



Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type
701-246-8	-	Oligomerisation products of beta-pinene	<p>Poly(β-pinene)</p>	full
701-463-8	-	Oligomerisation products of alpha-pinene and beta-pinene		full

Authority: Spain

Date: 19 March 2024

Revision history

Version	Date

Cover Note

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

1. Background

1.1 Analogue substances

Not relevant.

1.2 Overview of ongoing or completed other REACH and CLP processes & other EU legislation

EC/ List number	Evaluation		CLH		Restriction	Authorisation
	CCH	TPE	Previously on CoRAP	Annex VI (CLP)	Annex XVII*	Candidate List/ Annex XIV
701-246-8	x	-	-	-	-	-
701-463-8	x	x	-	-	-	-

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40)

EC/ List number	Other EU legislation	Previous legislation	Stockholm convention	Other
	PPP/ BPR	NONS/ RAR	POP	(e.g. UNEP)
701-246-8	-	-	-	-
701-463-8	-	-	-	-

2. Classification

You can find information on classification in the ECHA C&L Inventory database, which includes both harmonised classification (when available) and the notified self-classifications. (<http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>). The CLP Regulation and all published ATPs are available on ECHA website: <http://echa.europa.eu/web/guest/regulations/clp/legislation>.

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
701-246-8	-	Oligomerisation products of beta-pinene	-	Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1	Skin Irrit. 2 Aquatic Acute 1 Aquatic Chronic 1 (1)
701-463-8	-	Oligomerisation products of alpha-pinene and beta-pinene	-	Aquatic Chronic 4	Aquatic Chronic 4 (1)

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers. Therefore the number may differ from the C&L inventory which displays number of notifiers.

3. Tonnage and uses

3.1 Aggregated Tonnage

EC/ List No	Aggregated tonnage (as per ECHA dissemination website*) ¹²
701-246-8	≥ 100 to < 1 000 t/y
701-463-8	≥ 100 to < 1 000 t/y

* The total tonnage band has been calculated by excluding the intermediate uses, - See also the Manual for Dissemination and Confidentiality under REACH (section 2.6.11):

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

3.2 Overview of the Uses

Main types of applications	EC 701-463-8	EC 701-246-8
Industrial use	Used as a fuel in closed systems. Use in the rubber industry and industrial application of adhesives, coatings and inks	-
Professional use	Use in fertilisers and in plant protection products. Use in adhesives, sealants, coatings and inks Used as a fuel	Agricultural/horticultural spray application of plant protection product
Consumer Use	Use in adhesives (including DIY glues, universal glues and sprayed glues), sealants, coatings and inks	Amateur garden (pre-filled trigger spray) use in fertiliser
Article service life	Professional and consumer adhesives and sealants, rubber industry (including rubber tyres), professional coating and inks	-
Intermediate use (if TII)	-	-
Formulation	Formulation of solvent-borne and solvent-less adhesives, sealants, rubber, coatings and inks	Formulation of plant protection products

¹ The total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

² Substance Infocard on ECHA's dissemination website accessed on 12 September 2023. NB. REACH registration data on ECHA's webpage has not been updated since 19 May 2023.

4. Justification for inclusion on the CoRAP

4.1 Legal basis

- Article 44(2)³
 Article 45(5)⁴

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	<input type="checkbox"/> Carcinogenic <input type="checkbox"/> Mutagenic <input type="checkbox"/> Reproductive toxicant
Potential ED	<input type="checkbox"/> Human Health <input type="checkbox"/> Environment
Suspected Sensitiser	<input type="checkbox"/> Respiratory <input type="checkbox"/> Skin
Suspected PBT/ vPvB Suspected PMT/ vPvM	<input checked="" type="checkbox"/> Persistent <input checked="" type="checkbox"/> Bioaccumulative <input type="checkbox"/> Mobile <input checked="" type="checkbox"/> Toxic (as defined in section 4.3 below) <input checked="" type="checkbox"/> very Persistent <input checked="" type="checkbox"/> very Bioaccumulative <input type="checkbox"/> very Mobile
Other suspected human health hazard(s) (e.g. STOT RE)	<input type="checkbox"/> (as defined in section 4.3 below)
Other suspected environmental hazard(s)	<input type="checkbox"/> (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	<input checked="" type="checkbox"/>
Consumer use	<input checked="" type="checkbox"/>
Exposure of workers	<input type="checkbox"/>
Exposure of sensitive populations	<input type="checkbox"/>
Exposure of environment	<input checked="" type="checkbox"/>
Cumulative exposure	<input type="checkbox"/>
High RCR	<input type="checkbox"/>
High (aggregated) tonnages	<input type="checkbox"/>
Others (to be specified)	<input type="checkbox"/>

