2.5E+05	[-]	D
Reference-MOE, human environmental, oral (non-threshold)	2.5E+05	[-]	O

Copyright protected – No copying / use allowed

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for remaining interspecies differences	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor for dose-response relationship	1	[-]	D
Assessment factor for extrapolation to a low-risk level	2.5E+05	[-]	D
Reference-MOE, human environmental, inhalatory (non-threshold)	2.5E+05	[-]	O

HUMAN EQUIV. DOSE

INHALATORY

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor humans via environment, inhalatory, non-threshold	1	[-]	O
Human equivalent dose humans via environment, inhalatory, non-threshold	??	[mg.m-3]	O

TOTAL EXPOSURE

Assessment factor for allometric scaling	1	[-]	D
Assessment factor for differences in exposure route	1	[-]	D
Assessment factor humans via environment, total, non-threshold	1	[-]	O
Human equivalent dose humans via environment, total, non-threshold 1.d-1]	?? O	[mg.kg-	

ENVIRONMENTAL EXPOSURE

LOCAL

RISK CHARACTERIZATION OF [PRODUCTION]

WATER

RCR for the local fresh-water compartment	0	[-]	O
Intermittent release	No		D
RCR for the local marine compartment	0	[-]	O
RCR for the local fresh-water compartment, statistical method	0	[-]	O
RCR for the local marine compartment, statistical method	0	[-]	O

SEDIMENT

RCR for the local fresh-water sediment compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
RCR for the local marine sediment compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O

 Copyright protected – No copying / use allowed

SOIL			
RCR for the local soil compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	Yes		O
RCR for the local soil compartment, statistical method	??	[-]	O
STP			
RCR for the sewage treatment plant	0	[-]	O
PREDATORS			
RCR for fish-eating birds and mammals (fresh-water)	??	[-]	O
RCR for fish-eating birds and mammals (marine)	??	[-]	O
RCR for top predators (marine)	??	[-]	O
RCR for worm-eating birds and mammals	??	[-]	O
REGIONAL			
WATER			
RCR for the regional fresh-water compartment	0	[-]	O
RCR for the regional marine compartment	0	[-]	O
RCR for the regional fresh-water compartment, statistical method	0	[-]	O
RCR for the regional marine compartment, statistical method	0	[-]	O
SEDIMENT			
RCR for the regional fresh-water sediment compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
RCR for the regional marine sediment compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	No		O
SOIL			
RCR for the regional soil compartment	0	[-]	O
Extra factor 10 applied to PEC/PNEC	Yes		O
RCR for the regional soil compartment, statistical method	??	[-]	O

 Copyright protected – No copying / use allowed

HUMANS EXPOSED TO OR VIA THE ENVIRONMENTAL

LOCAL

RISK CHARACTERIZATION OF [PRODUCTION]

REPEATED DOSE

INHALATORY

MOS, local, inhalatory (repdose)	??	[-]	O
Ratio MOS/Ref-MOS, local, inhalatory (repdose)	??	[-]	O

TOTAL EXPOSURE

MOS, local, total exposure (repdose)	??	[-]	O
Ratio MOS/Ref-MOS, local, total exposure (repdose)	??	[-]	O

FERTILITY

INHALATORY

MOS, local, inhalatory (fert)	??	[-]	O
Ratio MOS/Ref-MOS, local, inhalatory (fert)	??	[-]	O

TOTAL EXPOSURE

MOS, local, total exposure (fert)	??	[-]	O
Ratio MOS/Ref-MOS, local, total exposure (fert)	??	[-]	O

MATERNAL-TOX

INHALATORY

MOS, local, inhalatory (mattox)	??	[-]	O
Ratio MOS/Ref-MOS, local, inhalatory (mattox)	??	[-]	O

TOTAL EXPOSURE

MOS, local, total exposure (mattox)	??	[-]	O
Ratio MOS/Ref-MOS, local, total exposure (mattox)	??	[-]	O

DEVELOPMENT-TOX

INHALATORY

MOS, local, inhalatory (devtox)	??	[-]	O
Ratio MOS/Ref-MOS, local, inhalatory (devtox)	??	[-]	O

TOTAL EXPOSURE

MOS, local, total exposure (devtox)	??	[-]	O
Ratio MOS/Ref-MOS, local, total exposure (devtox)	??	[-]	O

 Copyright protected – No copying / use allowed

CARC (THRESHOLD)

INHALATORY

MOS, local, inhalatory (carc)	??	[-]	O
Ratio MOS/Ref-MOS, local, inhalatory (carc)	??	[-]	O

TOTAL EXPOSURE

MOS, local, total exposure (carc)	??	[-]	O
Ratio MOS/Ref-MOS, local, total exposure (carc)	??	[-]	O

CARC (NON-THRESHOLD)

INHALATORY

MOE, local, inhalatory (non-threshold)	??	[-]	O
Ratio MOE/Ref-MOE, local, inhalatory (non-threshold)	??	[-]	O

TOTAL EXPOSURE

MOE, local, total exposure (non-threshold)	??	[-]	O
Ratio MOE/Ref-MOE, local, total exposure (non-threshold)	??	[-]	O

LIFETIME CANCER RISK

Lifetime cancer risk, local, exposure via air	??	[-]	O
Lifetime cancer risk, local, total exposure	??	[-]	O

 Copyright protected – No copying / use allowed

Annex 6: JUSTIFICATIONS FOR CONFIDENTIALITY CLAIMS

Blanked out item reference	Page number	Justification for confidentiality
CBI 1	116	**Demonstration of Potential Harm** Dissemination of this information could reveal the overall size of the Chemetall market which is not publicly available information. This could lead to competitors to engaging in predatory practices that could severely harm the commercial interests of Chemetall and its customers. This confidentiality claim will remain valid indefinitely

Copyright protected – No copying / use allowed