CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

International Chemical Identification:

Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]

EC Number:

CAS Number: **127087-87-0; 9016-45-9 and others**

Index Number: **none**

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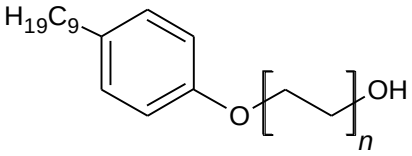
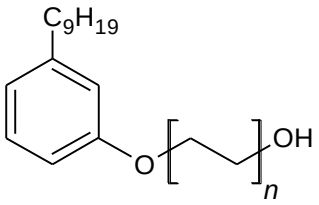
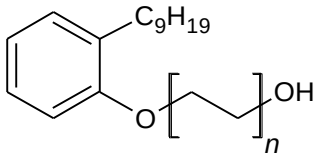
CONTENTS

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]
Other names (usual name, trade name, abbreviation)	
ISO common name (if available and appropriate)	
EC number (if available and appropriate)	
EC name (if available and appropriate)	
CAS number (if available)	127087-87-0 9016-45-9 and others
Other identity code (if available)	
Molecular formula	$(C_2H_4O)_n\ C_{15}H_{24}O$, with n= ≤ 11 to ≤ 30 Where n = represents the number of ethoxylated group(s) to the phenolic group
Structural formula	Representative structures: *para*- substitution  *meta*- substitution 

	ortho- substitution  n = represents the number of ethoxylated groups to the phenolic group n= ≤ 11 to ≤ 30
SMILES notation (if available)	
Molecular weight or molecular weight range	704 g/mol ≤ average molecular weight ≤ 1540 g/mol
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	The major positional isomer is -para (≥90%), while the -ortho isomer is typically less than 10%*. The alkyl chain is mostly branched.**
Description of the manufacturing process and identity of the source (for UVCB substances only)	
Degree of purity (%) (if relevant for the entry in Annex VI)	

*Naylor CG, 2004 and **Canada assessment report (page 17/2).

1.2 Composition of the substance

Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) will be denoted as NPEn, where n describes the number of ethoxylated groups. This abbreviation is used to refer to a specific NPE substance. Specific NPE oligermers may be reported as NPE-n, where n refers to the mean number of ethoxylate (EO) groups in the ethoxylate chain. For example, an oligomers with 15 EO groups is referred to NPE-15. The term NPE-15 may also refer to a mixture of various oligomers which the mean number of EO groups per molecule is 15 (i.e., the mixture may also contain NPE-14, NPE-16 etc.).

When referring to NPEs as a group, the reference long-chain NPE will be used.

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)
Not relevant			

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The impurity contributes to the classification and labelling
Not relevant				

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling
Not relevant					

Table 5: Test substances (non-confidential information

	Information in which the test substance is used		
Identification of test substance	**Environmental fate**	**Degradation**	**Aquatic toxicity**
NPE-12		X	X
NPE-15 NPE-15 (2-22)	X X		X
NPE-16.6*			X
$NPE\text{-}18_{average}$ n=7-24		X	
NPE-30			X

* The term NPE-16.6 refers to a mixture of various oligomers where the mean number of ethoxylated groups per molecule is 16.6

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry		No current entry									
Dossier		Nonylphenol,		127087-87-0 9016-45-9							

submitters proposal		branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]		and others							
Resulting Annex VI entry if agreed by RAC and COM		Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof]		127087-87-0 9016-45-9 and others							

Table 6: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	*Hazard class not assessed in this dossier*	No
Flammable gases (including chemically unstable gases)	*Hazard class not assessed in this dossier*	No
Oxidising gases	*Hazard class not assessed in this dossier*	No
Gases under pressure	*Hazard class not assessed in this dossier*	No
Flammable liquids	*Hazard class not assessed in this dossier*	No
Flammable solids	*Hazard class not assessed in this dossier*	No
Self-reactive substances	*Hazard class not assessed in this dossier*	No
Pyrophoric liquids	*Hazard class not assessed in this dossier*	No
Pyrophoric solids	*Hazard class not assessed in this dossier*	No
Self-heating substances	*Hazard class not assessed in this dossier*	No
Substances which in contact with water emit flammable gases	*Hazard class not assessed in this dossier*	No
Oxidising liquids	*Hazard class not assessed in this dossier*	No
Oxidising solids	*Hazard class not assessed in this dossier*	No
Organic peroxides	*Hazard class not assessed in this dossier*	No
Corrosive to metals	*Hazard class not assessed in this dossier*	No
Acute toxicity via oral route	*Hazard class not assessed in this dossier*	No
Acute toxicity via dermal route	*Hazard class not assessed in this dossier*	No
Acute toxicity via inhalation route	*Hazard class not assessed in this dossier*	No
Skin corrosion/irritation	*Hazard class not assessed in this dossier*	No
Serious eye damage/eye irritation	*Hazard class not assessed in this dossier*	No
Respiratory sensitisation	*Hazard class not assessed in this dossier*	No
Skin sensitisation	*Hazard class not assessed in this dossier*	No
Germ cell mutagenicity	*Hazard class not assessed in this dossier*	No
Carcinogenicity	*Hazard class not assessed in this dossier*	No
Reproductive toxicity	*Hazard class not assessed in this dossier*	No
Specific target organ toxicity-single exposure	*Hazard class not assessed in this dossier*	No
Specific target organ toxicity-repeated exposure	*Hazard class not assessed in this dossier*	No
Aspiration hazard	*Hazard class not assessed in this dossier*	No
Hazardous to the aquatic environment	*No acute classification, No chronic classification*	Yes
Hazardous to the ozone layer	*Hazard class not assessed in this dossier*	No

3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Nonylphenol, branched and linear, ethoxylated (with 704 g/mol ≤ average molecular weight ≤ 1540 g/mol) [includes ortho-, meta-, para- isomers or any combination thereof] are not listed in Annex VI of the CLP.

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

Requirement for harmonised classification by other legislation or process.

Nonylphenol ethoxylates (NPEs) fall under the Prior Informed Consent Regulation (PIC, EC/649/2012). The PIC regulation manages the import and export of certain hazardous chemicals and places obligations on companies who intend to export these chemicals to non-EU countries. It aims to promote shared responsibility and cooperation in the international trade of hazardous chemicals, and to protect human health and the environment by providing developing countries with information on how to store, transport, use and dispose of hazardous chemicals safety.

