CHEMICAL SAFETY REPORT

Legal name of Applicant: *IDEXX Laboratories Limited*

Submitted by: *IDEXX Laboratories Limited*

Substances: *4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]*

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]

Use title:

Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and use of 4-Nonylphenol, branched and linear, ethoxylated in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions

Use number: *Use 1*

Table of Contents

List of Tables

List of Figures

List of Abbreviations

AfA	Application for Authorization
Clocal	Local concentrations
CS	Contributing Scenario
CSR	Chemical Safety Report
DU	Downstream Users
EEA	European Economic Area
ELISA	Enzyme-linked immunosorbent assay
ERC	Environmental Release Category
ES	Exposure Scenario
EU	European Union
HSE	Health, Safety and Environment
IGEPAL CA-720	Tradename for a commercial chemical covered by entry 42 (4-tert-OPnEO)
IVD	*In Vitro* Diagnostic
LPD	Livestock, Poultry and Dairy
NPE	Nonylphenol ethoxylates
Nonidet P-40 Substitute	Tradename for a commercial chemical covered by entry 43 (4-NPnEO)
4-NPnEO	4-Nonylphenol, branched and linear, ethoxylated
4-tert-OPnEO	4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated
PBT	Persistent Bioaccumulative Toxic
PEC	Predicted Environmental Concentration
PNEC	Predicted No Effect Concentration
PROC	Process Category
RAC	Committee of Risk Assessment
RCR	Risk Characterisation Ratio
EU REACH	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
UK REACH	
RMM	Risk Management Measure
RUO	Research Use Only
R&D	Research and development
SEA	Socio-Economic Analysis
STP	Sewage treatment plant
Triton X-100	Tradename for a commercial chemical covered by entry 42 (4-tert-OPnEO)
Triton X-405	Tradename for a commercial chemical covered by entry 42 (4-tert-OPnEO)Tetramethylbutyl)phenoxy]ethoxy)ethanol
UVCB	Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials
vPvB	very Persistent very Bioaccumulative
WWTP	Waste water treatment plant
4-NPnEO	4-nonylphenol
4-tert-OP	4-tert-octylphenol

Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

Use 1: *Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and use of 4-Nonylphenol, branched and linear, ethoxylated in in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions*

ECS and WCS	**Task (ERC)**	**Daily local tonnage (t/day)**	**Technical RMMSs** *Containment, *Ventilation (general, LEV…) *customized technical installation, etc	**Organisational RMMs, including:** *Duration and Frequency of exposure *OSH management system *Supervision *Monitoring arrangements *Training, etc	**PPE**	**Other conditions**	**Effectiveness of wastewater and waste air treatment (for ERC)**	**Release factors: water, air and soil (for ERC)**	**Detailed info. in CSR (section)**
ECS1	ERC 8a	NR, Widespread use. Daily local widespread use: Current tonnage: 1.77 x 10^{-5} tons of 4-tert-OPnEO & 4-NPnEO	4-tert-OPnEO & 4-NPnEO containing liquid and solid waste is collected and sent for adequate disposal	- Instruments and reagents are handled only by trained professional clinical technicians - Technical training and guidance material; - instrument operations manuals, safety data sheets (SDS)	NA		Water: NA Air: NA	0 % to water 0 % to air 0 % to soil	9.3.

***Abbreviations**: WCS=Worker contributing scenario, ECS=Environmental Contributing Scenario, * ERC=Environmental Release Category (or spERC if available), PROC= Process category, LEV=Local Exhaust Ventilation, PPE=Personal Protective Equipment*

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

The Applicant declares that the risk management measures described in the exposure scenario and summarized above are implemented during their own use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated and 4-nonylphenol, branched and linear, ethoxylated.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

IDEXX Laboratories Ltd. declares that the risk management measures written in the exposure scenarios and summarised above are communicated to further downstream users.

Part B

9. EXPOSURE ASSESSMENT (and related risk characterisation)

9.0. Introduction

IDEXX supplies a range of *in vitro* diagnostic (IVD) veterinary products to professional users in the UK. The veterinary diagnostics market sectors are clinical biochemistry, immuno-diagnostics, hematology, urinalysis, molecular diagnostics and other veterinary diagnostic technologies.

