SUBSTANCE EVALUATION CONCLUSION

as required by REACH Article 48

and

EVALUATION REPORT

for

1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime

EC No 627-083-1

CAS No 244235-47-0

Evaluating Member State(s): Spanish Ministry of Agriculture, Food and Environment.

Dated: 8 July 2016

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2015

Member State concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

However, the PBT concern cannot be completely clarified, since it still needs to be clarified under a separate SEv process if one of the constituents, Phenol, 4-nonyl branched (4NP) (CAS 84852-15-3; EC 284-325-5), is a PBT substance. Therefore, it will be considered whether to initiate any RRM for the registered substance, once this issue on 4NP had been clarified.

Further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

DISCLAIMER

This document has been prepared by the evaluating Member State as a part of the substance evaluation process under the REACH Regulation (EC) No 1907/2006. The information and views set out in this document are those of the author and do not necessarily reflect the position or opinion of the European Chemicals Agency or other Member States. The Agency does not guarantee the accuracy of the information included in the document. Neither the Agency nor the evaluating Member State nor any person acting on either of their behalves may be held liable for the use which may be made of the information contained therein. Statements made or information contained in the document are without prejudice to any further regulatory work that the Agency or Member States may initiate at a later stage.

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work. The Community rolling action plan (CoRAP) of substances subject to evaluation, is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. The document consists of two parts i.e. A) the conclusion and B) the evaluation report. In the conclusion part A, the evaluating Member State considers how the information on the substance can be used for the purposes of regulatory risk management such as identification of substances of very high concern (SVHC), restriction and/or classification and labelling. In the evaluation report part B the document provides explanation how the evaluating Member State assessed and drew the conclusions from the information available.

With this Conclusion document the substance evaluation process is finished and the Commission, the Registrant(s) of the substance and the Competent Authorities of the other Member States are informed of the considerations of the evaluating Member State. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes. Further analyses may need to be performed which may change the proposed regulatory measures in this document. Since this document only reflects the views of the evaluating Member State, it does not preclude other Member States or the European Commission from initiating regulatory risk management measures which they deem appropriate.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

Contents

Part A. Conclusion

The evaluating Member State Competent Authority (eMSCA) concluded the evaluation without the need to request further information from the registrants under Article 46(1) decision.

The eMSCA concludes that based on the available data Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) is Persistant (P), not bioaccumulative (not B), and toxic (T).

However, Phenol, 4-nonyl-, branched (EC 284-325-5) which is a constituent of the substance and is present at concentrations relevant for PBT assessment. Uncertainities regarding B and P has been raised. Phenol, 4-nonyl-, branched is listed on the Community Rolling Action Plan (CoRAP) for evaluation by the UK in 2014, to clarify concerns related to 'Suspected PBT/vPvB', 'Consumer use', 'High (aggregated) tonnage', and 'Wide dispersive use'.

Consequently, the eMSCA considers that the suspected PBT/vPvB concern for the substance remains unverified pending clarification of the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched under substance evaluation be concluded. Since the registered substance contains 4-nonyl phenol branched (4-NP) as a relevant constituent and it is likely that the registered substance has similar properties, considering classification and labelling reported by all notifiers. 4-NP has been accepted as read-across substance for long-term fish toxicity. Based on the available information, the registered substance is likely to pose environmental endocrine disruption properites for fish based on the presence on 4-nonyl phenol branched as relevant constituent.

Therefore, according to the above rationale, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched should be taken into account for its consideration under article 57(f) of the REACH Regulation.

1. CONCERN(S) SUBJECT TO EVALUATION

1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime was originally selected for substance evaluation in order to clarify concerns about:

- the environment (suspected PBT) and,

- exposure (high aggregated tonnage)

During the evaluation also other concerns were identified. The additional concerns were:

- Endocrine disruption

- Reproductive toxicity

- Aquatic toxicity

2. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

The following other processes / EU Legislation are applicable to the constituents of the UVCB substance 1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime:

Phenol, 4-nonyl-, branched (EC 284-325-5) is an SVHC due to endocrine disrupting properties in fish, Furthermore, Phenol, 4-nonyl-, branched (EC 284-325-5) is listed on the Community Rolling Action Plan (CoRAP) for evaluation by the UK in 2014, to clarify concerns related to 'Suspected PBT/vPvB', 'Consumer use', 'High (aggregated) tonnage', and 'Wide dispersive use'

Phenol (EC 203-632-7) is listed on the CoRAP for evaluation by Denmark in 2015, to clarify concerns related to 'Suspected mutagenic', 'Other hazard based concern', 'Consumer use', 'Exposure of workers', 'High RCR', and 'High (aggregated) tonnage'.

2-ethylhexanoic acid (EC 205-743-6) is listed on the CoRAP for evaluation by Spain in 2012, to clarify concerns related to 'CMR', 'Consumer use', 'High RCR', 'Wide dispersive use', and 'High (aggregated) tonnage'.

3. CONCLUSION OF SUBSTANCE EVALUATION

The evaluation of the available information on the substance has led the evaluating Member State to the following conclusions, as summarised in the table below.

The substance contains, at relevant concentrations, the constituent Phenol, 4-nonyl-, branched (EC 284-325-5), which is an SVHC due to endocrine disrupting properties in fish.

Taking into account the toxicity information and that the substance is not readily biodegradable, the following conclusions are considered for classification and labelling:

H410: Very toxic to aquatic life with long lasting effects.

Based on the available data, harmonised classification and labelling as Repr. 2: H361fd or Repr. 1B: H360 may be warranted. However, the eMSCA will conclude on the need for harmonised classification for reproduction toxicity, once the evaluation of the constituent (Phenol, 4-nonyl-, branched) has been concluded.
Phenol, 4-nonyl-, branched (EC 284-325-5) is a constituent of the UVCB substance 1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime and is present at concentrations relevant for PBT assessment, Furthermore, Phenol, 4-nonyl-, branched is listed on the Community Rolling Action Plan (CoRAP) for evaluation by the UK in 2014, to clarify concerns related to 'Suspected PBT/vPvB', 'Consumer use', 'High (aggregated) tonnage', and 'Wide dispersive use'. Consequently, the eMSCA considers that the suspected PBT/vPvB concern for 1-(2-hydroxy-5- nonylphenyl)-, oxime, branched remains unverified pending clarification of the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched under substance evaluation. Therefore, the eMSCA will consider the need for any follow-up regulatory action(s) at EU level for 1-(2-hydroxy-5- nonylphenyl)-, oxime, branched once the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched has been clarified. Potential options are the inclusion in the Candidate List, Authorisation or Restriction.

Table 1. Conclusion of substance evaluation

CONCLUSION OF SUBSTANCE EVALUATION	
Conclusions	**Tick box**
Need for follow-up regulatory action at EU level	X
Harmonised Classification and Labelling	X
Identification as SVHC (authorisation)	X
Restrictions	X
Other EU-wide measures	
No need for regulatory follow-up action at EU level	

4. FOLLOW-UP AT EU LEVEL

4.1. Need for follow-up regulatory action at EU level

With regards to the PBT/vPvB concern, the eMSCA will consider the need for any follow-up regulatory action(s) at EU level for 1-(2-hydroxy-5- nonylphenyl)-, oxime, branched once the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched has been clarified. Also due to the endocrine disruption properties further risk management seems justified. Potential options are the inclusion in the Candidate List, Authorisation or Restriction.

4.1.1. Harmonised Classification and Labelling

Short-term and long-term toxicity tests results are available for the substance or read-across substance on freshwater fish, invertebrates and algae. Therefore, taking into account the toxicity information and not ready biodegradability, the following conclusions are considered for classification and labelling:

H410: Very toxic to aquatic life with long lasting effects.