As a result of the inclusion of NPEs within the PIC regulation, transportation of NPEs is restricted. This restriction also applies to mixtures containing NPEs above a concentration that leads to classification of the mixture as a result of the presence of NPEs. However, currently a harmonized classification is lacking for these substances. Further, self-classifications vary between the industries. As a result, classification of the mixtures is dependent on the self-classification of the suppliers and is therefore variable. This leads to lack of protection for human health or the environment and lack of clarity to law enforcement.

A harmonised classification for NPEs would result in clarification on the obligations for mixtures as falling under the PIC regulation. Law enforcement of this PIC regulation would be improved.

Most marketed NPE including registered forms are UVCBs containing NPEs varying in number of ethoxylate groups, linearity or branching of the nonyl group or the postion of the ethoxylate group(s) versus the nonyl group on the benzene ring (para-, meta- or ortho- or any combinations thereof). As the exact identity of the tested form is unknown, extrapolation to the other forms within the group for which extrapolation is proposed is difficult. However, in line with the extrapolation applied for the inclusion of these substances in the PIC regulation and applied for the restriction of NPEs in textiles, such extrapolation is considered justified also here.

An approach using groups of NPE's instead of covering only individual UVCB substances is used because often NPEs are exported as mixtures from which it is difficult to determine which NPEs were included. Therefore, inclusion of all possible NPEs (including mono-constituent, multi-constituent and UVCB substances) would allow the use of the additivity approach for the most relevant endpoint aquatic toxicity.

This CLH report is one of three proposals that cover various groups of NPEs. These groups were defined based on reliable (Klimisch scores 1 or 2) aquatic toxicity data for NPEs. These data indicate that aquatic toxicity decreases with the increase of the number of ethoxylate groups (see Table 7 for acute toxicity and Table 8 for chronic toxicity). This difference in toxicity within the whole range of ethoxylate groups was considered to be problematic for classification and labelling. For this reason the studies were grouped in short, medium and long ethoxylate groups according to the degree of toxicity. The borders of the groups are determined in such a way that most of the endpoints fit within the ranges of the group, although some endpoints make the exception.

The most logical ranges were determined as follows:

Short-chain group (NPEn where n = 1 to < 3 ethoxylate groups):
Acute and chronic data on NPE with 1 to 2 ethoxy groups are available for fish, invertebrates and algae. The (E)LC_{50} and NOEC values for fish and Daphnia are all < 1 mg/L. This led to the classification of this group

of NPEs as Aquatic Acute Cat. 1 and Chronic Cat. 1. The EC50 for algae of >3.0 mg/L and the NOEC of 1.22 mg/L for the same species was the only value that did not fit into the short chain group.

Medium-chain group (NPEn where n = ≤ 3 to < 11 ethoxylate groups):
Acute data on NPE for 3, 4, 5, 6, 9 and 9.5 ethoxy groups are available for acute fish, invertebrates and algae with (E)LC_{50} values ranging between 1 and 14 mg/L.

Chronic data on NPE 4 and 9 were available for fish with the NOEC values between 0.114 and 0.54 mg/L and for Daphnia with the NOEC value of 10 mg/L. In addition, chronic algae toxicity NOEC data were between 1 and 3 mg/L for NPE of 3 and 6 ethoxy groups, respectively. For the medium group of NPEs between 3 and 10 ethoxy group where there is missing data on certain NPE chain length these data are assumed to be comparable withdata of the same group For chronic toxicity values the division between the short and the medium-chain group is not sharp as the short chain group hold a NOEC of 0.122 mg/L while the medium-chain group holds a lower NOEC of 0.114 mg/L. This overlap is however minimal which makes the division between NPE-2 and NPE-3 acceptable. The medium-chain group was classified as Chronic Cat. 2 and no classification for acute toxicity.

Long-chain group (NPEn where n = ≤ 11 to ≤ 30 ethoxylate groups)
Acute data on NPEs with 11 to 30 ethoxy groups is available only for NPE-12 (algae) and NPE-30 (fish), with the (E)LC_{50} values > 1 mg/L. Chronic data are only available for NPE-12 (algae) with a NOEC of 20 mg/L. For this long-chain group there is no acute toxicity classification proposed, while for chronic toxicity a conclusion on classification was not possible due to limited data.

Table 7: Overview of valid acute toxicity data and grouping of NPEn

Only relevant and valid studies (Klimisch scores 1 and 2) for nonylphenol ethoxylates have been listed. The reliablity and description of each study can be found in section 11.5.

Substance tested	**Method and species**	**Results (mg/L)** L(E)C_{50}	**Proposed NPEn-group**
Fish			
NPE-1	OECD TG 203 Fathead minnow (*Pimephales promelas)*	96h-LC_{50} = 0.218	Short-chain
NPE-2	OECD Guideline 203 Fathead minnow (*Pimephales promelas)*	96h LC_{50} = 0.323	Short-chain
NPE-4 NPE-5 NPE-9 NPE-9.5	Test guideline not mentioned Bluegill sunfish (*Lepomis macrochirus*)	96h LC50 = 1.3 96h LC50 = 2.4 96h LC50 = 7.9 96h LC50 = 7.6	Medium-chain
NPE-9	Test guideline not mentioned Fathead minnow *(Pimephales promelas)*	96h-LC50 = 4.6	Medium-chain
NPE-30	Test guideline not mentioned Bluegill sunfish (*Lepomis macrochirus*)	96h LC50 > 1000	Long-chain

Invertebrates			
NPE-1	*EPA guideline* *Cerodaphnia dubia*	48h-EC_{50} = 0.328	Short-chain
NPE-1.5	No guideline *Mysidopsis bahia*	48h-EC_{50} = 0.11	Short-chain
NPE-2	*EPA guideline* *Cerodaphnia dubia*	48h-EC_{50} = 0.716	Short-chain
NPE-9	Test guideline not mentioned *Daphnia magna*	48h EC50 = 14	Medium-chain
Algae			
NPE-2	TG201 *Pseudokirchneriella subcapitata*	72h $EC_{50,growth}$ > 3.0	Short-chain
NPE-3 NPE-6 NPE-12	*Scenedesmus subpicatus* performed according to test guideline 201	72h-ErC50= 2.9 72h-ErC50=13 72h-ErC50=89	Medium-chain Medium-chain Long-chain

