Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	Resin acids and Rosin acids, hydrogenated, esters with glycerol Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol
Chemical Group:	Rosin esters
EC Number:	266-042-9 / 264-848-5
CAS Number:	65997-13-9 / 64365-17-9
Submitted by:	Finland
Published:	26/03/2014

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	Resin acids and Rosin acids, hydrogenated, esters with glycerol
IUPAC name:	Resin acids and Rosin acids, hydrogenated, esters with glycerol
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	UVCB
Molecular weight or molecular weight range:	378.6 - 951.5 (depending of the level of esterification)
Synonyms/Trade names:	*HRGE, Rosin, hydrogenated, esters with glycerol*

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

Structural formula: -

1.2 Similar substances/grouping possibilities

Table 2: Substance identity

EC name:	Resin acids and Rosin acids, hydrogenated, esters with pentaerythritol
IUPAC name:	Complex mixture of esters of hydrogenated resin and rosin acids, with pentaerythritol.
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	UVCB
Molecular weight or molecular weight range:	422.6 - 1282 (depending of the level of esterification)
Synonyms/Trade names:	*HRPE, Pentaerythritol esters of hydrogenated rosin*

Structural formula: -

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

HRGE and HRPE have no harmonized classification.

2.2 Self classification

HRGE and HRPE have not been classified in the registrations by self classification.

In addition to "Not classified", there is one self classification for HERGE in the C&L Inventory:

Aquatic Chronic 4; H413: May cause long lasting harmful effects to aquatic life.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

Harmonized classification has not been proposed for HRGE or HRPE.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA 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
Both HRGE and HRPE are HPV substances. The tonnage band is the same for both.		

☒ Industrial use	☒ Professional use	☒ Consumer use	☐ Closed System

Industrial use mostly in closed systems: in coatings, cleaning agents, binders and release agents, rubber production and processing, polymer processing, use in laboratories

Wide dispersive (ERC 8a, 8c, 8d) professional and consumer use: in coatings, cleaning agents, binders and release agents, road and construction applications, polymer processing, agrochemicals, lubricants, cosmetics, use in laboratories

4 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

4.1 Legal basis for the proposal

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

☒ Article 45(5) (Member State priority)

4.2 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

4.3 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[1]	
☐ 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)

[1] 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 selected hydrogenated rosin esters (HRGE and HRPE) have undergone PBT assessment under the supervision of the PBT Expert Group during 2012-2013. Only screening level data and modeling data (QSARs) were available for the evaluation. No definite PBT judgement could be obtained, due to lack of experimental data and/or somewhat contradictory modeling results.

The modeling results also indicated that the fate and behaviour of the different constituents of the rosin esters is divergent. Based on molecular size and log Kow values, it can be concluded that the larger molecules are unlikely to bioaccumulate (log Kow > 10; Dmax aver > 1.7 nm), whereas the smaller molecules (mono-esters of HRGE and HRPE) may have bioaccumulation potential (log Kow 5.22 for mono-HRGE and 5.78 for mono-HRPE). Moreover, none of the ester constituents are readily biodegradable based on Biowin 3 and 5 predictions.

The present judgement on T is as well based on inadequate information on ecotoxicological properties as no long-term data were available.

The registrant has stated in the PBT assessment that "the substances in this category are not considered to be PBT, but further information would be required to reach definitive conclusions regarding the vP/vB criteria".

In summary it is not possible to conclude on the PBT-properties without more information on the constituents (e.g. hydrolyses testing, ready biodegradation testing, bioaccumulation testing on relevant constituents). Therefore, the substances are proposed for Substance Evaluation.

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

☒ Compliance check, Final decision	☐ Dangerous substances Directive 67/548/EEC
☒ Testing proposal	☐ Existing Substances Regulation 793/93/EEC
☐ Annex VI (CLP)	☐ Plant Protection Products Regulation 91/414/EEC
☐ Annex XV (SVHC)	☐ Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

Compliance check final decision for both substances are published and the updated dossiers are under evaluation by ECHA.

The registrants have submitted a supplemented testing strategy for the UVCB category "Rosin esters" to ECHA, dated April 15, 2013. The testing stategy comprises of studies related to health hazards: Repeated dose (OECD 408), Two-Generation Reproduction Toxicity Study (OECD 416) and Prenatal Developmental Toxicity Study (OECD 414). Additionally a long-term aquatic toxicity test with aquatic invertebrates (OECD 211) has been proposed.

Therefore this proposal for substance evaluation is planned to focus mainly on environmental fate and behaviour of the selected hydrogenated rosin esters.

4.5 Preliminary indication of information that may need to be requested to 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)

Substance and/or constituent level experimental data on (bio)degradability, lipophilicity and bioaccumulation will probably be suggested. The need for additional long-term ecotoxicological data will be evaluated. Technical possibilities for constituent separation will be discussed with the registrant.

4.6 Potential follow-up and link to risk management

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

SVHC proposal