IDEXX IVD products contain substances that are covered by entries 42 and 43 of the UK REACH Authorisation List (Annex XIV of the regulation). Authorisation is required for uses of these products where the concentration is > 0.1 % (w/w) unless otherwise exempted. IDEXX has submitted an application for authorisation under EU REACH for professional users of the concerned IVD products before the latest application date given in the Annex XIV entries.[1],[2] Since the entry into force of UK REACH on the 01.01.2021, UK users are not covered by the EU REACH application and IDEXX has prepared this application to cover by UK users (excluding NI). End users of IDEXX IVD products in the UK are reference laboratories, veterinary hospitals & clinics, research institutes & universities, and point-of-care/in-house testing. IDEXX reference laboratories are the major end users of diagnostic instruments and consumables and accounted for the largest share of the veterinary diagnostics market in 2021, followed by veterinary hospitals and clinics, point-of-care/in-house testing, and research institutes.

This exposure/risk assessment is specific for uses of IDEXX IVD veterinary products that contain substances covered by entries 42 & 43 of the UK Authorisation list by professional users.

9.0.1. Overview on uses

The exposure/risk assessment covers the use of substances covered by 42[3] and 43[4] entries 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated (4-tert-OPnEO) and 4- Nonylphenol, branched

[1] All documentation relating to the application for authorisation for the "*Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions*" is available at https://echa.europa.eu/fi/applications-for-authorisation-previous-consultations/-/substance-rev/24325/del/200/col/synonymDynamicField_302/type/asc/pre/2/view

[2] All documentation relating to the application for authorisation for "*use of 4-Nonylphenol, branched and linear, ethoxylated in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions*" is available at https://echa.europa.eu/fi/applications-for-authorisation-previous-consultations/-/substance-rev/24324/del/200/col/synonymDynamicField_302/type/asc/pre/2/view

[3] Entry No. 42 of Annex XIV of UK REACH Regulation: 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated [covering well-defined substances and UVCB substances, polymers and homologues]

[4] Entry No. 43 of Annex XIV of UK REACH Regulation: 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

and linear, ethoxylated (4-NPnEO) on Annex XIV of the UK REACH Regulation by professional users of *in vitro* diagnostic veterinary (IVD) products supplied by IDEXX. The commercial chemicals covered by the entries are commonly referred to by their trade names; e.g. “Triton X-100”, “IGEPAL CA-630”, “Triton X-405”, “IGEPAL CA-720” and “Nonidet P-40 Substitute”.

The concerned IVD veterinary products supplied by IDEXX to users in the UK excluding NI can be divided in two main categories: SNAP[5] tests and ELISA[6] plate tests.

SNAP IVD products: SNAP tests are compact plastic devices that encase a sample wash solution, a substrate and a matrix pre-coated with a layer of antigen-specific antibodies or antibody-specific antigens (**Figure 1**). Each test is designed to detect the diagnostic markers for one or multiple diseases or semi-quantitatively measure the level of a specific enzyme. As IDEXX’s SNAP tests are compatible with several types of samples, namely, whole blood, serum, plasma and milk samples, the devices can be used to test a wide array of diseases and other marker substances, such as lipases, peptides or antibiotics. SNAP tests are easy-to-use IVD products that deliver reliable, accurate results within minutes. A typical SNAP test kit for whole blood, serum, plasma and milk samples is composed of a bottle of conjugate, a disposable sample tube, a pipette and the diagnostic device itself. The wash solution enclosed in the device is the only component of the SNAP tests that contains 4-tert-OPnEO (by tradename Triton X-100/IGEPAL CA-630 and Triton X-405/IGEPAL CA-720). The typical users of SNAP tests are professional workers from veterinary clinics and other bodies which provide IVD services to veterinary practices. Appendix 1 gives a short description of the five easy steps required to use a SNAP test.

to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]

[5] The SNAP assay was developed by scientists at IDEXX Laboratories to overcome limitations of other clinic-based assays. The SNAP product combines the simplicity and immediate results of an in-office test with the accuracy of a reference laboratory-format ELISA