Table 8: Overview of valid chronic toxicity data and grouping of NPEn

Substance tested	Method	Results (mg/L)*	Proposed NPEn-group and remarks
Fish			
NPE-1	Not a test guideline method 21 d exposure Rainbow trout (*Oncorhynchus mykiss*)	NOEC VTG[1] = 0.03	Short-chain
NPE-1	Not a test guideline method 100d exposure Medaka (*Oryzias latipes)*	NOECsurvival =0.105 NOEC SSC[2] = 0.035	Short-chain
NPE-1/ NPE-2	Not a test guideline method 90d exposure Medaka (*Oryzias latipes)*	NOEC = 0.05	Short-chain
NPE-2	Not a test guideline method rainbow trout	LOEC ≤ 0.038 VTG induction, GSI and germ cell stages	Short-chain
NPE-1/ NPE-2	Not a test guideline 21 d exposure Rainbow trout (*Oncorhynchus mykiss*)	LOEC GSI[3] < 0.122 gonadal histology LOEC = 0.122 VTG[1]	Short-chain
NPE-4	Method not specified 100d exposure Medaka (*Oryzias latipes*)	0.114, survival 0.38, SSC[2]	Medium-chain
NPE-9	Method not specified 100 d exposure Medaka (*Oryzias latipes*)	0.54, survival 0.54, SSC[2]	Medium-chain
Invertebrate			
NPE-1	TG211 *Daphnia magna* 21-d exposure	NOEC reproduction = 0.1	Short-chain
NPE-1.5	EPA OTS 797.1950 *Mysisdopsis bahia* 28-d exposure	NOEC reproduction = 0.0077	Short-chain

NPE-9	EPA guideline 7d exposure *Daphnia magna*	10 (mortality) >10 (growth)	Medium-chain
Algae			
NPE-2	TG201 *Pseudokirchneriella subcapitata*	72 h NOEC $_{Growth}$ = 1.22	Short-chain
NEP-3 NPE-6 NPE-12	*Scenedesmus subpicatus* performed according to test guideline 201	72h-NOE_bC = 1 72h- NOE_bC = 3 72h- NOE_bC = 20	Short-chain Short-chain Long-chain

1: VTG = vitellogenin
2: SSC = second sex characteristics

Fate and behaviour

NPEs are expected to be hydrolytically stable. They have a moderate potential to absorb to organic matter. Due to their low vapour pressure and low Henry's law constant, evaporation into the atmosphere is expected to be neglible. In general, degradation of NPEs involves progressive shortening of the ethoxylate chain. Hydrolytic or biodegradative ether cleavage leads to the accumulation of NPE-1 and NPE-2.

Individual short-chain NPEs are expected to show common biodegradation properties and pathways. NPE-1 and NPE-2 are expected to degrade the slowest (Van Vlaardingen et al., 2003) and several studies show that in solution NPE-1/NPE-2 ethoxylates compounds degrade overtime to nonylphenol (European Chemical Agency, 2013; Metcalfe et al., 2001). Short-chain NPEs are considered as substances with potential to bioaccumulate.

Medium-chain NPEs are not readily biodegradable using the standard screening test methods (e.g. the application of the 10-day window criterion). However, significant levels of biodegradation (52 – 99%) are observed for all NPEs tested indicating they metabolize to some extent. This rate of degradation seems to rise with increasing number of ethoxylated group. The bioaccumulation potential for this group varies with increasing ethoxy group. Based on $logK_{ow}$ values, the lower end of the group have the potential to bioaccumulate whilst the upper end group a low potential to bioaccumulate.

Long-chain NPEs are considered rapidly degradable and as substances with low potential for bioaccumulation since the estimated LogKow values are above the CLP trigger of ≥ 4.

Conclusion

The grouping of the various lengths of ethoxylated NPEs in short-, mid- and long-chain groups was based on their acute and chronic toxicity. The majority of the endpoints given in Table 7 and Table 8 fall within the choosen borders of the groups. Endpoints on the fate and behaviour of NPEs did not further influence this choice. Overall, the choice of grouping based on valid (E)LC_{50} and NOEC values and the corresponding classification are summarised inTable 9. It is shown that the choice of the ranges of each group resulted in distinctive differences in their classification.

Table 9: Grouping and classification of NPEs

Nonylphenol Ethoxylate	Proposed Classification	
	Acute	Chronic

Short-chain: 1 to < 3 ethoxy groups	Category 1 (M = 1)	Category 1 (M = 10)
Medium-chain: ≤ 3 to < 11 ethoxy groups	no acute classification	Category 2
Long – chain: ≤ 11 to ≤ 30 ethoxy groups	no acute classification	no chronic classification

5 IDENTIFIED USES

According to the registration dossier for for nonylphenol, branched, ethoxylated (CAS 68412-54-4), the substance is only used by workers in industrial settings (manufacture and formulation of the substance). For example, industrial manufacture of NPE and industrial formulation of mining products (floating agents) containing NPE.

In general, nonylphenol ethoxylates have a broad range of uses due to their effectiveness as detergents, emulsifiers, wetting agents and dispersing agents. The commercial and industrial application of NPEs depend partly upon the length of their ethoxylate chains. The uses of nonylphenol and nonylphenol ethoxylates in the textile industry have been reported by the Danish EPA (2013). Especially, NPE with 7 to 15 ethoxylate units are used in the manufacture of textiles but also NPEs with 4 to 6 ethoxylate units and NPEs with more than 30 ethoxylate units are used in the production of textiles. In textile production, NPE is used in several process steps, including both the washing, dyeing and bleaching processes. Apparently, NPE is used both in the production of synthetic fabrics (acrylic, polyester) and in the production of natural textiles (e.g. cotton and wool). NP/NPE is thus expected to be present in all types of textile materials. However, the use of NPE in the treatment of wool and to some extent cotton is highlighted in several sources.

6 DATA SOURCES

The data presented in this CLH report is reproduced from several sources.

- Annex XV dossier – Identification of 4-nonylphenol, branched and linear, ethoxylated as SVHC. Germany, 2012.
- ECHA (2013), Support document for identification of 4-nonylphenol, branched and linear, ethoxylated.
- REACH registration dossiers for nonylphenol polyethylene glycol ether (CAS 9016-45-9)
- REACH registration dossiers for nonylphenol, branched, ethoxylated (CAS 68412-54-4)
- Public literature

7 PHYSICOCHEMICAL PROPERTIES

Experimental physical chemical properties for long chain ethoxylates are scarce. Whereever possible data are retrieved from the literature.

Table 10: Summary of physicochemical properties

Property	**NPE-n**	**Value [mg/L]**	**Comment (e.g. measured or estimated)**

Property	**NPE-n**	**Value [mg/L]**	**Comment (e.g. measured or estimated)**
Critical micelle concentration water solubility	NPE-12* NPE-15* NPE-20* NPE-30*	43 97-115 150-190 390-460	All measured Van Vlaardingen *et al.* 2003

* mixtures

To get an overview for the properties of the substances several physical chemical properties were calculated with EPI Suite (v4.11). However, the estimates of NPE-30 shown in Table 11 are less reliable because they fall outside the descriptor domain. The target chemical is outside of the molecular weight range i.e. between 18 and 720. That said the estimates show a trend that the physical chemical properties depend on the number of ethoxylate groups.

