Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**Nonylphenol, branched, ethoxylated**
EC Number:	**500-209-1**
CAS Number:	**68412-54-4**
Authority:	**UK MSCA**
Date:	**22/03/2016**

Note

This document has been prepared by the evaluating Member State given in the CoRAP update

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1 IDENTITY OF THE SUBSTANCE

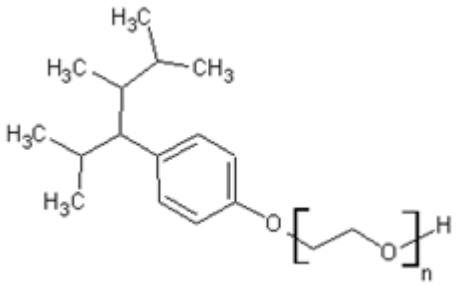
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Nonylphenol, branched, ethoxylated
IUPAC name (public):	-
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	UVCB
Molecular weight or molecular weight range:	UVCB
Synonyms:	-

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

Structural formula:



n = 1 - 2.5

Other relevant information about substance composition

The registered substance is a UVCB, primarily comprising mono- and di-ethoxylates (NP1EO and NP2EO). The alkyl chain has multiple branching patterns.

No relevant impurities identified in the registration (e.g. nonylphenol, NP).

1.2 Similar substances/grouping possibilities

None

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

When filling out this table and dealing with a substance for which the composition is of concern, please specify if each of the completed or ongoing processes is related to the substance as such or to the relevant constituent, impurity, additive or degradation (transformation) product/metabolite.

Table: Completed or ongoing processes

RMOA	☒ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☒ Compliance check, Terminated following dossier update after receipt of draft decision
		☒ Testing proposal – Terminated following dossier update after receipt of draft decision
		☒ CoRAP and Substance Evaluation – Screened for the CoRAP in round 2014-2016 for PBT concerns - not put forward.
	Authorisation	☒ Candidate List
		☒ Annex XIV
	Restri -ction	☒ Annex XVII – Entry 46
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☒ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	

(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)

The substance belongs to a group of substances called nonylphenol ethoxylates (NPEOs). The longer chain lengths are considered to be polymers for REACH purposes. NP (and by extension NPEOs) was assessed under the ESR by the UK, which lead to marketing and use restrictions for some applications (entry 46 in REACH Annex XVII).

NPEOs have already been subject to an RMOA under REACH by Sweden (targeted for textiles) and Germany. Consequently, Germany prepared an SVHC dossier to identify them as environmental endocrine disrupters (due to their ability to transform to NP) and they have been added to the Candidate List and are currently being prioritised for inclusion on Annex XIV. A restriction proposal for NPEO in textiles has also been submitted by Sweden.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

None

3.1.2 Self classification

- In the registration:

  Aquatic Acute 1 H400: Very toxic to aquatic life (M-factor: 1)

  Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects (M-factor: 10)

The basis for the environmental self-classification is not explained though might be based on NP.

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  Aquatic Chronic 2 H411

  Aquatic Chronic 3 H412

  M-factors are not always proposed for Aq. Ac./Ch. 1, or are different to those proposed by the registrants (e.g. chronic M-factor of 1).

There are thirty-six aggregated notifications on the CLP Inventory (checked 6 May 2015). The wide variation in proposals might reflect a number of chain lengths rather than the specific ones covered by the registration.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
Joint submission.		

4.2 Overview of uses

The substance has been registered for use as a flotation aid in mining applications. Manufacture and formulation seem to take place outside the UK at very few sites. There is no information about how or where the formulation(s) containing the substance is used in mines.[2]

NP1EO and NP2EO are nevertheless widely detected in surface waters due to the transformation of longer chain length NPEOs.

Table: Uses
Part 1:

☒Manufacture	☒ Formulation	☒ Industrial use	☐ Professional use	☐ Consumer use	☐ Article service life	☐ Closed system

[1] *Date when the dissemination site was accessed – 6 May 2015.*

[2] The information on the dissemination database does not include any additional use pattern information, so presumably the second registrant has similar ES.

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2. Selection criteria met (why the substance qualifies for being in CoRAP)

☐ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☒Fulfils criteria as potential endocrine disrupter

☐ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☒ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☐ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR ☐ C ☐ M ☐ R	☒ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser	
☐ PBT/vPvB	☐ Suspected PBT/vPvB	☒ Other (please specify below)
Exposure/risk based concerns		
☐ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☒ High (aggregated) tonnage	☐ Other (please specify below)
The substance is already on the Candidate List as an environmental endocrine disrupter since it is a source of nonylphenol. As it is likely that it will be added to Annex XIV for authorisation, there will be a sunset date for authorisation applications so exposure concerns do not need to be addressed in the Substance Evaluation. However, as the substance was included on the Candidate List because of hazards arising from nonylphenol only, applicants will not be obliged to consider the potential endocrine disrupting effects of the ethoxylates themselves. The SVHC dossier concluded that the possible endocrine activity of short chain ethoxylates (NP1EO and NP2EO) add to the concern, but whilst NP1EO could be as potent as nonylphenol for Rainbow Trout, the available data did not permit an assessment of whether such activity may result in		

endocrine-mediated apical effects.

The registration dossier contains a mix of ecotoxicity data for different chain lengths, formulations of unspecified composition and nonylphenol, so that each end point does not necessarily have comprehensive information to enable a judgement about relative ecotoxicities of all constituents. The $PNEC_{water}$ is derived using data on nonylphenol coupled with a toxic equivalence factor (TEF) approach for NP1EO and NP2EO based on a publication by Coady *et al*. (2010)[3].

The purpose of Substance Evaluation will be to check the reliability of the TEF approach, including whether it takes account of endocrine effects and needs to be extended to other constituents of the registered substance and/or their breakdown products.

5.4 Preliminary indication of information that may need to be requested t clarify the concern

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☐ Information on fate and behaviour	☐ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☒ Information ED potential	☐ Other (provide further details below)
Depending on the data set used to justify the TEF, further ecotoxicity testing may need to be requested for the main constituents, which could include additional studies on endocrine disruption.	

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☐ Other (provide further details)
By clarifying the level of hazard posed by short chain NPEOs, more confidence can be assigned to the $PNEC_{water}$. This will help in the evaluation of applications for authorisation, as well as targeted restriction of NPEOs (e.g. due to uses or presence in articles that are not subject to authorisation). If endocrine disrupting properties of equivalent concern are confirmed for the short chain NPEOs, the Candidate List entry may need to be updated in due course.			

[3] Coady K *et al.* (2010). A hazard assessment of aggregate exposure to nonylphenol and nonylphenol mono- and di-ethoxylates in the aquatic environment. Human and Ecol. Risk Assess. 16: 1066-1094.