[6] ELISA: enzyme-linked immunosorbent assay

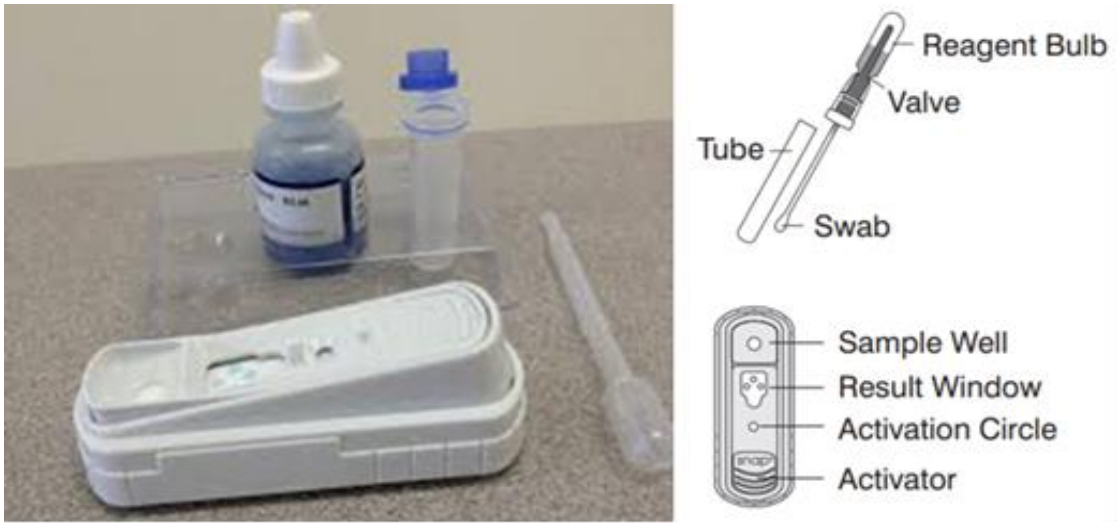


Figure 1. (left) The components of SNAP test kit for whole blood, serum, plasma and milk samples. (right) The typical content of SNAP test kit intended for fecal samples. The wash solution enclosed in the device is the only component of the SNAP tests that contains concerned substances

ELISA IVD products: IDEXX has developed a wide array of ELISAs for the detection of various diseases in ruminants, equine, swine, cervids and poultry. Typically, an ELISA plate kit contains several coated plates, a bottle of sample diluent, a bottle of conjugate, a bottle of substrate, a bottle of stop solution, several bottles of controls and a bottle of wash concentrate (see **Figure 2**). Some kits contain fewer components as each ELISA is designed for a specific test. The components of different kits or lots cannot be mixed as each component is carefully manufactured and specifically optimized to work as a unit. The test procedure for ELISA plates is described in Appendix 2. The estimated percentage of 4-tert-OPnEO and 4-NPnEO in liquid waste of plate products ranges from 3.9E-4 to 9.1E-6 % (w/w). The sample diluent and the controls are the components of the ELISA kits that contain 4-tert-OPnEO and 4-NPnEO (by tradename Triton X-100/IGEPAL CA-630, Triton X-405/IGEPAL CA-720 or Nonidet P-40). They may also be included in wash concentrate for specific products but this is rare. Professional workers in private laboratories, university laboratories, IDEXX owned laboratories and government reference laboratories are typical users of ELISA plate kits.

Figure 2. Typical content of an IDEXX ELISA diagnostic kit. Components from left to right: substrate, wash concentrate, positive and negative controls, conjugate, sample diluent and coated plates

A full list of the kits that contain 4-tert-OPnEO and 4-NPnEO is given in Appendix 1 of the Analysis of Alternatives and Socio-Economic Analysis report.

Technical function of the substances in the IVD products: The use of 4-tert-OPnEO and 4-NPnEO in IVD kits prevents the nonspecific binding of undesired macromolecules, such as conjugates and sample impurities, to the bottom of the wells in ELISA plate tests and to the assay's matrix in SNAP tests. The technical function of the concerned substances in the IVD products is described in detail in the Analysis of Alternatives report.

The use is covered by one exposure scenario and covers use of the SNAP and ELISA IVD products containing the concerned substances by UK downstream users.

Table *3* summaries the use names, exposure scenarios and typical concentration of the substances during use.

9.0.2. Introduction to the assessment for the environment

Tonnage information:

Since the IVD kits are manufactured outside of and imported to the UK, the quantities of the concerned substances are directly related to the number of kits being placed on the UK market. All the IVD kits are for the professional market. The amount of 4-tert-OPnEO and 4-NPnEO included with the kits can be estimated based on the amounts of each substance added. As more than one substance is covered by entry 42, IDEXX used the CAS identifiers for the chemicals in its estimation of the total volume included with the kits (see **Table 1**). **Table 1** also gives the tonnage grouped by CAS identifiers for the reference year 2021 and 2034 (the year of expiry of a 12 year review period starting from the sunset date in 2022). **Table 2** gives the sum of the volumes of 4-tert-OPnEO and 4-NPnEO used in 2021 and the forecast volume for 2034.