As the substance poses endocrine disruption properties for fish based on the presence on 4-nonyl phenol branched, it should be taken into account for its consideration under article 57(f) of the REACH Regulation.

As indicated in section 3, the eMSCA will conclude on the need for harmonised classification for reproduction toxicity, once the evaluation of the constituent (Phenol, 4-nonyl-, branched) has been concluded.

4.1.2. Identification as a substance of very high concern, SVHC (first step towards authorisation)

The registered substance contains 4-NP. 4-NP is an SVHC due to environmental endocrine disrupting properties in fish. 4-NP is on the REACH Candidate List because of its environmental endocrine disrupting properties and is already subject to specific restrictions on its marketing and use under REACH Annex XVII. This substance is also on the Annex X list of priority substances (Decision 2455/2001/EC) under the Water Framework Directive 2000/60/EC (WFD).

4.1.3. Restriction

See above, this is a potential option that may be considered later.

4.1.4. Other EU-wide regulatory risk management measures

Currently not applicable.

5. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5.1. No need for regulatory follow-up at EU level

Not applicable.

5.2. Other actions

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS (IF NECESSARY)

The registered substance contains 4-NP. 4-NP is an SVHC due to environmental endocrine disrupting properties in fish. 4-NP is on the REACH Candidate List because of its environmental endocrine disrupting properties and is already subject to specific restrictions on its marketing and use under REACH Annex XVII. This substance is also on the Annex X list of priority substances (Decision 2455/2001/EC) under the Water Framework Directive 2000/60/EC (WFD).

Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched should be taken into account for its consideration under article 57(f) of the REACH Regulation.
However, Phenol, 4-nonyl-, branched (EC 284-325-5) which is a constituent of the substance and is present at concentrations relevant for PBT assessment.Uncertainities regarding B and P has been raised. Phenol, 4-nonyl-, branched is listed on the Community Rolling Action Plan (CoRAP) for evaluation by the UK in 2014, to clarify concerns related to 'Suspected PBT/vPvB', 'Consumer use', 'High (aggregated) tonnage', and 'Wide dispersive use'.

Consequently, the eMSCA considers that the suspected PBT/vPvB concern for the substance remains unverified pending clarification of the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched under substance evaluation be concluded.

With regards to the PBT/vPvB concern, the eMSCA will consider the need for any follow-up regulatory action(s) at EU level for 1-(2-hydroxy-5- nonylphenyl)-, oxime, branched once the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched has been clarified.

The eMSCA will conclude on the need for harmonised classification for reproduction toxicity, once the evaluation of the constituent (Phenol, 4-nonyl-, branched) has been concluded.

Table 2. Follow-up

FOLLOW-UP		
Follow-up action	**Date for intention**	**Actor**
Annex XV dossier for restrictions	*To be decided*	*To be decided*
Harmonised Classification and Labelling	*To be decided*	*To be decided*
Identification as SVHC (authorisation)	*To be decided*	*To be decided*

Part B. Substance evaluation

7. EVALUATION REPORT

7.1. Overview of the substance evaluation performed

1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime was originally selected for substance evaluation in order to clarify concerns about:

- the environment (suspected PBT) and,

- exposure (high aggregated tonnage)

During the evaluation also other concern was identified. The additional concern was:

- Endocrine disruption

- Reproductive toxicity

- Aquatic toxicity

Table 3. Evaluated endpoints

EVALUATED ENDPOINTS	
Endpoint evaluated	**Outcome/conclusion**
Suspected PBT	Concern under evaluation. See further information on section 7.2
Environmental exposure (high aggregated tonnage)	Concern not substantiated. No further action needed.
Endocrine disruption	Concern substantiated. Need for follow-up regulatory action at EU level
Reproductive toxicity	Concern substantiated. Need for follow-up regulatory action at EU level

7.2. Procedure

The substance was selected as a candidate CoRAP substance based on its low water solubility (<0.1 mg/L) and potential to fulfil the Toxicity and Persistance criteria. The measured Log Kow is 4.8 and there were concerns regarding the Bioaccumulation potential. Furthermore, environmental fresh and marine water exposure was also indicated. STP effluents are released directly to the marine compartment while fresh water emissions are released only during the wet season.

- The updated Community Rolling Action Plan (CoRAP) was published on the ECHA website on 26 March 2014.

- The substance was included in the CoRAP for the substance evaluation to be evaluated in 2015 for these environmental concerns by the Competent Authority of Spain.

- In the course of the evalution,

- The evaluating MSCA noted that one constituent (4-nonyl phenol branched; CAS: 84852-15-3; EC: 284-325-5) (4-NP) was listed on the CoRAP for suspected PBT concerns and would be evaluated by another MS (UK) in 2014. Threrefore, the evaluating MSCA decided to wait for the outcome of the UK's evaluation of 4-nonyl phenol branched, before concluding on the suspected PBT concern for the substance subject to this SEv report.
- 4-NP poses environmental endocrine disrupting properties in fish.
- The substance is claimed for classification as Repro 1B for all the notifiers. This issue, which is relevant for the environmental T criterion, may require harmonised classification.
- An environmental exposure assessment was performed, which resulted in RCRs <1 for all environmental compartments.
- On 3th December 2015, Registrant agreed on the need to provide additional information on the non-specified constituents, which pose a wide range of concentrations. On 25 January 2016 additional information on the identification of the non-specified constituents was provided by the Registrant(s), in the form of a dossier update.

- During the evaluation period the Registrant(s) provided additional information to further clarify the identied concerns.

7.3. Identity of the substance

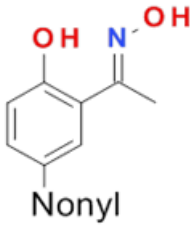
The following identifiers are considered for 1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime.

Table 4. Substance identity

SUBSTANCE IDENTITY	
Public name:	1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime
EC number:	627-083-1
CAS number:	244235-47-0
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$C_{17}H_{27}NO_2$
Molecular weight range:	≥ 220.0 – 291.0
Synonyms:	Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched

Type of substance ☐ Mono-constituent ☐ Multi-constituent ■ UVCB

Structural formula:



UVCB substance

As the substance contains one main constituent with typically higher than 80% summarized over all isomers, is seems to be more feasible to refer to this constituent as identifier. Composition of the substance is included in **Table 5**.

No additives are present.

Table 5*. Substance composition*. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

Constituent **5 Constituents**	**Typical concentration**	**Concentration range**	**Remarks**
Ethanone, 1-(2-hydroxy-5-nonylphen yl)-, oxime, branched (main component) CAS nº 244235-47-0; EC nº 627-083-1	*	*	*
Phenol, 4-nonyl-, branched CAS nº 84852-15-3; EC nº 284-325-5	*	*	*
Ethanone, 1-(2-hydroxy-5-decylphenyl)-, oxime, branched CAS -; EC -	*	*	*
Phenol CAS nº 108-95-2 EC nº 203-632-7	*	*	*
2-ethylhexanoic acid CAS nº 149-57-5 EC nº 205-743-6	*	*	*
non-specified constituents	*	*	*

* Confidential information. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

7.4. Physico-chemical properties

A summary of the relevant physicochemical properties of the UVCB substance are included in Table 6. These values have been used by the eMSCA in this assessment.

