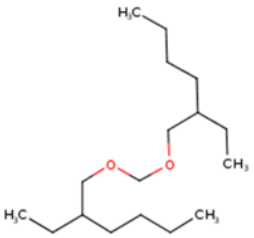
Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y) [1]
244-815-1	22174-70-5	3,3'-[methylenebis(oxymethylene)]bisheptane		≥ 10 to < 100 Full registration(s)

Authority: **Health and Safety Authority, Ireland**
Portuguese Environment Agency, Portugal

Date: **21 March 2023**

Revision history

Version	*Date*

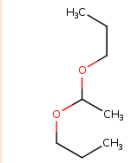
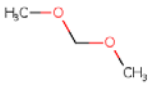
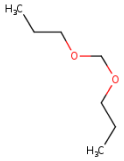
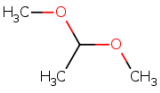
Cover Note

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

[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

1. Background

1.1 Analogue substances

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y)
203-335-2	105-82-8	1,1-dipropoxyethane		Intermediate
203-714-2	109-87-5	dimethoxymethane		Full ≥ 1 000 to < 10 000
207-330-6	462-95-3	diethoxymethane		Intermediate Full ≥ 100
208-021-9	505-84-0	Dipropoxymethane		Full ≥ 1 to < 10
208-589-8	534-15-6	1,1-dimethoxyethane		Full ≥ 1 to < 10
219-909-0	2568-90-3	1,1'-[methylenebis(oxy)]dibutane		Full ≥ 100

1.2 Overview of ongoing / completed / other 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
244-815-1	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)*

A compliance check decision was issued in September 2018, which included requests for information on water solubility, long-term toxicity in aquatic invertebrates, long-term toxicity testing in fish, algae growth inhibition and activated sludge respiration inhibition.

EC/ List number	Other EU legislation PPP/ BPR	Previous legislation NONS/ RAR	Stockholm convention POP	Other (e.g. UNEP)
244-815-1	-	-	-	-

2. Classification

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
244-815-1	22174-70-5	3,3'-[methylenebis(oxymethylene)]bisheptane	None	Aquatic Chronic 4-H413	Aquatic Chronic 4 H413 (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)* §
244-815-1	≥ 10 to < 100 tpa

** 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*

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3.2 Overview of the Uses

Main types of applications	EC 244-815-1 Key information
Industrial use	Laboratory chemicals Washing & cleaning products Processing aids
Professional use	Coating products Laboratory chemicals Washing & cleaning products
Consumer Use	Adhesives Sealants Biocides (e.g. disinfectants, pest control products) Surface treatment products Inks and toners Textile treatment products and dyes Indoor and outdoor use as processing aid
Article service life	-
Intermediate use (if TII)	-
Formulation	Formulation of mixtures.

4. Justification for inclusion on the CoRAP

4.1 Legal basis

☒ Article 44(2)[2]

☐ Article 45(5)[3]

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	☐ Carcinogenic ☐ Mutagenic ☒ Reproductive toxicant
Potential ED	☐ Human Health ☐ Environment
Suspected Sensitiser	☐ Respiratory ☐ Skin
Specific target organ toxicity – repeated (STOT RE)	☐ (as defined in section 4.3 below)
Suspected PBT/ vPvB **Suspected PMT/ vPvM**	☒ Persistent ☒ Bioaccumulative ☐ Mobile ☒ Toxic (as defined in section 4.3 below) ☐ very Persistent ☐ very Bioaccumulative ☐ very Mobile
Other human health hazard(s)	☐ (as defined in section 4.3 below)
Other environmental hazard(s)	☐ (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	☒
Consumer use	☒
Exposure of workers	☒
Exposure of sensitive populations	☐
Exposure of environment	☒
Cumulative exposure	☐
High RCR	☐
High (aggregated) tonnages	☐
Others (to be specified)	☐

[2] "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."

[3] "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

Regarding the reproductive toxicity concern:
An oral reproduction/developmental toxicity screening study with 3,3'-[methylenebis(oxymethylene)]bisheptane (EC 244-815-1), hereafter "the Substance", is reported in the registration dossier. The study summary reports that there was an increase in the mean mating duration and a decrease in the mean number of corpora lutea and mean number of implantation sites at the high dose (1000 mg/kg bw/day). At the mid (400 mg/kg bw/day) and high doses, an increase in pre- and post-implantation loss was reported. There was a trend for lower numbers of live pups on post-natal day 1 in all treatment groups. No other reproductive toxicity data is reported in the registration dossier. The registrants conclude there is an effect on reproduction and development at the highest dose, but do not apply a self-classification for reproductive toxicity.

The registration data reports industrial, professional and consumer uses of the Substance.

A review of the available data is required in order to determine whether further information is needed to clarify the concern for reproductive toxicity.

Regarding the PBT concern:
Persistency
According to the information in the registration dossier, the Substance is not ready biodegradable based on results from an OECD TG 301D test and predicted as not P/vP in QSAR model (biotic degradation in sediment and in soil).

Additionally, following CCH of similar substances of the group of dialkoxymethane derivatives (butylal EC 219-909-0; ethylal EC 207-330-6), ECHA requested, among others, water simulation tests (OECD TG 309) for these substances. However, no relevant information was found from the results of preliminary OECD TG 309 tests and no DT50 values are available for these similar substances.

From the available data, no conclusion is possible on persistency of the Substance.

Bioaccumulation
The Substance screens as potentially B (log Kow > 4.5) with a predicted log Kow of 6.53, which exceeds the screening criterion for bioaccumulation potential indicated in ECHA Guidance R.11. However, the Substance is a surface active substance and log Kow is not a good descriptor for assessing the bioaccumulation potential of surface active substances. Log Kow only mimics passive diffusion across lipid membranes, but does not predict other bioaccumulation mechanisms, e.g. protein binding (ECETOC, 2014). Thus, no conclusion is possible from the available data on B/vB.

Toxicity
The Substance is considered T as it fulfils the toxicity criterion (NOEC < 0.01 mg/L). In a toxicity test on the algae *Pseudokirchneriella subcapitata* (OECD TG 201), a 72h-NOEC of 0.0015 mg/L (2019) was obtained. Additionally the long-term toxicity tests on fish and aquatic invertebrates also resulted in NOEC values below 0.01 mg/L.

Other relevant information to justify the inclusion in CoRAP

N/A

Information to be potentially requested

- Following the evaluation of the existing data, further information may be requested to address reproductive toxicity.
- There is a need to further clarify degradation and bioaccumulation of the Substance.

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

EC/ List number	Harmonised C&L	Restriction	Authorisation	Other
244-815-1	☒	☒	☒	☐