Table 1. Summary of tonnage information by CAS identifier and Annex XIV entry

CAS number	Covered by entry	Examples of tradenames	Tonnage in 2021 (tons/year)	Forecast tonnage in 2034
9002-93-1	42	Triton X-100 IGEPAL® CA-620	0.000177 tons (0.18 kg)	0.0004 tons (0.4 kg)
9036-19-5	42	Triton X-405 IGEPAL® CA-720	0.00529 tons (5.3 kg)	0.0113 tons (11.3 kg)
9016-45-9	43	Nonidet® P 40 Substitute	0.00099 tons (1 kg)	0.0021 tons (2.1 kg)

Table 2. Summary of the tonnage information by Annex XIV entry

Substances covered by the entry	Tonnage used in 2021 (tons/year)	Forecast tonnage used in 2034
4-tert-OPnEO	0.005475 tons (5.5 kg)	0.0117 tons (11.7 kg)
4-NPnEO	0.00099 tons (1 kg)	0.0021 tons (2.1 kg)
4-tert-OPnEO & 4-NPnEO	0.006465 tons (6.5 kg)	0.00138 tons (13.8 kg)

Assessed tonnage: 0.006465 tonnes per year based on information from 2021

Table *3* gives the tonnage used in the assessment for the environmental contributing scenario. The value is the sum of all volumes for 4-tert-OPnEO & 4-NPnEO. The tonnage used is projected to increase over the duration of the requested review period (12 years) 13.8 kg based on an annual increase of 6 % in sales.

Table 3. Identifiers, titles, market sector and tonnage for the use

Identifiers	Market sector	Titles of exposure scenarios and the related contributing scenarios	Total tonnage (tons per year)
ES1 – PW1	PC21: Laboratory Chemicals	- Widespread use by professional workers – Use of *in vitro* veterinary diagnostics kits containing 4-tert-OPnEO and 4-NPnEO Environment contributing scenario(s): - Use of 4-tert-OPnEO and/or 4-NPnEO in SNAP tests and/or ELISA Plate tests - Scenario where DUs are instructed to collect all 4-tert-OPnEO and/or 4-NPnEO for adequate treatment (ERC 8a)	0.006465
Exposure scenario: ES-#, Formulation: F-#, Industrial end use at site: IW-#, Professional end use: PW-#.			

Waste management

Liquid wastes:

- the wash solution, which is enclosed in the device, is the only component of the SNAP tests that contains 4-tert-OPnEO;
- the sample diluent, controls, conjugate solutions, wash solutions, detection solutions or tissue soaking buffer are the components of the ELISA kits that contain 4-tert-OPnEO or 4-NPnEO.

Solid wastes:

- SNAP test device;
- ELISA plates and containers of the different solutions.

IDEXX ran a downstream user survey in 2019 to collect information on waste (liquid and solid) handling practices of downstream users for the preparation of its application for authorisation under EU REACH application. 281 downstream users of SNAP and ELISA plate tests responded and the responses were from veterinary clinics, reference laboratories, universities, governmental laboratories or private livestock and milk laboratories situated in Spain, France, UK, Germany, Ireland, Italy, the Netherlands and Denmark.

The survey results showed that more than 50 % of users already collect 4-tert-OPnEO or 4-NPnEO containing waste and sent it for disposal by incineration although it was not a requirement at that time. The survey also collected information on whether the users had existing facilities or services in place to dispose of hazardous waste. As expected, ca. 80 % reported that they have hazardous waste collection services in place as these tests are used in laboratories and clinics that would be normally handling hazardous waste. The survey also showed that the users typically do not use both ELISA and SNAP tests.

In the ECHA committee opinion on the EU REACH application, the ECHA risk assessment committee recommended that conditions be imposed on the downstream users to collect all 4-tert-OPnEO or 4-NPnEO containing waste. Specifically, RAC proposes that the applicants shall recommend their downstream users to collect all solid and liquid waste for adequate

treatment. The decision on the application is not yet available but it is likely that the Commission will follow the recommendation and require downstream users to collect all 4-tert-OPnEO or 4-NPnEO containing waste and dispose of it by adequate treatment.

In preparation for the eventual decision, IDEXX has updated its SDSs and product insert information to instruct downstream users to collect all 4-tert-OPnEO or 4-NPnEO containing waste for disposal.

For this reason, the exposure scenario included with the application for authorisation instructs all downstream users to collect all 4-tert-OPnEO or 4-NPnEO containing waste for adequate disposal. No release to the environment is foreseen from this use.

