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Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name): Phenol, dodecyl-, branched

EC Number: 310-154-3

CAS Number: 121158-58-5

Authority: Germany

Date: 21/03/2017

Cover 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

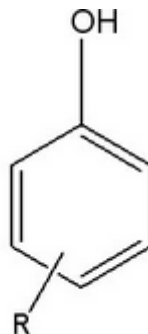
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Phenol, dodecyl-, branched
IUPAC name (public):	Phenol, para alkylation products with C12-rich branched olefins from propene oligomerisation
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	
Molecular weight or molecular weight range:	
Synonyms:	Branched laurylphenol

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input checked="" type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input type="checkbox"/> Other (provide further details below)	
Further details	The substance has been included in the 9 th ATP to the CLP regulation with a new entry for Annex VI (cf. section 3.1)	

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The following entry has been included in the 9th ATP to the CLP regulation:¹

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
604-092-00-9	phenol, dodecyl-, branched	310-154-3	121158-58-5	Repr. 1B Skin Corr. 1C Eye Dam. 1 Aquatic Acute 1 Aqu. Chronic 1	H360F H314 H318 H400 H410	M = 10 M = 10'	

3.1.2 Self classification

- In the registration:
Skin Corr. 1C; Repr. 2; Aquatic Acute 1; Aquatic Chronic 1.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Skin Irrit. 2; Eye irrit. 2; Eye Dam. 1; Skin Corr. 1A; Skin Corr. 1B; Repr. 1B; Acute Tox. 4;

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

In December 2013 RAC adopted the following opinion: Repr. Cat 1B, Skin Corr. 1C, Aquatic acute 1, Aquatic chronic 1. This harmonised classification and labelling has been included in the 9th ATP to the CLP regulation.

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R1179>

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site (19.09.2016)		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa
<input type="checkbox"/> 1000 – 10,000 tpa	<input checked="" type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential

4.2 Overview of uses

According to the information provided at the ECHA dissemination site, the substance is used as an intermediate for the manufacture of chemicals, rubber products and plastic products.

However, according to a risk evaluation report provided by UK in 2007, it is used for the production of oil and lubricant additives and additives may contain a significant amount of unreacted alkylphenol. They are used in petrol and diesel powered road vehicles and marine diesel engines and thus a wide dispersive use can be assumed.

Table: Uses

Part 1:

<input checked="" type="checkbox"/> Manufacture	<input type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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² ECHA dissemination site was accessed in September 2016.

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input checked="" type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ³	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)

³ CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)

Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)

Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

There are indications for Phenol, dodecyl-, branched to be an endocrine reacting substance from in vitro tests (binding affinity to the hepatic estrogen receptor of rainbow trout (Tollefsen and Julie Nilsen, 2008) and receptor binding assay to human estrogen receptor hER α (Akahori et al., 2008)) and in vivo tests (from tests on mammals (Yamasaki et al., 2003) and (Akahori et al., 2008)).

Furthermore there are structural alerts for an estrogen mode of action from the substance. It is very likely that a large proportion of the substance is a para-alkylated phenol with an alkyl chain length of C9–C15. (Nonylphenol and 4-tert-octylphenol as similar substances have been identified as endocrine disruptors.)

Although the main focus of the substance evaluation are the endocrine disruptive properties, environmental relevance should be also verified. In order to investigate environmental relevance of the substance, information regarding exposure and wide dispersive use will be also evaluated. Whether the substance reaches the environment, it needs to be further investigated as limited information is available on uses and emissions. The substance is used e.g. for manufacturing of fuel additives, surfactants and phenolic resins (Source: <http://www.transtank.hk/msds/26.pdf>), as well as monomer for alkylphenol formaldehyde resins, ink resins (Source: <http://www.siigroup.com/EHSPdf/PDDPGPS.pdf>). For surfactants, it can probably be assumed that the substance does reach the environment. Regarding resins, it is possible that they contain rest monomers that could be released into the environment. For these reasons the wide dispersive use cannot be excluded.

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
The necessity of an in vivo test on endocrine properties (e.g. a fish sexual development test) is to be evaluated during substance evaluation.	

5.5. Potential follow-up and link to risk management

<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input checked="" type="checkbox"/> Other (provide further details)
If the substance has to be considered an Endocrine Disruptor according to WHO/IPCS definition, SVHC identification and candidate listing might be the first steps that will be further analysed in a risk management option analysis.			

References:

Akahori, Y., Nakai, M., Yamasaki, K., Takatsuki, M., Shimohigashi, Y., Ohtaki, M., 2008. Relationship between the results of in vitro receptor binding assay to human estrogen receptor alpha and in vivo uterotrophic assay: comparative study

with 65 selected chemicals. *Toxicology in vitro* : an international journal published in association with BIBRA 22, 225-231.

Tollefsen, K.E., Julie Nilsen, A., 2008. Binding of alkylphenols and alkylated non-phenolics to rainbow trout (*Oncorhynchus mykiss*) hepatic estrogen receptors. *Ecotoxicology and Environmental Safety* 69, 163-172.

Yamasaki, K., Takeyoshi, M., Sawaki, M., Imatanaka, N., Shinoda, K., Takatsuki, M., 2003. Immature rat uterotrophic assay of 18 chemicals and Hershberger assay of 30 chemicals. *Toxicology* 183, 93-115.