Table 6. Relevant physicochemical properties

OVERVIEW OF PHYSICOCHEMICAL PROPERTIES	
Property	**Value**
Physical state at 20°C and 101.3 kPa	viscous liquid
Melting / freezing point	-27°C glass transition temperature
Boiling point	decomposes at ≥234°C before boiling
Vapour pressure	≤1.5 Pa at 20°C. The vapour pressure was estimated using Grain-Watson method.
Water solubility	> 0.02 < 0.1 mg/L at 20°C at pH 6.9
Partition coefficient n-octanol/water (Log Kow)	log Pow 1= 4.8 at 25°C logPow 2= ≥5.7 at 25°C (of two main peaks)

7.5. Manufacture and uses

7.5.1. Quantities

The aggregated tonnage band registered for 1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime is considered as confidential information.

Table 7. Aggregated tonnage

AGGREGATED TONNAGE (PER YEAR)				
☐ 1 – 10 t	☐ 10 – 100 t	☐ 100 – 1000 t	☐ 1000- 10,000 t	☐ 10,000-50,000 t
☐ 50,000 – 100,000 t	☐ 100,000 – 500,000 t	☐ 500,000 – 1000,000 t	☐ > 1000,000 t	☒ Confidential

7.5.2. Overview of uses

This substance is used as extraction agent and in the manufacture of metals.

Release to the environment is likely to occur from industrial use in the manufacturing of the substance, formulation of mixtures and of substances in closed systems with minimal release.

ECHA has no registered data indicating the type of article into which the substance has been processed.

7.6. Classification and Labelling

7.6.1. Harmonised Classification (Annex VI of CLP)

No agreed/harmonised classification is reported as included in Annex VI of the CLP Regulation (EC) No 1272/2008).

7.6.2. Self-classification

Registrants present the following classification and hazard classess according to EU-GHS

- Classification according to CLP / GHS for physicochemical properties

None.

- Classification according to CLP / GHS for health hazards

Skin Irrit. 2

Eye Irrit. 2

Skin Sens. 1

Repr. 1B;

- Classification according to CLP / GHS for environmental hazards

Aquatic Acute 1, M-Factor acute: 1
Aquatic Chronic 1, M-Factor chronic: 10

Labelling
Signal word: Danger

Hazard pictograms:

GHS07: exclamation mark	
GHS08: health hazard	
GHS09: environment	

Hazard statements:

H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H360: May damage fertility or the unborn child <state specific effect if known > <state route of exposure if it isconclusively proven that no other routes of exposure cause the hazard>.
H410: Very toxic to aquatic life with long lasting effects.

7.7. Environmental fate properties

Only relevant information on fate properties, agreed by the eMSCA and relevant for this assessment, has been compiled in this report. A summary of the information on persistency is included in Table 8.

Table 8. Summary of degradation properties.

	COMPONENTS				**READ-ACROSS SUBS**
	C9 Ketoxime (**main component**) **(A)**	C10 Ketoxime **(B)**	4-Nonyl phenol branched **(C)**	Non especified constituents	Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched **(D)**
Abiotic degradation					
Hydrolysis	Not relevant		Not relevant		Not relevant
Photolysis DT50 (h)	6.42 (QSAR)	-	Not relevant		2.5 (QSAR)
Biotic degradation					
OECD 301	**Not Ready B** 301D: c.a1% after 28 d		Ready not fulfilling 10d-w Biphasic degradation		-
OECD 302	**Not inherent** 302C: 0% after 28 d		Potential Inherent (based on 301 biphasic degradation)		Not inherent 302C: 0% after 28 d
OECD 309			(Ekelund equivalent to 309)* 46% after 8w (sed) 50% after 58 d (seawater)		

7.7.1. Assessment of Read-Across

Main properties of the identified components of 1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime are included in **Error! Reference source not found.**. Additionally, further refinement of the QSARs, with regard to the ketoxime and benzaldehyde substructures has been performed for the consideration on the acceptability of the proposed read-across approach (Table 9).

Table 9. Properties of the identified components.

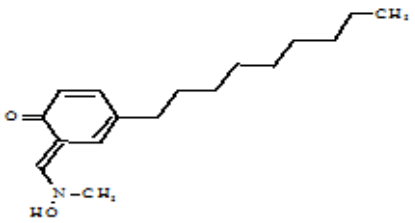
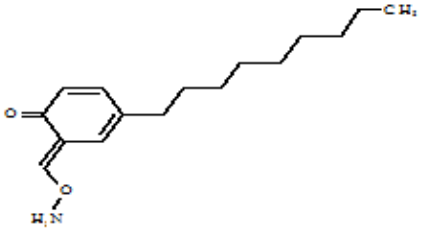
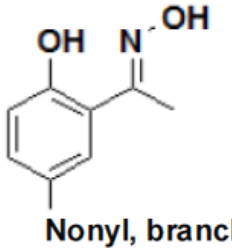
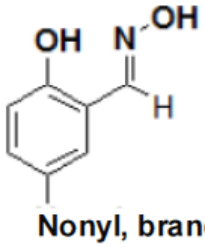
	COMPONENTS				READ-ACROSS SUBS
	C9 Ketoxime* **(main comp) (A)**	C10 Ketoxime** **(B)**	4-Nonyl phenol branched **(C)**	Non especified consts **(D)**	Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched **(E)**
EC	627-083-1		284-325-5		605-717-8
CAS	244235-47-0		84852-15-3		174333-80-3
Typical conc.	Main	low	relevant	relevant	-
Mol weight	220-291		220.34		251.36
VP	≤1.5		0,3		0,37
Log Pow	4.8 and ≥ 5.7		4.48		5.5
WS (mg/L)	0.02-0.1		6		0.4
Log Koc	3.9		4.35-5.69		3.7
SMILES	CCCCCCCCCC1=CC(=CN(C)O)C(=O)C=C1		Oc1ccccc1CCCCCCCCC		CCCCCCCCCC1=CC(=CON)C(=O)C=C1

* C9 Ketoxime: Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched (main component)
****** C10 Ketoxime: Ethanone, 1-(2-hydroxy-5-decylphenyl)-, oxime, branched

The substance Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched (CAS 174333-80-3; EC 605-717-8) has been considered to be appropriate for the read-across approach. The only structural difference between the source substance and the target substance is the lack of a ketoxime group at the phenol ring of the molecule. The read across substance Benzaldehyde, 5-nonyl-2-hydroxy, oxime, branched, lacks a methyl group at the oxime carbon atom. There are no scientific reasons to believe that the additional methyl group at the oxime carbon atom in Ethanone, 1-(2-hydroxy-5-nonylphenyl)-, oxime, branched will significantly differentiate the behaviour and fate of the read across substance (see Table 10). Ecotoxicity values estimated for the read-across substance will cover the expected toxicity of Ketoxime.

Table 10. Properties of the substructures.

	Ketoxime	**Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched**
EC	627-083-1	605-717-8

Structure		
Sub-structure	 Nonyl, branched	 Nonyl, branched
	CC1=CC(=CN(C)O)C(=O)C=C1	CC1=CC(=CON)C(=O)C=C1
MW	165.19	151.17
Water Sol (mg/L)	2.519e+004	2.18e+004
Log Pow	0.48	0.63
Ready Biodeg	No	No
Bioconcent.	3.16	3.16
Toxicity (mg/L)	31.5[a] 2.185[b] 10.80[c]	0.014[d] 0.076[e] -

[a] chronic toxicity on fish (aliphatic amines); [b] chronic on daphanids (aliphatic amines); c chronic toxicity on algae (aliphatic amines); [d] chronic on fish (oxyamines); [e] chronic toxicity on daphnis (oxyamines)

The read across is justified by similarity of structure and functional groups and accordingly similar physico-chemical properties, which is expected to result in similar environmental behavior and fate. **Error! Reference source not found.**

Additionally, 4-nonyl phenol branched is a relevant constituent of the substance and a substructure of 1-(2-Hydroxy-5-nonyl(branched)-phenyl)ethanone oxime. Therefore, similar fate and behaviour properties are expected to be predicted from 4-nonyl phenol branched as read-across substance.