9.0.2.2. Scope and type of assessment for the environment

IDEXX treated 4-tert-OPnEO and 4-NPnEO as non-threshold substances and did not attempt to derive PNECs or RCRs. This CSR describes how the operational conditions (OCs) and risk management measures (RMMs) in the exposure scenario (ES) prevent or minimise releases to the environment as far as technically and practically possible (with the view to minimising the likelihood of adverse effects).

Comments on assessment approach:

Total releases to the environment are given in section 10.1.1. (**Table 6**)

9.0.2.5. Scope and type of assessment for humans via the environment

Risk to humans via the environment does not need to be assessed in the CSR included in the application for Authorisation for all 4-tert-OPnEO or 4-NPnEO containing waste as these substances were listed on Annex XIV solely on the basis of their endocrine disrupting properties for the environment (Article 62(4)).

9.0.3. Introduction to the assessment for workers

9.0.3.1. Scope and type of assessment for workers

The exposure assessment for workers is not within scope as all 4-tert-OPnEO or 4-NPnEO containing waste are listed on Annex XIV solely on the basis of their endocrine disrupting properties for the environment (Article 62(4)).

9.0.4. Introduction to the assessment for consumers

Exposure assessment is not applicable as there are no consumer-related uses for the substances.

9.3. Exposure scenario 1: Use of in vitro diagnostics kits containing 4-tert-OPnEO or 4-NPnEO

Market sector: Widespread use, UK (professionals)

Sector of use: SU 1: Agriculture, forestry, fishery; SU 20: Health services; SU 24: Scientific research and development

Article categories: AC 0: Use of in vitro diagnostic kits

Environment contributing scenario(s):

ECS1: ERC 8a: Use of 4-tert-OPnEO and/or 4-NPnEO in SNAP tests and/or ELISA Plate tests - Scenario where DUs collect all 4-tert-OPnEO and/or 4-NPnEO for adequate treatment

Worker/Consumer contributing scenario(s): not relevant

Subsequent service life exposure scenario(s): not relevant

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): not relevant

Explanation on the approach taken for the ES:

As outlined in the previous section, IDEXX instructs all users to collect all 4-tert-OPnEO or 4-NPnEO containing solid and liquid waste for adequate treatment. There is no foreseen release of 4-tert-OPnEO or 4-NPnEO coming from this use.

Table 4. Summary of substances, tonnages and product category

Annex XIV entries	Substance (trade name)	Tonnage (t/year)	Product category (Form in the product)
4-tert-OPnEO & 4-NPnEO	CAS-No: 9002-93-1 (Triton X-100/IGEPAL CA-630) CAS-No: 9036-19-5 (Triton X-405/IGEPAL CA-720) CAS-No: 9016-45-9 (Nonidet P-40 Substitute)	0.006465	SNAP tests (wash solutions) and ELISA plates kits (sample diluent and controls) ELISA plates kits (sample diluent and controls)

9.3.1. Env CS 1: Use of 4-tert-OPnEO and/or 4-NPnEO in SNAP tests and ELISA Plate tests - Scenario where DUs collect all 4-tert-OPnEO and/or 4-NPnEO for adequate treatment

9.3.1.1. Conditions of use

Amount used, frequency and duration of use (or from service life)
• Daily local widespread use amount: ≤ 1.77 x 10^{-5} tons/day The daily local widespread use amount of 4-tert-OPnEO or 4-NPnEO in the UK is calculated as follows: 0.006465 tons (6.5 kg) of the substances are distributed over several regions and towns, dividing by 365 days per year results in a local daily use 1.77 x 10^{-5} tons (0.02 kg) per day. This value is taken for the assessment. • Type of release: no release
Technical and organizational conditions and measures
• The following measures have been implemented to reduce the releases of 4-tert-OPnEO and 4-NPnEO to the environmental compartments as much as possible: - IDEXX has communicated via Safety Data Sheets (SDS) to their customers that there is an environmentally hazardous chemical in their products; - IDEXX has communicated via SDSs to their supply chain that waste generated containing traces of hazardous substances needs to be collected and disposed of in accordance with national and local regulations; - 70-80 % of the ELISA plates kits are distributed to reference laboratories, university laboratories, IDEXX owned laboratories and governmental reference laboratories which already have strict waste management rules.
Conditions and measures related to external treatment of waste (including article waste)
• Particular considerations on the waste treatment operations: Other DUs are instructed in the SDS to collect and reclaim or dispose in sealed containers at licensed waste disposal sites There are no emissions to water, air or soil as customers are instructed to collect all waste for adequate treatment

9.3.1.2. Releases

The local releases to the environment are reported in the following table.
As outlined in the previous section, users are instructed to collect the waste streams containing traces of the detergents and dispose of them according to national and local regulations. The insert supplied with the kits informs users to follow the waste disposal instructions given in the Safety Data Sheets (SDS). The SDS provided with the kits instructs users to dispose of residual waste as per local regulations.