³ "The Agency shall use the criteria in paragraph 1 [...]. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment."

⁴ "A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. [...]".

4.3 Justification of the concern(s) – to be clarified under Substance evaluation

Existing data supporting the hazard-based concern and other relevant information to justify the inclusion in CoRAP

Both substances are UVCBs. In the case of EC 701-246-8 the constituents include dimers, trimers, tetramers and higher oligomers of beta-pinene. Unreacted monomers are also reported in the composition. In the case of EC 701-463-8 the constituents include dimers, trimers, tetramers and higher oligomers of alpha- and beta-pinene (terpenic oligomers).

The PBT properties of the different constituents may differ.

Persistence:

Negligible degradation of EC 701-246-8 was observed after 28 days in the available screening tests performed according to OECD TG 301B, OECD TG 301D and OECD TG 302C tests conducted on the substance EC 701-246-8. Similarly, 4% degradation according to OECD Guideline 301 D for the terpenic oligomers is indicated for EC 701-463-8. Therefore, both substances screen potentially P/vP.

Based on BIOWIN QSAR predictions, the constituents of both substances screen potentially P/vP.

Bioaccumulation:

HPLC studies performed following EU Method A.8 are available for both substances. For EC 701-246-8 a log Kow of > 6.5 is reported, and for EC 701-463-8, log Kow values between 7.41 and 8.02 are reported for the dimers of the substance (which represented 79.2% of the test item).

The log Kow values of the constituents predicted by KOWWIN QSAR model increase with the number of monomeric units in the constituents, the dimer and trimer having log Kow values of 9.3 and 13.74, respectively. Hence, they all screen for potential B/vB. However, the dimers may have higher bioaccumulation potential than the trimers and higher oligomers which may potentially have limited bioavailability based on their predicted log Kow > 10.

Regarding EC 701-246-8, the BCFBAF QSAR models predict BCF values below 2000 L/kg and a biotransformation half-life of 149 days in fish for the dimer based on the predicted log Kow value. If using the lower limit value log Kow of 6.5 determined in the HPLC study as input, the predicted BCFs are in the range of 4100-18600 L/kg and the biotransformation half-life is 21 days. No QSAR estimation is available for EC 701-463-8.

Based on this information, the substances screen potentially B/vB but it is not possible to conclude on the bioaccumulative properties of the individual constituents.

Toxicity:

No long term tests with fish are available for the substances.

In the available algal study (OECD TG 201) a NOEC of 0.1 mg/L is reported for the substance EC 701-246-8. No information on algal toxicity is available for EC 701-463-8.

In an available short term test with Daphnia an EC50 of 0.26 mg/L is determined for the substance EC 701-246-8. The effects of a chronic exposure to EC 701-463-8 on the

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reproduction of *Daphnia magna* were investigated by exposing the daphnids to Water Accommodated Fractions (WAFs) of the test item over a range of nominal loading values (10, 32, 100, 316 and 1000 µg/L). After 21 days, a NOELR of 316 µg/L was determined at levels far above the water solubility of the test item.

It is not possible to conclude on the toxicity of individual constituents based on this information.

Information to be potentially requested

Information on persistence and bioaccumulation, and potentially also on toxicity, of the worst case constituent(s) may be needed to conclude on the PBT properties of both substances EC 701-246-8 and EC 701-463-8.

Possible follow-up (demonstrating the improvement of risk management measures)

EC/ List number	Harmonised C&L	SVHC	Restriction	Authorisation	Other
701-246-8	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
701-463-8	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>