7.7.2. Degradation

Abiotic degradation

Hydrolysis: Data waived as the substance is insoluble in water.

Photolysis: No experimental studies investigating the phototransformation in air of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) are available. Thus, phototransformation in air was calculated for the substance to register and the relevant impurity Phenol, 4-nonyl-, branched (CAS 84852-15-3) using AOPWIN v1.92. The results indicate that Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched as well as Phenol, 4-nonyl-, branched are susceptible to indirect photodegradation in air. The estimated half-life for the reaction with OH-radicals is 6.42 h and 7.48 h, respectively (24 h day; OH-concentration: 0.5E+06 OH/cm³).

Summary: Photolysis is considered to be negligible, since the test substance is not expected to be present in the atmosphere to a significant degree due to its relatively low vapour pressure under ambient conditions (< 1.5 Pa at 20 °C).

Biotic degradation

Biodegradation in water: One test (OECD 301D) investigating the ready biodegradability of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) is available. According to the ECHA website, the characterisation of the test substance should be 89% OXM Ethanone, 1-(2-hydroxy-5-tert-nonylphenyl)-11% tert-Nonylphenol. The test was performed according to GLP and ISO guideline 10708 (BOD adapted to insoluble test substances) using non-adapted activated sludge as inoculum (Report R9600597 from ECHA website, study from 1996). Only 1% biodegradation was observed in a test period of 28 days (based on oxygen consumption). Thus, the test substance is considered as not readily biodegradable.

An inherent biodegradation study (OECD 302C) with the test substance Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched (EC 605-717-8; CAS 174333-80-3) was performed according to GLP using non-adapted activated sludge as inoculum (ECHA website, study from 2007). The biochemical oxygen demand (BOD) of the test substance in the test media was in the normal range found for the inoculum controls. Consequently, the test substance was not inherently biodegradable under the test conditions within 28 days. Based on the high structural similarity, which leads to similar behavior in the environment (as explained at section 7.7.1.), this conclusion can also considered to be true for Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0).

In addition, several screening tests for 4-nonylphenol are available. In general, these tests show that 4-nonylphenol is not readily biodegradable according to OECD criteria (MITI 2002, Huels 1996 a,b in EU RAR, 2002). Degradation is observed if adapted inoculum was used (Staples et al. 1999, in EU RAR 2002) indicating 4-nonylphenol to be inherently biodegradable. However, the degradation potential is depending on several factors, such as the branching of the alkyl chain (see Corvini et al. 2006). Additional information on these studies can be found on the ECHA dissemination webpage.

Biodegradation in sediments: No information for the substance is available in the registration dossier. Branched nonylphenol is considered to be inherently biodegradable in marine water and sediment.

Biodegradation in soil: In soil, branched nonylphenol is rapidly integrated into organic matter, such as humin, but slowly mineralized.

Summary: The substance is considered as not readily biodegradable. Therefore, in order to apply a very conservative approach, persistence of the substance is assumed in the environment.

Concerns regarding the potential persistency of 4-nonyl phenol branched will be concluded by the evaluating MSCA (UK) as part of their substance evaluation. Consequently, the UK's conclusion on the persistency of 4-nonyl phenol branched will be

used to conclude on the potential persistency of Ethanone, 1-(2-hydroxy-5- nonylphenyl) -, oxime, branched, once this is available.

7.7.3. Environmental distribution

Adsorption/desorption: One study (OECD 121), performed according to GLP, investigating the adsorption potential of Ethanone, 1-(2-hydroxy-5- nonylphenyl) -, oxime, branched (CAS 244235-47-0) is available (ECHA website, study from 2010). The log Koc value at 25 °C is determined to be 3.9 (Koc = 7943.3). This value indicate that the substance exhibits potential for adsorption to organic soil and sediment particles. For additional information on this study see the ECHA dissemination website.

Volatilization: The substance is not expected to volatilize to a significant degree based on its relatively low vapour pressure under ambient conditions (< 1.5 Pa at 20 °C).

Distribution model: The following levels have been estimated by using the EPIWIN programme (Table 11). Levels in air are expected to be negligible based on its relatively low vapour pressure under ambient conditions (< 1.5 Pa at 20 °C). The substance exhibits potential for adsorption to organic soil and sediment particles.

Table 11. Environamental distribution

	C9 Ketoxime	4-NP branched
air	0.0784	0.177
Water	19.7	13.3
Soil	73.4	67.6
Sediment	6.79	18.9

7.7.4. Bioaccumulation

Relevant information for the bioaccumulation assessment is summarized in Table 12.

Table 12. Summary of the information on bioaccumulation

	COMPONENTS	READ-ACROSS SUBS

	C9 Ketoxime* (**main component**) **(A)**	C10 Ketoxime** **(B)**	4-Nonyl phenol branched **(C)**	Non especified constituents	Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched **(D)**
QSARs			Not B; BCF 1280		
Measured			Fish BCF 741 – 1300 Mussels BCF 2.500		
OECD 305	**Not B, based on D?**				Not B (Aqueous exposure) BCF 280 (normalised lipid and growth rates)
BMF			1.15 – 1.51		

There is no study for assessing the bioaccumulation potential of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) available, therefore information from the read-across to the structurally related source substance Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched (CAS 174333-80-3) has been considered in the assessment (see section 7.7.1.).

The bioaccumulation study (OECD 305) with Benzaldehyde,2-hydroxy-5-nonyl, oxime, branched (CAS 174333-80-3) was performed according to GLP using Oncorhynchus mykiss as test organism. The fish were exposed for 4 weeks followed by a three week depuration period. Test substance concentrations of 7 and 35 µg/L were used. Based on whole body weight and total fat and assuming steady state, for both concentrations a plateau was reached after 6 days. The BCF is determined to be 138 and 159, respectively. Higher value is considered for the Assessment, that after lipid and growth normalization results in a BCF of 280.

This value is in agreement with QSAR estimations BCF of 393 (EPIWIN 4.10)

Summary: Based on reliable experimental data for a structurally similar substance used in a read across approach, it can be concluded that Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) has low potential for bioaccumulation and biomagnification via the food chain (BCF of 280).

Concerns regarding the PBT potential of 4-nonyl phenol branched will be clarified by the evaluating MSCA (UK) as part of their substance evaluation. Consequently, the UK's conclusion on 4-nonyl phenol branched will be used to conclude on the bioaccumulation potential of Ethanone, 1-(2-hydroxy-5- nonylphenyl) -, oxime, branched, once this is available.

7.8. Environmental hazard assessment

Only relevant information for the environmental hazard assessment, agreed by the eMSCA and relevant for this assessment has been compiled in this report. Additional information on this substance can be found within the bibliography or at the ECHA dissemination website.

The substance Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched (CAS 174333-80-3; EC 605-717-8) has been considered to be appropriate as a read-across approach. The only structural difference between the source substance and the target substance is the lack of a ketoxime group at the phenol ring of the molecule. Therefore, the read across is justified by similarity of structure and functional groups and accordingly similar physico-chemical properties, which is expected to result in similar environmental behavior and fate (see section 7.7.1.). **Error! Reference source not found.**

This environmental hazard assessment, is based on the effects of the identified components, in accordance with REACH guidance.

7.8.1. Aquatic compartment (including sediment)

GLP guideline studies evaluating the **short-term** toxicity of Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime,branched (CAS 244235-47-0) to three trophic levels (fish, invertebrates, algae) are available. The test results indicate that the test substance is acutely very toxic to aquatic organisms and that fish are more sensitive than algae and invertebrates.