Table 11: Physical chemical properties calculated with EPI Suite

Physical Chemical Property	***para*-Substitution of the nonyl group on the phenol molecule** (n=number of ethoxylated groups)			
	Linear nonyl group		**Branched nonyl group**	
	n=11	n=30	n=11	n=30
Molecular weight (g/mole)	704.95	1541.97	704.95	1541.97
Log Kow v 1.68[2]	2.83	-2.38	2.54	-2.68
Water solubility at 25°C mg/L (WaterNT v1.01)[1]	147.5	1×10^{6}	1163.2	1×10^{6}
Vapour pressure mmHg at 25°C (Modified Grain method) (MPBPWIN v.1.43)	9.39×10^{-21}	3.22×10^{-44}	1.11×10^{-19}	3.17×10^{-43}
Henry's Law Constant (atm m3/mol) (HENRYWIN v3.20, Bond method)	1.35×10^{-25}	Incomplete. via VP/WSol: 1×10^{-28}	1.35×10^{-25}	5.675×10^{-29}

1: WaterNT is based on a new set of (larger) fragments which are optimized for water solubility. The set of fragments contains the whole molecule of nonylphenol ethoxylate. The estimation of water solubility is therefore reliable.
2: As nonyl ethoxylate is a surfactant the Kow estimation as well as the experimental determination is difficult as the border between the fractions water and octanol is disturbed by nonyl ethoxylate.

8 EVALUATION OF PHYSICAL HAZARDS

Not evaluated in this dossier

9 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Not evaluated in this dossier

10 EVALUATION OF HEALTH HAZARDS

Not evaluated in this dossier

11 EVALUATION OF ENVIRONMENTAL HAZARDS

11.1 Rapid degradability of organic substances

Table 12: Summary of relevant information on rapid degradability

Ready biodegradability						
Test substance	**Test Method**	**Results**	**10-day Window?**	**Remarks**	**KS***	**Reference**
NPE-12	OECD 301 A GLP	75% at 28 days	No	70% level of DOC Not readily biodegradable	1	Anonymous (1994a)

* Klimisch score assigned by dossier submitter.

11.1.1 Ready biodegradability

11.1.1.1 Screening Studies

One screening study is available with the test substance isononylphenol ethoxylate (CAS Nr 37205-87-1) with ethoxylate group 12.

Anonymous (1994a)

A DOC-DIE away test was performed under GLP according to EG- 92/69 EWG, part II, C.4-A. This is the current OECD 301A DOC Die-away. Test was performed with NPE-12 (isononylphenol ethoxylate (cas nr. 37205-87-1. Test was performed in 2000 mL Erlenmeyer flasks. The test substance was tested at 10.3 mg DOC/L and inoculum. Inoculum was retrieved from the sewage plant effluent Marl-Ost in Germany. The control was performed with inoculum only. A reference control was performed with natriumbenzoate (10.47 mg DOC/L) and inoculum. All tests were performed in duplicate. The test was performed in the dark at 22.0-22.2°C for 28 days. Biodegradation was monitored by measuring the dissolved organic carbon (DOC) reduction after 0 and 3 h, and after 7, 14, 21, 27 and 28 days.

Results

Removal of the test substance was 75% after 28 days. Pass level for ready biodegradability of 70% removal of DOC within the 10-d window was not met as maximum removal was just below 70% within 10 days (day 1-11). The 10-d window was met for the reference control with a removal of 99%. The study is reliable (Ri= 1).

Additional information

Hughes et al. (1989)

The study of Hughes *et al.* (1989) was discussed in a unpublished report of the Environment Agency UK, (Environment Agency UK, 2008): "*Hughes et al. (1989) compared the ready biodegradability of NPE-12 in different standard test systems: the modified Sturm test (OECD 301B), the Gledhill test (US EPA method*

835.3120) and the closed bottle test. In all tests, ultimate biodegradation ranged between 30 and 65% as measured by conversion to carbon dioxide. Using the Gledhill test, the effect of using both acclimated and unacclimated microbial seed on biodegradation of NPE-12 to carbon dioxide was investigated. However, no significant differences were noted: 45% ThCO2 mineralisation was reached with the unacclimated seed versus 42% ThCO2 mineralisation with an acclimated inoculum". This description is provided for informational purposes only.

11.1.2 BOD_5/COD

No information available.

11.1.3 Hydrolysis

No information is available on long chain ethoxylates.

According to the SVHC support document for 4-nonylphenol (ECHA, 2013) it is expected that 4-nonylphenol ethoxylates will not be subject to abiotic degradation via hydrolysis. The nonyl group and the phenolic ring structure are chemically stable against hydrolysis. Also the ethoxylate chain is not suspected to be degraded via hydrolysis, but via biotic degradation. In summary, it is supposed that hydrolysis for long chain ethoxylates is also not a relevant degradation process under environmental conditions.

11.1.4 Other convincing scientific evidence

11.1.4.1 Field investigations and monitoring data (if relevant for C&L)

No information available.

11.1.4.2 Inherent and enhanced ready biodegradability tests

No information available.

11.1.4.3 Water, water-sediment and soil degradation data (including simulation studies)

Table 13: Summary of simulation tests in surface waters

Test substance	Test Method	Results	Remarks	KS*	Reference
NPE-18 (n=7-24)	Static die-away test Similar to OECD301	100% degradation of NPE-18 after 4-24 days at 28°C	Primary degradation occurred Metabolites generated: NPE-2, NPE-1, NPEC-1 and NPEC-2 Calculated mineralisation: 36% to 56% by day 76	2	Potter *et al.* (1999)[1]
NPE-15 (n= 2-22)	River die-away test Non-GLP Unpolluted river water Similar to	~85% degradation after 30 days at 21°C	Primary degradation occurred Metabolites generated: NPE-2, NPEC-1 and NPEC-2 Calculated mineralisation: 64% to 85% by day 30	2	Manzano *et al.* (1998)[2]

	OECD301				
NPE-15 (n=2-22)	River die-away test (undefined) Non-GLP Unpolluted river water Similar to OECD301	Degradation 68%, 80%, 87% and 96% after 30 days at 7, 13, 21 and 25°C, respectively	Primary degradation occurred Metabolites generated: NPE-2 (main), NPEC-1 and NPEC-2 Mineralisation: 32-34% at 7ºC and 71-96% at 25ºC	2	Manzano *et al.* (1999)[2]

*Klimisch scores indicated in the REACH registration dossiers or evaluated by the dossier submitter for the publications retrieved from the open literature If the dossier submitter does not agree with the reliability assignment made in the REACH dossier, then this will be indicated in the study summaries below.

