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

Justification Document for the Selection of a CoRAP Substance

– Update –

Substance Name (public name):	Hydrogenated rosin alcohols
EC/List Number:	701-057-0
CAS Number:	n.a.
Authority:	German CA
Date:	22/03/2016
	21/03/2017 (1. updated version)
	20/03/2018 (2. updated version)

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

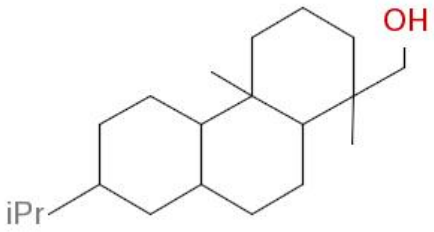
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Hydrogenated rosin alcohols
IUPAC name (public):	Hydrogenated rosin alcohols
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	n. a. (UVCB)
Molecular weight or molecular weight range:	n. a. (UVCB)
Synonyms:	*hydroabietyl alcohol* *Abitol*

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

Structural formula: This structural furmula represents one of the constituents of the UVCB substance.



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☒ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisa-tion	☐ Candidate List
		☐ Annex XIV
	Restri-ction	☐ Annex XVII
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)	

There has been testing proposals for bioaccumulation aquatic/sediment, oral sub-chronic toxicity (90-d) and prenatal development toxicity.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available.

3.1.2 Self classification

- In the registration:

Aquatic Chronic 4	H413
Skin Sens. 1	H317

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

Aquatic Chronic 2	H411
Skin Sens. 1B	H317

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available.

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
Joined submission. The disseminated tonnage is lower than overall tonnage. The relevance of this is under verification.		

**the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):*

https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

4.2 Overview of uses

The substance is used as a binding agent in coatings, inks, adhesives and sealants. The uses include professional and consumer uses.

Table: Uses

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

[1] *ECHA dissemination site accessed in 1 February 2017.*

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[1] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ 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)

[2] 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

The substance is fulfilling the screening criteria for PBT/vPvB as definded in Annex XIII, i.e.

P/vP criterion

The substance is not readily biodegradable. However, the available simulation test on degradation in surface water indicates that the substance is degraded with a half-live of 4.5 days. Therefore, the substance itself is not considered to be persistent. Two major metabolites were found in the simulation test and the registrant announces a follow-up study to identify these metabolites. As the PBT/vPvB assessment shall include the PBT/vPvB properties of metabolites, the identity and the properties of these metabolites have to be assessed further.

Regarding the result of the test on ready biodegradability, it is possible that in analogy to the simulation test the two metabolites were formed and that actually these are not readily biodegradable.

Therefore, the metabolites of the substance are considered as potentially persistent. Further information is required to draw a conclusion on the persistency of the degradation products.

B/vB criterion

The substance has a log Pow > 4.5. No measured data on bioconcentration in fish are available. The substance is therefore considered to be potentially bioaccumulative. A fish bioaccumulation study is planned by the registrant.

No data are available for the two degradation products. Therefore a conclusion on bioaccumulation cannot be drawn.

T criterion

Data on short-term ecotoxicology on aquatic organisms are available and show low ecotoxicity. No long-term studies for ecotoxicology on aquatic organisms are available. No data on aquatic ecotoxicology are available for the two unknown metabolites. Therefore a definitive conclusion on toxicity could not be drawn. However, it is likely that the parent substance does not fulfill the T criterion.

Use and Exposure

The substance has wide dispersive uses for professionals and consumers. Based on the uses of this substance it can be assumed that it may be released to the environment.

The assumptions in the environmental exposure scenarios are partly insufficient. This relates to the use of spERCs and to the assessment of the life cycle steps. There is no justification showing the applicability of the spERCs used based on e.g. operational conditions. An assessment of article service life and waste life cycle stage is not provided. However, there is no conclusive justification why these life cycle steps should not be relevant.

The risk characterization ratios for secondary poisoning, especially for fish-eating birds and mammals (fresh water) and for marine top predators are already close to 1 for several exposure scenarios. An assessment of aggregated exposure is not provided. Therefore, unacceptable risks arising from combined releases from multiple uses cannot be excluded.

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)

Further information on the biodegradation of the two transformation products of tetradecahydro-7-isopropyl-1,4a-dimethylphenanthren-1-methanol is required to clarify whether they are persistent or very persistent. Further information on bioaccumulation is required to clarify whether the substance and transformations products are bioaccumulative or very bioaccumulative. Further information on toxicity may be required to clarify the toxic potential of both tetradecahydro-7-isopropyl-1,4a-dimethylphenanthren-1-methanol and its metabolites. For the assessment of environmental exposure further information on operational conditions and emissions are required. More information is needed on the life cycle steps of the substance. An assessment of aggregated Exposure is required to assess risks arising from multiple uses. Depending on the outcome a refinement of the exposure assessment may be necessary.

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☒ Restriction	☒ Authorisation	☒ Other (provide further details)

If the substance is identified as a PBT/vPvB substance, an analysis of risk management options will be provided, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List, Authorisation, or Restriction.