Long-term tests evaluating the acute toxicity of Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched (CAS 244235-47-0) to invertebrates and algae are available. Since no study assessing the long-term toxicity of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) to fish is available, in accordance to Regulation (EC) No. 1907/2006 Annex XI, 1.5 Grouping of substances, a read-across to 4-nonylphenol was conducted, which is a secondary component and structurally similar to the main component of the substance. The only structural difference between the source substance and the target substance is the lack of a ketoxime group at the phenol ring of the molecule (see section 7.7.1. for additional information).

Based on the results of the OECD 209 study, it can be concluded that the test substance does not have any effect on microbial community in STPs and is not expected to inhibit the degradation process.

Endocrine mode of action

No study is available focusing on potential effects of Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched (CAS 244235-47-0) based on an endocrine mode of action. However, various studies are available assuming endocrine disrupting effects of 4-nonylphenol in fish and invertebrates (see ECHA 2012, SVHC Support Document). In general, effects occur in the range of 1 to 10 µg/L. Thus, the PNEC value derived for freshwater and marine water on the basis of a long-term toxicity fish test with 4-nonylphenol has been considered to cover effects related to this specific mode of action.

Table 13 summarises the relevant information on ecotoxicity taken into account in this assement.

Table 13. Summary of the ecotoxicity data (mg/l).

	COMPONENTS				**READ-ACROSS SUBS**
	C9 Ketoxime* (**main component**) **(A)**	C10 Ketoxime** **(B)**	4-Nonyl phenol branched **(C)**	Non especified constituents	Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched **(D)**
Short-term toxicity					
OECD 203 (96h LC50 on Fish)	0.46		0.05 – 0.22*		1.1
OECD 202 (48h EC50 on Invertebrates)	9.55		0.08 – 0.14		2.7
OECD 201 (72h EC50 on algae)	760		0.33 – 1.3		36.3
Long-term					
ASTM 1241-05 (91d NOEC on fish)			0.006		-
OECD 211 (72h NOEC on invertebrates)	2.8		0.024 – 0.116		0.189
OECD 201 (72h NOEC on algae)	472		0.5**		14.9
OECD 209 (3h EC50 on microorganisms)	260.1		950		200.4
CMR			Reprotox		

7.8.1.1. Fish

Short-term

One study investigating the short-term toxicity of the substance to freshwater fish is available. The study was performed according to EU Method C.1 under GLP conditions (ECHA website, study from 1995). In a semi-static study Brachydanio rerio was exposed to the test substance for 96 h. The test material was applied directly, i. e. without solvent. Analytical monitoring was performed. All validity criteria were fulfilled. An **96h-LC50 of 0.46 mg/L** is determined based on measured concentrations.

Long-term

No study is avalilable for assessing the long-term toxicity of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) to fish. Therefore, a read-across to nonylphenol was conducted, which is a secondary component and structurally similar to the main component of the substance. For read-across justification see section 7.7.1.

The available study investigated the long-term toxicity of **nonylphenol** to early life stage of rainbow trout (Oncorhynchus mykiss) under flow through conditions (Spehar et al. 2010). The study was performed according to ASTM guideline E 1241-05 over an exposure time of 91 days. 100 fertilized eggs per test concentration were exposed to measured concentrations of 6.0, 10.3, 23.1, 53.0 and 114 µg/L nonylphenol. The test system was maintained at ~ 11 ºC and a pH of 6.97. Mean percent hatch of any test concentration was not significantly different from controls. Time to hatch was 39 ± 5 days with swim-up at approximately day 45. The most sensitive end point was growth. The **91-day NOEC value of 6.0 µg/L**, based on sublethal effects (growth measured by mean standard length, wet weight and dry weight) is determined.

7.8.1.2. Aquatic invertebrates

Short-term

One study investigating the short-term toxicity of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched to aquatic invertebrates is available. The study was performed according to GLP and OECD guideline 202 using Daphnia magna as test organism (ECHA website, study from 2010). Loading rate WAFs between 2.5 and 40 mg/L were tested. Analytical monitoring was performed but showed that recovery of test substance was very low using LC-MS analysis. Thus, effects were attributed to the nominal concentration. All validity criteria were fulfilled. The **48h-EC50 of 9.55 mg/L** is determined based on nominal concentrations.

Long-term

One study investigating the long-term toxicity (OECD 211) under GLP conditions of the **registered substance** to aquatic invertebrates is available (ECHA website, study from 2010). Analytical purity of the test substance was 95% (83% of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched + 12% Phenol, 4-nonyl-, branched). Test solutions ranging from 0.18 to 7.0 mg/L were prepared by direct adding of the test substance to the test medium, 24h stirring and subsequent filtering. The test organisms were exposed for 21 days under semi-static conditions. As the analytical measurements were not reproducible (probably due to low water solubility and hydrolysis), nominal concentrations were reported. All validity criteria (no immobilised Daphnia in control group with a mean offspring of 104 (> 60) and a variation of CV=7.3%) were met. No significant immobility was observed, while effects on reproduction rate of Daphnia magna were observed at nominal 7.0 mg/L. Thus, a **21d-NOECr of 2.8 mg/L** loading rate WAF value was obtained for reproduction and is determined.

7.8.1.3. Algae and aquatic plants

One study investigating the toxicity of the **registered substance** to freshwater algae (OECD 201) under GLP conditions is available. The study was performed according to GLP and OECD guideline 201 using Desmodesmus subspicatus as test organism (ECHA

webstie, study from 2010). As the substance is practically not water soluble, test solutions were prepared by adding 6.25, 12.5, 25, 50 and 100 mg into 1000 mL culture medium, stirring for 24h and filtering. As a result, test substance preparations were clear solutions. After 72h under static conditions, only low effects (yield and biomass) were observed for the highest concentration (yield: 5.1% and growth rate: 1% inhibition). Thus, the EC50 and EL10 value for growth rate and biomass is determined to be > 100 mg/L loading rate WAF (**EC50/LC50 for freshwater algae: 760.7 mg/L**). Extrapolating the observed effects, a growth rate **72h-EC10 of 472.2 mg/L** (nominal) is calculated for the test substance to algae.

7.8.1.4. Sediment organisms

Since no study assessing the long-term toxicity of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) to sediment organisms is available, a read-across to Phenol, 4 -nonyl-, branched was conducted. The only structural difference between the source substance and the target substance is the lack of a ketoxime group at the phenol ring of the molecule (see section 7.7.1).

A second study investigated the 28-day long-term toxicity of **4-nonylphenol** to **Chironomus riparius** under semi-static conditions (Bettinetti and Provini 2002). Chironomids were exposed to nonylphenol at nominal concentrations of 270 to 1100 mg/kg sediment dw. The sublethal effects assessed included emergence and egg production. The most sensitive endpoint was emergence. The lowest **28-day EC10 of 203 mg/kg dw** is determined.

A 28-day long-term toxicity test of **4-nonylphenol** to the **marine benthic crustacean**, Leptocheirus plumulosus was performed under static conditions (Zulkosky et al. 2002). Crustaceans were exposed to control and 4-nonylphenol at average measured concentrations of 2.1, 4.5, 10.5, 27.2 and 61.5 mg/kg dw. A significant negative correlation ($p < 0.034$) was observed between 4 -nonylphenol sediment concentration and the number of young produced per female, but it explained only 12% of the variance. Reproductive output in animals exposed to 61.5 mg/g NP was reduced by 40% of control values, but this difference was not statistically significant ($p = 0.299$). Thus, **28d-NOEC ≥ 61.5 mg/kg dw** based on reproduction and mortality is determined.

7.8.1.5. Other aquatic organisms

No data on other aquatic organisms.