[1]As summarised the ECHA support document for identification of 4-nonylphenol, branched and linear as support of very high concern

[2] Summarized from the literature

Simulation studies in surface waters

Three simulation studies in surface water are available for long-chain ethoxylates. The studies are reliable with a reliability score of 2.

Potter et al. (1999)

A static die-away test was performed with estuarine water from four sampling sites in Tampa Bay, FL. Depending on sampling site (middle of the Bay, port area and tidal river) the temperature ranged from 27.5 to 31.0 °C. Bottles were spiked with Intan-100 at 4 mg/L (7-24 ethoxy units with a mean of 18). The concentration of total Intan, NPE-2, NPE-1, NPEC-2, NPEC-1, NP and total surfactant were monitored at intervals of 4-8 days for 89 days and at 30-day interval thereafter until 183 days. No replicates, no reference compound and no sterile control were included in the experiments. The experiment was conducted at 28 ± 1 °C in the dark. The percent recovery of Intan-100 averaged 93% with 2.3% RSD. Mean degradation products recoveries ranged from 61 to 80% with % RSD in the 4.1-11.8% range.

Due to the different sampling locations the following results are stated as a range. Complete primary degradation of NPE-18 was detected after 4-24 days with a lag period between 0 and 12 days. The formation of NPE-2 reached its maximum concentration in 4-16 days and gradually degraded up to about 56 days. NPE-2 was subsequently oxidized to yield its carboxylic acid analogue NPEC-2. NPEC-2 increased until day 20-76 with little or no decrease until the end. Smaller amounts were detected for NPE-1 (<0.1 mg/L) and NPEC-1 (maximum concentration 20% of NPEC-2). NP was not measured (detection limit 0.01 mg/l). Potter *et al.* (2004) estimated that approximately 36 to 56 % of the surfactants converted to CO_2 and H_2O. However, this was not confirmed analytically. The results are less reliable as the set-up of the experiment was not correct (no replicates etc.) Ri 2.

Manzano (1998)

River die-away test using nonylphenol polyethoxylate with an average NPE-15 (range 2-22). River water was taken near the source of the river Guadalete in the South-West of the Iberian Peninsula. The study was not said to be performed under GLP and was performed according to a 'River die-away test' of Okpokwasili and Olisa (1991). Reactors contained 4L of river water and were dosed with 2.5, 5 and 10 mg/L of NPE-15 for 30 days. Assays were performed in the dark, at 21 °C in duplicate. In addition a blank control was included to measure abiotic losses. A reference compound was not included. The inoculum was not pre-conditioned.

Results

Results of the blank control were not provided. At 2.5 mg/L the lag phase was between 1 and 2 days, whereas at 5 and 10 mg/L, it was between 2 and 3 days. At all three doses, primary biodegradation, loss of the polyethoxylate structure, of approximately 80% was observed after 5 days, reaching 85% after 30 days, the NPE-15 had not been completely eliminated in any of the tests. Mineralisation of 64 to 85% was calculated by assuming that the lost of ethoxylated groups (as ethylene glycol) are rapidly mineralized to CO_2. During the biodegradation process the following metabolites were formed NPE-2, p-nonylphenoxy acetic acid (NPEC-2) and 3-oxa-pentanoic acid (NPEC-1) and 5-(p-nonylphenoxy). The authors mention that the dominant mechanism is the shortening of the ethoxylate chain until practically all the initial nonylphenol polyethoxylate has been transformed into nonylphenol diethoylate (NPE-2), with the corresponding liberation of ethylenglycol. From this point on, there is no further shortening of the ethoxylate chain since no nonylphenol monoethoxylate (NPE-1) was not detected in any of the assays. Once the ethoxylated chain has been shortened to two units, the main mechanism becomes the oxidation of the terminal ethoxylate unit of the NPE-2, producing NPEC-2 which then forms NPEC-1.

Manzano et al. (1999)
The study was conducted to address the effect of temperature on the biodegradation of NPE-15 (range 2-22). River water from the river Guadalete in Spain which was free of urban and industrial contamination was used. The study was not said to be performed under GLP and was performed according to an undefined 'river die-away test'. The test substance was tested in a river water (4L) was kept in a 6-L reactors (in darkness) at 7, 13, 21 and 25°C for 35 d. Test was performed in duplicate. A blank control was included to measure abiotic losses. Results of this blank control were not provided. A reference compound was not included.

The inoculum was not pre-conditioned. The test was performed at 5 mg/L. Biodegradation was monitored by measuring the residual NPE-15 over time. Measurements were made every day until day 5 and every other 5 days thereafter. The last measurement was at day 30.

Results

The results obtained indicate that temperature has a strong influence on the period of acclimation of the microorganisms and on the rate of biodegradation. The lag phase increased with decreasing temperature. The percentages of primary biodegradation varied from 68% at 7ºC to 96% at 25ºC, and at all the temperatures studied, metabolites (NPE-2, NPEC-1 and NPEC-2) were generated during the biodegradation process which did not totally disappear at the end of the assay. The percentages of mineralization reached in the various assays, ranged from 30% at 7ºC to 70% at 25ºC, also show the influence of temperature. Total elimination or mineralization of the nonyl-phenol polyethoxylate was not observed in any of the test conditions over the duration of the assays, due to the persistence of the degradation intermediates in the medium under all the test conditions studied. The NPE range tested in this study was 2-22. The lower ethoxylate units were not specified. But since the lower ethoxylate units were present and more difficult to mineralize than the higher ethoxylate units, the percentage of biodegradation is possibly an underestimation. Even though this study covers the range NPE 2 -22, the test material test was an NPE with an average of 15 ethoxylated units. With this average the test results better fit in this long chain group.

In this case an underestimation is acceptable for classification and labelling purposes. The study is reliable but results of the blank control were not included (Ri = 2).

Sjostrom et al. (2008)
Sjostrom *et al.* examined degradation of NPE-12 in four contrasting agricultural soils. A biphasic dissipation kinetic was observed. The rapid initial dissipation with DisT50 = 0.3 – 5.2 days were followed by a slower dissipation phase (DisT50 = 11.4 - 48.0 days). After 30 days results showed the formation of nonylphenol from NPE-12. NP remained nearly stable at the end of the experiment. No detectable NPE-12 remained in the soils after 105 days and no intermediate degradation products were found.