Table 5. Local releases to the environment

Release	Release estimation method	Explanations
Water	Estimated release factor	**Release factor after onsite RMM:** 0 **Local release rate:** 0 kg/day **Explanation:** The liquid waste resulting from the use of the products is treated as hazardous waste and sent for adequate treatment (e.g. incineration)
Air	Estimated release factor	**Release factor after onsite RMM:** 0 **Explanation:** Emissions to air are considered negligible.
Non-agricultural soil	Estimated release factor	**Release factor after onsite RMM:** 0 **Explanation:** Emissions to soil are considered negligible.

Releases to waste

Release factor to external waste: 100 %

9.3.1.3. Exposure and risks for the environment and man via the environment

As all users are instructed to collect solid and liquid waste containing 4-tert-OPnEO or 4-NPnEO and send it for adequate treatment, there are no emissions to the environment. As such no exposure or risk calculations are required.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

10.1. Environment (combined for all emission sources)

10.1.1. All uses (regional scale)

10.1.1.1. Total releases

The total releases to the environment from all the exposure scenarios covered are presented in the **Table 6**.

Table 6. Total releases ti the environment per year from all life cycle stages

Release route	Total releases per year
Water	0 kg/year
Air	0 kg/year
Soil	0 kg/year

10.1.2. Regional assessment

As there is no release to the environmental compartments, the regional predicted environmental concentration (PEC regional) is zero.

REFERENCES

All documentation relating to the application for authorisation for the "*Use of 4-(1,1,3,3-tetramethylbutyl)phenol, ethoxylated in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions*" is available at https://echa.europa.eu/fi/applications-for-authorisation-previous-consultations/-/substance-rev/24325/del/200/col/synonymDynamicField_302/type/asc/pre/2/view

All documentation relating to the application for authorisation for "*use of 4-Nonylphenol, branched and linear, ethoxylated in vitro diagnostic veterinary products (SNAP tests and ELISA Plate tests) as an ingredient in the wash solutions, sample diluents, control solutions, conjugate solutions, SNAP wash solutions, tissue soaking buffers and detection solutions*" is available at https://echa.europa.eu/fi/applications-for-authorisation-previous-consultations/-/substance-rev/24324/del/200/col/synonymDynamicField_302/type/asc/pre/2/view

APPENDICES

Appendix 1. Test procedure for SNAP test kits

Whole blood/serum/plasma and milk samples

Step 1. Dispense sample and conjugate into the sample tube.

Step 2. Gently invert the sample tube 4-5 times to mix.

Step 3. Pour the sample into the sample well of the SNAP device.

Faecal samples

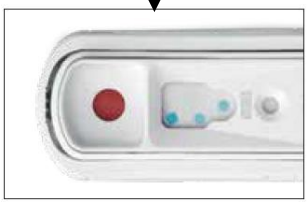
Step 1. Swab sample and place swap into tube. Break seal and release conjugate.

Step 2. Squeeze and release bulb 3 times to mix sample and conjugate.

Step 3. Squeeze bulb to dispense 5 drops into the well of a SNAP device.

Step 4. When colour appears in the activation circle, press firmly to activate. You will hear a distinct “snap”

Step 5. Read the results after the appropriate time has passed



Alternative step 4 and 5. Use the SNAP Pro* Analyzer to automatically activate the SNAP test and interpret the results

Appendix 2. Test procedure for ELISA plates

Step 1. Dilute the sample with sample diluent in test tubes. Dilute controls in the same way.

Step 2. Add the diluted sample to the pre-coated plate. (In some assays the sample is added undiluted)

Step 3. Incubate the plate.

Step 4. Dilute the wash concentrate tenfold with distilled water. Wash the plate with the diluted wash solution manually or using an automated plate washer.

Step 5. Add the conjugate to the plate wells

Step 6. Incubate the plate and repeat step 4.

Step 7. Add the substrate to the plate wells

Step 8. Measure the colour development in each well with a spectrophotometer