7.8.2. Terrestrial compartment

In a long-term toxicity test performed similar to OECD guideline 217, **soil microbes** were incubated with 100 and 1000 ppm branched **4-nonylphenol** over an exposure time of 40 days (Trocme et al. 1988). An aged mixture of sewage sludge compost and sandstone was used as inoculum. Respiration (CO_2 evolution) was recorded daily throughout the test period. Respiration started at the same rate (37 µg C/g organic C per h) in control and treatments. The rates then decreased progressively, indicating depletion of easily mineralizable C and N. CO_2 evolution did not differ significantly between the 100 ppm samples and the controls. In contrast, in 1000 ppm samples, CO_2 evolution was significantly depressed by the 4th day. Thus, the **40d-NOEC of 100 mg/kg** dw is determined.

The toxicity of **4-nonylphenol** to terrestrial plants was investigated according to OECD guideline 208 using L. perenne and B. rapa as test organisms (Domene et al. 2009). Artificial soil according to OECD guideline was used. Germination and biomass production was recorded after an exposure time of 15 days. Fresh weight was found to be a more sensitive endpoint than germination. However, all **15d-EC50 value showed to be > 574 mg/kg**, which is not considered as toxic according to OECD criteria.

The effect of increasing 4-nonylphenol concentrations (0, 10, 30, 90, and 270 mg/kg) **in soil microcosms** containing a simplified soil community was investigated over three sampling dates (28, 56, and 112 days) using the principal response curves method (Domene et al. 2010). The soil community did not change significantly at concentrations below 90 mg/kg, which was selected as the non-observed effect concentration (NOEC). The highest concentration (**270 mg/kg) changed the community significantly after 28** and 56 days, but this effect disappeared after 112 days.

7.8.3. Microbiological activity in sewage treatment systems

One study investigating the toxicity of test substance (analytical purity: 95% (83% + 12% Phenol, 4-nonyl-, branched) to aquatic microorganisms is available. The study was performed according to GLP and OECD guideline 209 (ECHA website, study from 2010). In a static study domestic activated sludge was exposed for 3h. The test material was applied directly to the test vessels. Analytical monitoring was not performed. All validity criteria were fulfilled. The **3h-EC50 is determined to be > 1000 mg/L**, while the respective **3h-EC10 value is determined to be 260.1 mg/L** based on the nominal concentration.

7.8.4. PNEC derivation and other hazard conclusions

Table 14. PNECs derivations

PNEC DERIVATION AND OTHER HAZARD CONCLUSIONS		
Hazard assessment conclusion for the environment compartment	**Hazard conclusion**	**Remarks/Justification**
Freshwater	Hazard assessment conclusion (freshwater): PNEC value of 0.0006 mg/L	Assessment factor: 10
Marine water	Hazard assessment conclusion (marine waters): PNEC value of 0.00006 mg/L	Assessment factor: 100
Intermittent releases to water	No intermittent releases are expected (releases time per year between 350-365 days for all the registered uses/processes)	
Sediments (freshwater)	Hazard assessment conclusion (sediment freshwater): PNEC value of 2.03 mg/Kg sediment dw	Assessment factor: 100
Sediments (marine water)	Hazard assessment conclusion	Assessment factor: 1000

	(sediment marine water): PNEC value of 0.0615 mg/Kg sediment dw	
Sewage treatment plant	Hazard assessment conclusion (STP): PNEC value of 2.6 mg/L	Assessment factor: 100
Soil	Hazard assessment conclusion (soil): PNEC value of 27 mg/Kg soil dw	Assessment factor: 10

7.8.5. Conclusions for classification and labelling

Only considerations about C&L for the environment have been included.

Short-term and long-term toxicity tests results are available for the substance or read-across substance on freshwater fish, invertebrates and algae. Therefore, taking into account the toxicity information and not ready biodegradability, the following conclusions are considered for classification and labelling:

H410: Very toxic to aquatic life with long lasting effects.

Based on the available data, the substance poses endocrine disruption properites for fish based on the presence on 4-nonyl phenol branched. Therefore it should be taken into account for its consideration under article 57(f) of the REACH Regulation.

7.9. Human Health hazard assessment

In connection with the environmental concern suspected PBT, , relevant information in the assessment "T" criterion has been taken into account. The substance poses endocrine disruption properites in fish due to the presence of 4-nonyl phenol branched and therefore should be classified as T based on endocrine disruption.

7.9.1. Toxicokinetics

No relevant information is available.

Absorption

Oral route:
Regarding to the log Pow of 4.8 and >5.7, the substance is very lipophilic.

Inhalation route:
The substance appears in the liquid form but based on the very low vapour pressure, inhalation exposure under normal use conditions is unlikely.
Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched is not considered to bioaccumulate based on data obtained in a BCF study. No information on mammals is available.

7.9.2. Acute toxicity and Corrosion/Irritation

Not evaluated.

7.9.3. Sensitisation

Not evaluated.

7.9.4. Repeated dose toxicity

Not evaluated.

As the NOAEL of 150 mg/kg bodyweight/day (ECHA website) is higher than the guidance value of 100 mg/kg bodyweight/day as specified in Regulation (EC) No. 1272/2008, the registered substance does not have to be classified with regard to specific target organ toxicity — repeated exposure.

7.9.5. Mutagenicity

No evaluation of the mutagenic studies has been performed.

However, according to the public information at the ECHA website, it can be stated that under the experimental conditions reported, the registered substance, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched, did not induce structural chromosome aberrations in V79 cells (Chinese hamster cell line) when tested up to the cytotoxic or highest evaluable concentrations (according to OECD Test Guideline 473).

Based on the results in a scientific publication, for which a test similar to OECD Test Guideline 471 was performed, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched is considered not to be mutagenic. Similar result was obtained with a OECD Test Guideline 476 performed for the registered substance under certified GLP conditions.

Considering information for the read across substances, based on the results of a study according to OECD Test Guideline 471 under GLP, Benzaldehyde, 2-hydroxy-5-nonyl, oxime, branched, is not considered to be mutagenic.

7.9.6. Carcinogenicity

No information is available.

7.9.7. Toxicity to reproduction (effects on fertility and developmental toxicity)

No information is available.

According to the ECHA website, the registered substance, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched has notified classification and labelling according to CLP criteria claims for toxic to reproduction with Cat. 1B Fertility and Development (H360) classification.

4-nonylphenol branched, which is a relevant constituent of the registered substance, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched, is classified as Repro 2 – H361fd (index number: 601-053-00-8).

No information is available regarding reprotoxic effects of Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched in mammals, but it may be considered for harmonised classification based on the presence of 4-nonyl phenol branched as a relevant constituent and potentially classified as Repro 2 - H361fd. The eMSCA will conclude on the need for harmonised classification for reproduction toxicity, once the evaluation of the constituent (Phenol, 4-nonyl-, branched) has been concluded.

7.9.8. Hazard assessment of physico-chemical properties

Not evaluated.

7.9.9. Selection of the critical DNEL(s)/DMEL(s) and/or qualitative/semi-quantitative descriptors for critical health effects

Not evaluated.

7.9.10. Conclusions of the human health hazard assessment and related classification and labelling

According to the ECHA website, the registered substance, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched has notified classification and labelling according to CLP criteria claims for a classification as toxic to reproduction with Cat. 1B Fertility and Development (H360).
4-nonylphenol branched, which is a relevant constituent of the registered substance, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched, is classified as Repro 2 – H361fd (index number: 601-053-00-8).
However, no information is available regarding reprotoxic effects of Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched in mammals. Harmonised classification for reproduction toxicity should be considered based on the presence of 4-nonyl phenol branched and other similar constituents of the registered substance. The eMSCA will conclude on the need for harmonised classification for reproduction toxicity, once the evaluation of the constituent (Phenol, 4-nonyl-, branched) has been concluded.