11.1.4.4 Photochemical degradation

No information available.

11.1.4.5 Summary and discussion on degradation

Five relevant studies on degradation of long-chain NPEs were summarized above. In short:

- Only one ready biodegradability test is available for the long-chain NPE group (Anonymous, 1994a; Table 12). NPE-12 reached degradation level of 75% at 28 days. The pass level of the test was achieved by the end of the test but the 10-day window criterion was not met.
- The degradation of NPE-18 in a static die-away test with seawater (Potter et al., 2004; Table 13) showed primary degradation (roughly 100%) by day 16. NPE-2 was the predominant metabolite detected. NPE-2 concentrations peaked between 4-16 days and slowly decreased to below detection limit by day 56. Concentrations of NPEC-1 and NPEC-2 also increased during the test.
- In a river die-away test (Manzano *et al.*, 1988; Table 13), primary degradation of ca. 85% after 30 days at 21°C and mineralisation of 64 to 85% was observed for NPE-15 (range 2-22). The metabolites NPE-2, NPEC-2 and NPEC-1 were identified.
- In another river die-away test with NPE-15 (Manzano *et al*. 1999; Table 13), the effect of temperature on the biodegradation was investigated. Primary degradation varied from 68% at 7°C to 96% at 25 °C and at all temperatures metabolites were identified, NPE-2, NPEC-1 and NPEC-2.

Experimental data on the degradation properties of long-chain NPEs is fairly limited.

It is worth pointing out a CLH proposal for medium-chain NPEs (n= ≤ 3 to < 11) has been prepared by the Dossier Submitter. In this proposal, the medium-chain NPEs were considered as not rapidly degradable for classification purposes. The data showed that medium chain NPEs undergo dissipation or primary degradation. In general, the degradation involves the progressive shortening of the ethoxylate chain (-O-C-C-) until practically all the initial nonylphenol polyethoxylated has been transformed into shorter chain NPEs with the corresponding liberation of ethyleneglycol. During the degradation process metabolites were formed such as NPE-2, NPE-1, p-phenoxy acietic acid (NPEC-2) and 3-oxa-pentanoic acid (NPEC-1) and 5-(nonylphenoxy). In the majority of the studies, the metabolites did not totally disappear at the end of the assays. The abundance of a particular metabolite was very dependent on the treatment conditions. Aerobic biodegradation favors formation of NPEC-1 and NPEC-2 while anerobic biodegradations favors the formation of NPE-1 and NPE-2 (Naylor 2006). NPE-1 and NPE-2 are expected to degrade the slowest (Van Vlaardingen *et al.*, 2003) and several studies show that in solution NPE-1/NPE-2 ethoxylates compounds degrade overtime to nonylphenol (European Chemical Agency, 2013; Metcalfe *et al.*, 2001).

If it is assumed that the chain length to a certain extent does not influence the degradation process for NPEs the available data from medium chain ethoxylated may be extrapolated to longer chain ethoxylates. In that case the long-chain NPEs (n= ≤ 11 to ≤ 30) can also be considered as not rapidly degradable.

However, assuming that the few information presented in Tables 12 and 13 are reliable, enough evidence is available to proof otherwise.

According to Annex I section 4.1.2.9.5 of the CLP guidance the data presented in Tables 12 and 13 can be regarded as convincing scientific evidence, demonstrating that long chain ethoxylates can be degraded in the aquatic environment to a level >70% within a 28-day period. The available ready biodegradability test indicates more than 70% degradation after 28 days (although the test did not pass 10-day window). The three simulation tests show that the long chain ethoxylates are rapidly biodegradable to some degree:

- 100% degradation of NPE-18 after 4-24 days at 28°C;

- ~85% degradation of NPE-15 after 30 days at 21°C;
- 68%, 80%, 87% and 96% degradation of NPE-15 after 30 days at 7, 13, 21 and 25°C, respectively.

We note that the studies of Manzano et al.(1998 and 1999) were not monitored on day 28 but at day 30. However, the Manzano (1999) study shows that at temperatures > 7°C the criterium of 28 days is probably met. Based on the above, we can conclude that long-chain NPEs are rapidly degradable for classification purposes.

11.2 Environmental transformation of metals or inorganic metals compounds

Not relevant for this dossier.

11.3 Environmental fate and other relevant information

No information available.

Volatilisation
The estimated vapour pressures values of $7.72x10^{-26}$ – $6.62x10^{-25}$ mmHg at 25°C for NPE-15 (EPA, 2001, refered to in Van Vlaardingen *et al.*, 2003) suggests that this long-chain ethoxylate has a low potential to distribute into the atmospheric compartment.

Distribution modelling
No information available.

11.4 Bioaccumulation

No information available.

11.4.1 Estimated bioaccumulation

Estimated Log Kow (using EPI Suite (v4.11) is 2.83 for NPE-11 and -2.38 for NPE-30. The estimate for NPE-30 is however not reliable as it falls outside the descriptor domain. As the number of ethoxylated groups increases, the water solubility increases and as a result the Log Kow decreases. Even though the predicted logKow data are less reliable the data for this subgroup suggest low potential for bioaccumulation.

11.4.2 Measured partition coefficient and bioaccumulation test data

No information available.

11.5 Acute aquatic hazard

Table 14: Summary of relevant information on acute aquatic toxicity

Method	Substance tested	Results (mg/L)	Remarks	KS*	Reference**
Fish		$L(E)C_{50}$			
Test guideline not mentioned Bluegill sunfish	NPE-30	96h LC50 > 1000	Static, based on nominal concentations	2	Macek and Krzeminski (1975)**

(*Lepomis macrochirus*)					
Crustaceae					
No reliable tests					
Algae					
Scenedesmus subpicatus performed according to test guideline 201	NPE-12	72h-ErC50=89	Static, based on nominal concentations	2	Anonymous (1994b)***

* Klimisch scores indicated in the REACH registration dossiers or evaluated by the dossier submitter for the publications retrieved from the open literature. If the dossier submitter does not agree with the reliability assignment made in the REACH dossier, then this will be indicated in the study summaries below.
**Study was summarized from a publication retrieved from open literature.
***Confidential study from industry.