7.10. Assessment of endocrine disrupting (ED) properties

The concern for the endocrine disrupting effects of Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched refers only to the environment based on the endocrine disrupting effects in fish of 4-nonyl-, branched (4-NP) (EC 284-325-5), as a relevant constituent.

7.10.1. Endocrine disruption – Environment

The registered substance contains 4-NP in relevant concentration. 4-NP is an SVHC due to environmental endocrine disrupting properties in fish. 4-NP is on the REACH Candidate List because of its environmental endocrine disrupting properties and is already subject to specific restrictions on its marketing and use under REACH Annex XVII. This substance is also on the Annex X list of priority substances (Decision 2455/2001/EC) under the Water Framework Directive 2000/60/EC (WFD).

Since the registered substance contains 4-nonyl phenol branched as a relevant constituent and it is likely that the registered substance has similar properties, considering classification and labelling reported by all notifiers. Based on the available information, is likely to pose environmental endocrine disruption properites for fish based on the presence on 4-nonyl phenol branched as relevant constituent.

7.10.2. Endocrine disruption - Human health

7.10.3. Conclusion on endocrine disrupting properties (combined/separate)

See the above section 7.10.1. According to the above rationale, Ethanone, 1-(2-hydroxy-5 nonylphenyl) -, oxime, branched should be taken into account for its consideration under article 57(f) of the REACH Regulation.

7.11. PBT and VPVB assessment

The PBT assesssment of Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched has been performed considering the different constituents of the substance.

Persistance
The substance is considered as not readily biodegradable. Therefore, in order to apply a very conservative approach, persistence of the substance is assumed in the environment.

Concerns regarding the potential persistency of the constituent 4-nonyl phenol branched, will be concluded by the evaluating MSCA (UK) as part of their substance evaluation.

Bioaccumulation
Based on reliable experimental data for a structurally similar substance used in a read across approach, it can be concluded that Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) has low potential for bioaccumulation and biomagnification via the food chain (BCF of 280).

Concerns regarding the bioaccumulation potential of the constituent 4-nonyl phenol branched, will be concluded by the evaluating MSCA (UK) as part of their substance evaluation.

Toxicity
Based on the long-term toxicity of the read across substance, nonylphenol, to early life stage of rainbow trout. The 91-day NOEC value of 6.0 µg/L, based on sublethal effects (growth measured by mean standard length, wet weight and dry weight) is determined.

Furthermore, the substance is claimed for classification as Repro 1B for all the notifiers. This issue, which is relevant for the environmental T criterion, may require harmonised classification.

According to this information the substance will fulfil the T criterion.

Overall
The eMSCA concludes that based on the available data Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (CAS 244235-47-0) is Persistant (P), not bioaccumulative (not B), and toxic (T).

However, Phenol, 4-nonyl-, branched (EC 284-325-5) which is a constituent of the substance and is present at concentrations relevant for PBT assessment. Uncertainties regarding B and P have been raised. Phenol, 4-nonyl-, branched is listed on the Community Rolling Action Plan (CoRAP) for evaluation by the UK in 2014, to clarify concerns related to 'Suspected PBT/vPvB', 'Consumer use', 'High (aggregated) tonnage', and 'Wide dispersive use'.

Consequently, the eMSCA considers that the suspected PBT/vPvB concern for the substance remains unverified pending clarification of the suspected PBT/vPvB concern for Phenol, 4-nonyl-, branched under substance evaluation to be concluded.

7.12. Exposure assessment

The RIP documents have been used for the assessment, but refinement has also been applied for the exposure assessment besed on ECETOC TRA v3, 2012 for environmental exposure assessment (ECETOC, 2012) and EUSES parameters (EC, 2003).

All deviations require mandatory justifications, which are documented in the Chemical Safety Report to assure full transparency of the calculations and underlying assumptions.

7.12.1. Human health

7.12.1.1. Worker

Not evaluated.

7.12.1.2. Consumer

Not evaluated.

7.12.2. Environment

Exposure scenarios have been calculated on the basis of the latest versions of the ECHA REACH Guidance chapters R12 (as of December 2015), R14, R15, and R16 (as of 2012) and the EUSES programme.

The uses and relevant descriptor codes for each identified use are summarised in Table 15.

Table 15. Overview on exposure scenarios and coverage of substance life cycle.

ES number	Volume (tonnes*)	Manufacture	Identified uses			Resulting life cycle stage		Sector of Use		Chemical Product Category (PC)	Process category (PROC)	Environmental Release Category (ERC)
			Formulation	Ind. Use	Consumer use	Service life (for articles)	Waste stage	Main user group (SU)	Sector of end uses (SU)			
ES 1	*	X		X					3		1,3,8B	1
ES 2	*		X	X					10		1,3,8B	2
ES 3	*			X					14		1,2,8B	7

* Confidential information. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

On the next sections are summarized the characteristics of the three exposure scenarios considered.

ES 1. MANUFACTURING

The exposure scenario is defined based on the conditions described by the only registrant and written in site-specific terms.

This exposure scenario covers the manufacture of the substance. Specific conditions also cover the ES2 (Formulation), since both processes are carried out at the same plant. According to registrant's information, Manufacture and use takes place in closed continuous processes.

Transfer of the substance (e.g. from vessels/tankers) takes place at dedicated facilities. The substance is also transferred into small containers for shipping, using a dedicated filling line.

Table 16. Duration, frequency and volume for Manufacturing. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

Information type	Generic scenario	Explanation
Used amount of substance per day	*	This is based on a specific production volume.
Annual amount used per site	*	This is based on a specific production volume.
Emission days per site	*	Specific number of days

* Confidential information. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

Environmental surrounding characteristics

Environmental surrounding characteristics are considered for both fresh water and marine water as follows:

Fresh water flow rate: 18,000 m^3/d (default value),

Municipal Sewage Treatment plant discharge: The effluents from the BASF plant are discharged into the municipal WWTP Carrigrennan Wastewater Treatment Plant. The flow rate of the Carrigrennan Wastewater Treatment Plant is 109,575,000 L/day. This results in a Local freshwater dilution factor of 1,164.

Marine water flow rate: A default dilution factor for discharges to a coastal zone (marine environment) of 100 is assumed to be representative for a realistic worst case.

Operational conditions

The floollowing specific characteristics are considered for the SpERC.

Release fraction to air from process	0%
Release fraction to wastewater from process	0.0001%
Release fraction to soil from process	0%
Fraction tonnage to region	100%
Fraction used at main source	100%

There is no direct discharge to freshwater compartment, since the STP discharges directly to the sea.

Risk management Measures

On Table 17 are summarized the Risk Management measures applied and their effectivity.

Table 17. Risk Management Measures applied for Manufacturing. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

Environmental compartment	Measure	Efectivity
Risk management measures (air)	Incineration	100%
Risk management measures (water)	Oil-Water Separation, Oxidation	99.99%
Risk management measures (soil)	Sealing of all relevant soil surfaces	100%

ES 2. FORMULATION

Manufacturing and formulation are carried out at the same plant with the same Environmental sourrounding chacharteristics, Operational conditions and Risk management Measures applied. Only a diferent Duration, frequency and volume is considered.

Table 18. Duration, frequency and volume for Formulation. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

Information type	Generic scenario	Explanation
Used amount of substance per day	*	This is based on a specific formulation volume.
Annual amount used per site	*	This is based on a specific formulation volume.
Emission days per site	*	Spacific number of days

* Confidential information. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

ES 3. USE IN EXTRACTION PROCESSES AT MINING.

This scenario contribute to the scenario Use in extraction processes at mining operations.