11.5.1 Acute (short-term) toxicity to fish

Table 15: Summary of acute fish toxicity tests

Method	Substance tested	Results (mg/L)	Remarks	KS*	Reference**
Fish bioassay procedure described in Japanese Industrial Standard (JIS) K0102 Medaka (*Oryzias latipes*	NPE-13.1	48h LC50=48	Static test, based on nominal concentrations	4	Yoshimura (1986)
Fish bioassay procedure described in Japanese Industrial Standard (JIS) K0102 Medaka (*Oryzias latipes*)	NPE-16.6	48h LC50=110.0	Static test, based on nominal concentrations	4	Yoshimura (1986)
Test guideline not mentioned Bluegill sunfish (*Lepomis macrochirus*)	NPE-30	96h LC50 > 1000	Static, based on nominal concentrations	2	Macek and Krzeminski (1975)

*Klimisch scores indicated in the REACH registration dossiers or evaluated by the dossier submitter for the publications retrieved from the open literature. If the dossier submitter does not agree with the reliability assignment made in the REACH dossier, then this will be indicated in the study summaries below.
** All studies were summarized from publications retrieved from open literature

Yoshimura (1986)
In a study by Yoshimura (1986), a static acute toxicity test was carried out to determine the 48h- LC50 of NPEs. Medaka of 2 cm average length and 0.2 g of average weight were placed at random in groups of 10 in glass beakers containing 2L of each concentration of samples. After the preliminary range finding test, the LC_{50} determinations were carried out by observing fish survival in single test solution prepared for each concentration. The 48-LC50 values of NPEs for medaka were determined to be 1.4 mg/L (NP), 3.0 mg/L (NPE-1), 2.5 mg/L(NPE-3.3), 3.6 mg/L (NPE-5), 6.4 mg/L (NPE-5.4), 11.6 mg/L (NPE-8.4), 11.2 mg/L (NPE-8.9), 48.0 mg/L (NPE-13.1), and 110.0 mg/L (NPE-16.6). For this dossier, the focus is only on NPE-

13.1 and NPE-16.6. The reliability of this study is 4 because of absence in some essential information such as purity of the test substances, test concentrations, number of fish, the chemical analysis etc.

Macek and Krzeminski (1975)
Static bioassays were conducted without artificial aeration, and with a single introduction of the surfactants of NPE-4, NPE-5, NPE-9, NPE-9.5, and NPE-30 dissolved in water. Bluegill sunfish (*Lepomis macrochirus*) with mean body weight of 1 gram were held in the laboratory for at least 30 days and are in good condition. Fish were acclimated to the test conditions for 72 hours, and to the test system for at least 24 hours, prior to testing. Test solutions were prepared by adding the appropriate amount of surfactant to 15 liters of the test diluent. Ten fish were tested at each concentration, using a minimum of six concentrations per bioassay; the mass/volume ratio never exceeded 1.0 gram of fish per liter of diluent. Dissolved oxygen concentrations ranged from 9.0 mg/l initially to 5.1 mg/l at the end of the test. The recovery of nonionic surfactants from samples taken at the beginning (0 hour) of bioassays ranged from 96-106% surfactants indicating the nominal concentrations varied minimally from actual concentrations of surfactant. There were no significant differences in the concentration of surfactants between water samples taken at the beginning and end of the static bioassays (96 hours), indicating little, if any biodegradation of these materials. In these bioassays nominal concentrations were assumed to be accurate and relatively constant. The 96h-LC50 values for NPE-4, NPE-5, NPE-9, NPE-9.5, and NPE-30 were 1.3, 2.4, 7.9, 7.6, and >1000 mg/L, respectively. For this dossier, the focus is only on NPE-30. Ri=2.

11.5.2 Acute (short-term) toxicity to aquatic invertebrates

Table 16: Summary of crustacean toxicity tests

Method	Substance tested	Results E(L)C50 (mg/L)	Remarks	KS*	Reference**
Mysidopsis bahia USEPA (1985) Methods for measuring the acute toxicity of effluents to freshwater and marine organisms	NPE-15	48h LC50=2.57	Static renewal Not measured	3	Hall *et al.* (1989)

*Klimisch scores assigned by dossier submitter.
** Study was summarized from a publication retrieved from open literature.

Hall et al. (1989)
Three- to eight-day old mysids (*Mysidopsis bahia*) were used to evaluate the acute toxicities of NPE-1.5, NPE-9, NPE-15, NPE-40 and NPE-50 (Hall *et al.*, 1989). For this dossier, the focus is only on NPEn > 10. All tests were 48-hr static renewals (renewals at 24 hr) at 25 ± 1^0C under a light:dark photoperiod of 16-hr:8-hr. All mysids were 3 to 8 days old at the start of tests. Aged, natural saltwater of 25 to 28 ‰ salinity (25 micron filtered) was the control and dilution water in all experiments. All toxicant exposures contained two replicates of four organisms per concentration and controls contained four replicates of four organisms. With the exception of one chemical (NPE-1.5), concentrations were nominal values obtained by adding pure chemical to the saltwater. A modification of the gas chromatography following continuous distillation and extraction with octanol was used to measure NPE-1.5. *M. bahia* were fed live *Artemia* (<24-hr old) at the start of tests and after renewing solutions. Dissolved oxygen, pH, and salinity were monitored at the start, after 24-h, at renewal, and at termination of experiments. Dissolved oxygen was measured in all solutions at the start, at 24-h and 48-h of all tests. Salinity and pH were monitored only in the controls and the two highest toxicant concentrations, since changes in these parameters were not observed as a result of addition of chemicals. With the exception of one test, only experiments with <20 percent control mortality were used

in comparing the toxicity of different surfactants. Control mortality above the recommended 10% was deemed acceptable because this occurred on only a few occasions and lower levels of mortality occurred for mysids exposed to low levels of surfactant. To ensure that mysids obtained from the two suppliers were of similar and consistent sensitivity, one of the surfactants NPE-9 was used as an internal reference toxicant throughout the tests, because it is readily soluble and of high acute toxicity. Under the test conditions, the 48h-LC50 values for *Mysidopsis bahia* was determined to be 0.11 mg/L (NPE-1.5); 0.9-2 mg/L (NPE-9); 2.57 mg/L (NPE-15); >40 mg/L (NPE-40) and >4110 mg/L (NPE-50). The chemical concentrations were not measured and the study on NPE-40 is considered as Ri=3.

11.5.3 Acute (short-term) toxicity to algae or other aquatic plants

Table 17: Summary of algal acute toxicity tests

Method	Substance tested	Results EC50 (mg/L)	Remarks	KS *	Reference
OECD TG 201 *Scenedesmus subpicatus* (Chodat)	NPE-12	72h-E_rC_{50} = 89 72h-E_bC_{50} = 39	Static, nominal concentration	2	Anonymous (1994b)**
Selenastrum capricornutum	NPE-30	3-week EC_{50} >500	Static, nominal concentration	3	Nyberg (1988)***

* Klimish score assigned by dossier submitter
**Confidential study from industry
***Study was summarized from a publication retrieved from open literature

Anonymous (1994b)
The toxicity of NPE-12 to green alga (*Scenedesmus subpicatus* (Chodat)) was determined under GLP using OECD test guideline 201. The test was performed with NPE-12 (purity 99.0%). Preparation of test solutions started with stock solutions by directly dissolving 1 g of NPE-9.3 into 1 L water. The study was conducted under static conditions with an initial cell density of 2 x 10^4 cells/mL. Exponentially growing algal cultures were exposed for 72 hours to nominal concentrations of 5, 10, 20, 40, 80 and 160 mg/L. Concentrations were measured photometrically at 275 nm at 0 and 72 h after test initation in additional test vessels without algae. The photoperiod (L:D) is 24:0 h, temperature 24 °C, light intensity 8000 lux, pH 8.0-8.1 at test start and 8.1-9.5 at the end of the test. A control was included in the test. Five replicates were tested for each tested concentrations, 8 replicates in the control. Algae were counted photometrically at 685 nm at 0, 24, 48 and 72 h. Measured concentrations were >80% of nominal at 0 and 72h. Nominal concentrations were used to determine the effect concentrations. All validity criteria were met. The following values were reported: 72h-E_rC50 = 89 mg/L; 72h-E_rC10 = 26 mg/L; 72h-E_bC50 = 39 mg/L; 72h-NOEC = 20 mg/L. This study is considered as Ri=2 since measurements were only done in vessels without algae.

Nyberg (1988)
In a study by Nyberg (1988), the alga *Pseudokirchneriella subcapitata* was cultured in 50 ml Erlenmeyer flasks using 25 ml liquid synthetic medium in each flask. The flasks were inoculated with 0.1 ml of an algal suspension. The inoculate contained *ca* 1.5 x 10^5 cells. The surfactants were added to the cooled autoclaved medium as stock solutions using sterile MiUipore filters to avoid any possible decomposition during sterilization. The algae were cultured at 25°C for 3 wk with gentle shaking (ll0rpm) under Airam 40W-35 white fluorescent tubes. After the growth period, at the approximate onset of the stationary phase, the cell counts in each flask were measured with a Fuchs-Rosenthal counting chamber. The 3 week EC50 values for growth were >500 mg/L for all surfactants of NPE-6, 9 and 30. The exposure period for algal species is

normally 72 or 96 hour EC_{50} and/or aquatic plants 7 days EC_{50}. For this dossier, the focus is NPE-30 > 15. This study is considered as , Ri=3.

11.5.4 Acute (short-term) toxicity to other aquatic organisms

No experimental studies are available.

11.6 Long-term aquatic hazard

Table 18: Summary of relevant information on chronic aquatic toxicity (only valid studies included)

Method	Substance tested	Results NOEC/EC10 (mg/L)	Remarks	KS*	Reference
Fish					
No studies available					
Aquatic invertebrates					
No studies available					
Algae					
Scenedesmus subpicatus performed according to test guideline 201	NPE-12	72h-E_rC10 = 26	Static, based on nominal concentations	2	Anonymous (1994b)**

* Klimish score assigned by dossier submitter.
**Confidential study from industry.

11.6.1 Chronic toxicity to fish

No experimental studies are available.

11.6.2 Chronic toxicity to aquatic invertebrates

No experimental studies are available.

11.6.3 Chronic toxicity to algae or other aquatic plants

Table 19: Summary of algae chronic toxicity tests

Method	Substance tested	Results (mg/L)	Remarks	KS*	Reference
OECD TG 201 *Scenedesmus subpicatus* (Chodat)	NPE-12	72h-E_rC50 = 89 72h-E_bC50 = 39 72h-E_rC10 = 26	Static, nominal concentration	2	Anonymous (1994b)**

Method	Substance tested	Results (mg/L)	Remarks	KS*	Reference
		72h-NOE_bC = 20			

* Klimish score assigned by dossier submitter.
**Confidential study from industry.

The study of Anonymous (1994b) is already evaluated in section 11.5.3. The chronic endpoints are given in Table 19.

11.6.4 Chronic toxicity to other aquatic organisms

No experimental studies are available for long-chain NPEs.

11.7 Comparison with the CLP criteria

Valid aquatic toxicity data will be used to derive the classification for NPEs covered in this dossier.

11.7.1 Acute aquatic hazard

Valid acute aquatic toxicity data are available for NPE 30 (fish, 96h LC50 value of > 1000 mg/L) and NPE 12 (algae, 72h LC50 value of 89 mg/L). Using Table 4.1.0 (a) of the CLP guidance, the group NPEn (n= ≤ 11 to ≤ 30) is not classified as acute hazard to the aquatic environment given that all valid acute toxicity values are higher than 1 mg/L.

11.7.2 Long-term aquatic hazard (including bioaccumulation potential and degradation)

For purposes of classification, long-chain NPEs (n= ≤ 11 to ≤ 30) are considered as rapidly degradable (section 11.1.4.5). No experimental data are available on bioaccumulation and estimated $logK_{ow}$ values are available of 2.83 for NPE-11 and -2.38 for NPE-30. Even though the predicted logKow data are less reliable (e.g. estimation of surfactants with EPI Suite) the data suggests low potential for bioaccumulation. In the absence of more reliable data, this group is considered to have a low potential for bioaccumulation since the estimated $LogK_{ow}$ values are below the CLP trigger of ≥ 4.

Only valid chronic toxicity data is available for algae with a NOEC of 20 mg/L. Using Table 4.1.0 (b)(ii), the group would not warrant classification. In the absence of adequate long term toxicity data, the subsequent step would be to apply the surrogate method. Only one acute toxicity test result is valid for fish, LC50 > 1000 mg/L. Using Table 4.1.0 (b)(iii), the group would not warrant classification for chronic toxicity. Based on the available data long-chain NPEs does not fulfil the criteria for chronic classification.

11.8 CONCLUSION ON CLASSIFICATION AND LABELLING FOR ENVIRONMENTAL HAZARDS

Aquatic acute: No classification
Aquatic chronic: No classification

The conclusions on classification (acute and chronic) might change if new reliable data become available.

12 EVALUATION OF ADDITIONAL HAZARDS

12.1 Hazardous to the ozone layer

Not evaluated in this dossier.

13 ADDITIONAL LABELLING

Not relevant

14 REFERENCES

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15 ANNEXES

Conditenital annex includes full reference to selected study reports.