Table 19. Duration, frequency and volume for Use. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

Information type	Generic scenario	Explanation
Used amount of substance per day	*	This is based on a specific use volume.
Annual amount used per site	*	This is based on a specific use volume.
Emission days per site	*	Specific number of days

* Confidential information. Further confidential information is provided within a separate Annex that is not available in the published version of this report.

<u>Environmental surrounding characteristics</u>

Environmental surrounding characteristics are considered for both fresh water and marine water as follows:

Fresh water flow rate: 18,000 m^3/d (default value),

Municipal Sewage Treatment plant discharge: The effluents are discharged into a municipal WWTP with a flow rate of 2,000,000 L/day. This results in a default Local freshwater dilution factor 10.

Marine water flow rate: A default dilution factor for discharges to a coastal zone (marine environment) of 100 is assumed to be representative for a realistic worst case.

Operational conditions

The floollowing specific characteristics are considered for the SpERC.

Release fraction to air from process	0%
Release fraction to wastewater from process	0.0005%
Release fraction to soil from process	0%
Fraction tonnage to region	100%
Fraction used at main source	100%

Risk management Measures

On Table 20 are summarized the the Risk Management measures applied and their effectivity.

Table 20. Risk Management Measures applied for Use.

Environmental compartment	Measure	Efectivity
Risk management measures (air)	Fabric filter, Gas scrubber	100%
Risk management measures (water)	Nanofiltration (NR), Ultrafiltration (UF) or Reverse Osmosis (OR), Oil-Water Separation	99.99%
Risk management measures (soil)	Sealing of all relevant soil surfaces	100%

7.12.2.1. Aquatic compartment (incl. sediment)

In Table 21 are included the aquatic PECs calculated for ES1 (Manufacturing), ES2 (Formulation) and ES3 (Use) scenarios.

Table 21. PECs for the aquatic compostment and the different scenarios considered.

Protection target	ES1	ES2	ES3
Fresh Water (mg/L)	4.82E-05	8.31E-05	1.72E-04
Fresh Water sediment (mg/kgwwt)	3.47E-03	6.10E-03	1.24E-02
Marine Water (mg/L)	4.11E-06	4.51E-06	1.69E-05
Marine sediment (mg/kgwwwt)	2.96E-04	3.27E-04	1.22E-03
Sewage Treatment Plant (mg/L)	1.0E-06	4.36E-05	1.49E-03

It should be taken into account that there is no aquatic emissions from ES1 and ES2. Discharges go directly to the WWTP.

7.12.2.2. Terrestrial compartment

In
Table 22 are included the terrestrial PECs calculated for ES1 (Manufacturing), ES2 (Formulation) and ES3 (Use) scenarios.

Table 22. PECs for the terrestrial compostment and the different scenarios considered.

Protection target	ES1	ES2	ES3
Agricultural soil (mg/kgwwtL)	4.04E-04	2.28E-04	4.07E-03

7.12.2.3. Atmospheric compartment

Not relevant for this assessment.

7.12.3. Combined exposure assessment

As there is only one production and processing plant, the combined exposure assessment will be covered by the local assessment.

7.13. Risk characterisation

In Table 23 and Table 24 are presented the RCRs for the aquatic and terrestrial compartments, respectively and the scenarios referred.

Table 23. RCRs for the aquatic compartment and the different scenarios considered.

Protection target	ES1	ES2	ES3
Fresh Water	8.3E-02	1.4E-01	2.87E-01
Fresh Water sediment	1.71E-03	3.0E-03	6.11E-03
Marine Water	6.8E-02	7.5E-01	2.810E-01
Marine sediment	5.3E-03	8.4E-06	1.98E-02
Sewage Treatment Plant	3.85E-07	1.68E-05	5.74E-04

Table 24. RCRs for the terrestial compartment and the different scenarios considered.

Protection target	ES1	ES2	ES3
Agricultural soil	1.51E-05	8.43E-06	1.51E-04

7.14. References

Bettinetti R and Provini A. 2002. Toxicity of 4-nonylphenol to Tubifex tubifex and Chironomus riparius in 28-day whole-sediment tests. Ecotoxicol Environ Saf. 2002 Sep;53(1):113-21.

Domene, D; Ramírez, W; Solà, L; Alcañiz, JM and Andrés, P. 2009. Soil pollution by nonylphenol and nonylphenol ethoxylates and their effects to plants and invertebrates. J Soils Sediments (2009) 9:555–567

Domene, X; Chelinho, S and Sousa, JP. 2010. Effects of nonylphenol on a soil community using microcosms. Journal of Soils and Sediments. Volume 10, Issue 3, pp 556-567

ECETOC, 2012. ECETOC TRA v3: Background and rationale for the improvements. Technical Report nº 114. http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-114-ECETOC-TRA-v3-Background-rationale-for-the-improvements.pdf

EC, 2003. Technical Guidance Document on Risk Assessment. Part IV. Emission Scenarios. https://echa.europa.eu/documents/10162/16960216/tgdpart4_2ed_en.pdf

ECHA, 2012. Member State Committee. Support document for identification of 4-nonylphenol, branched and linear as Substances of Very High Concern because due to their endocrine disrupting properties they cause probable serious effects to the environment which give rise to an equivalent levels of concern to those of CMRs and PBTs/vPvBs. http://echa.europa.eu/documents/10162/3024c102-20c9-4973-8f4e-7fc1dd361e7d

ECHA website, 2016. Ethanone, 1-(2-hydroxy-5-nonylphenyl) -, oxime, branched (EC 627-083-1; CAS 244235-47-0). http://echa.europa.eu/information-on-chemicals

EU RAR 2002. 4-Nonylphenol (Branched) and nonylphenol CAS Nos: 84852-15-3 and 25154-52-3; EINECS Nos: 284-325-5 and 246-672-0. Summary Risk Assessment Report http://echa.europa.eu/documents/10162/6c460d8a-9f18-475f-823c-b8941e18fa3a

Trocmé M., Tarradellas J., Védy J-C. (1988). Biotoxicity and persistence of nonylphenol during incubation in a compost-sandstone mixture. Biol. Fertility Soils, 5, 299-303.

Zulkosky AM; Ferguson PLand McElroy AE. 2002. Effects of sewage-impacted sediment on reproduction in the benthic crustacean Leptocheirus plumulosus. Mar Environ Res. 2002 Sep-Dec;54(3-5):615-9.

7.15. Abbreviations

4-NP	Phenol, 4-nonyl-, branched (EC 284-325-5)
BCF	Bioconcentration factor
BMF	Biomagnification factor
BOD	Biological Oxygen Demand
CAS	Chemicals Abstract Service number

C&L	Classification and Labelling
CLP	Regulation (EC) 1272/2008 on the Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic and Reprotoxic
CoRAP	Community Rolling Action Plan
DT50	Disappearance Time 50% (Half-life)
EC	European Community number
eMSCA	evaluating Member State Competent Authority
ERC	Environmental Release Category
ES	Escenario
EU	European Union
GLP	Good laboratory Practices
ISO	International Organization for Standardization
MW	Molecular weight
PBT	Persistent, Bioacumulative, Toxic
PC	Production category
PEC	Predicted Environmental Concentration
PNEC	Predicted non-effect concentration
PROC	Process category
QSARs	Quantitative Structure-Activity relationships
REACH	Regulation 1907/2006 on Registration, Evaluation, Authorization and restriction of Chemicals.
RCR	Risk Characterization Ratio
RIP	REACH Implementation Projects
SpERC	Specific Environmental Release Category
SVHC	Substance of Very High Concern
UK	United Kingdom
VP	Vapour pressure
vPvB	very Persistent, very Bioaccumulative
WS	Water solubility