Justification Document for the Selection of a CoRAP Substance

- Update -

Substance Name (public name): Bis(2,6-diisopropylphenyl)carbodiimide

EC Number: 218-487-5

CAS Number: 2162-74-5

Authority: Italy

Date: 21/03/2017

20/03/2018 (1. update)

18/03/2020 (2. update)

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

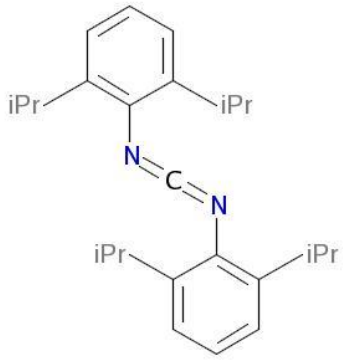
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Bis(2,6-diisopropylphenyl)carbodiimide
IUPAC name (public):	N,N'-bis(2,6-diisopropylphenyl)carbodiimide
Index number in Annex VI of the CLP Regulation:	--
Molecular formula:	C25H34N2
Molecular weight or molecular weight range:	362.5509
Synonyms:	2,2',6,6'-Tetraisopropyldiphenylcarbodiimide Benzeneamine, N,N'-methanetetraylbis[2,6 bis (1-methylethyl)]- *N,N'-bis[2,6-di(propan-2-yl)phenyl]methanediimine*

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	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☒ Testing proposal, Final decison
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[1]
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	☐ Assessment	

[1] Please specify the relevant entry.

	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The Harmonised Classification is not available.

3.1.2 Self classification

- In the registration:

  Acute Tox. 4 H302

  Repr. 1B H360

  STOT RE 1 H372 (heart, white blood cells, lymphoid organs, gastro-intestinal tract, kidneys)

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

  STOT RE 1 H372

  Skin Irrit. 2 H315

  Eye Irrit. 2 H319

  STOT SE 3 H335 (na)(Inhalation)

  Acute Tox. 2 H310

  Acute Tox. 3 H301

  Acute Tox. 4 H332

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

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4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

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
This substance has 3 active registrations under REACH, 1 Joint Submission and 0 Individual Submission.		

*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

This substance is used in the following products: adhesives and sealants and polymers. This substance has an industrial use resulting in manufacture of another substance (use of intermediates).

This substance is used in the following areas: formulation of mixtures and/or re-packaging. This substance is used for the manufacture of: plastic products and rubber products.

Release to the environment of this substance is likely to occur from industrial use: in the production of articles, formulation of mixtures, manufacturing of the substance and formulation in materials. Other release to the environment of this substance is likely to occur from: indoor use, outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment).

[2] The date when the dissemination site was accessed is 22 September 2016.

This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones).

Table: Uses

Part 1:

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

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2)

☐ Article 45(5)

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[3]	
☐ 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)

[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

PBT assessment

Persistence assessment

The following studies on ready biodegradability were reported: 1) OECD 301F, the degradation was 1% after 28 d; 2) OECD 301B, the degradation was 3% after 28 d; 3) (Q)SAR, BIOWIN v4.10, the result was not readily biodegradable; 4) QSAR TOXTREE, with START plugin, the result was Class II - persistent chemical. The substance was concluded by the Registrants to be not readily biodegradable.

The Registrants waived the simulation test in water based upon the low water solubility of the substance (< 0.05 mg/L). Moreover, the justification for soil simulation test waiving was that direct and indirect exposure of soil is unlikely, however no exposure assessment for the environment was performed by the Registrants.

In conclusion, on the basis of the screening information, the substance is potentially P or vP.

Bioaccumulation assessment

The aquatic bioaccumulation estimate carried on by QSAR approach (BCFBAFWIN v3.01) provided a BCF value of 1912 L/Kg, although no QSAR documentation was provided. Moreover an experimental log Kow of 6.20 was reported.

In conclusion the bioaccumulation potential of the registered substance cannot be completely excluded.

Toxicity assessment

The substance met the criteria for classification in relation to the endpoint: specific target organ toxicity after repeated exposure (STOT RE 1) according to Regulation EC No 1272/2008, as declared by the Registrants.

Regarding the environmental toxicity, the data provided are not enough accurate to conclude on T.

In conclusion the substance is considered to fulfil the T criterion.

Exposure assessment

Despite classification of the substance for hazard classes as indicated in Annex I of REACH, no environmental exposure and risk assessment has been provided by the registrant. Therefore, for the environment, the safe use of the substance has not been demonstrated.

In section 3.7.3 of IUCLID, among the significant routes of exposure for environment, water, air, soil waste and soil are checked by the Registrants, nevertheless potential releases are not reported. The substance has a wide dispersive use, therefore a potential for exposure/release due to the uses of the substance is expected.

It is to be noted that a CCH was performed in order to request further information related to environmental aspects (Decision number: CCH-D-21 14366654-4L-0I/F).
Registrant has to submit the requested information in an updated registration dossier by 10 February 2020.

5.4. 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 on ED potential	☐ Other (provide further details below)

The manual screening conclusion on the substance is that both standard (requested in CCH, as above mentioned) and non-standard information are needed to verify the initial concern as suspected PBT. These are specified below.

Only screening information are available for P assessment, that provide a conclusion as potentially P or vP, moreover the substance has a wide dispersivre use so that direct and indirect exposure of soil can't be excluded.Therefore, based on the physicochemical property of the substance (poor water solubility, Log Kow > 6, Log Koc > 5) the simulation tests on water and/or sediment/soil, that are standard REACH information requirements, are needed.

Based on the physicochemical property of the substance (poor water solubility, Log Kow > 6, Log Koc > 5) exposure from sediment or soil is expected to be more relevant than that from the water column. Therefore an experimental dietary biomagnifications in fish (OECD TG 305-III) and/or an experimental terrestrial bioaccumulation (OECD TG 317) could be necessary for a proper evaluation.

Based on a wide dispersive use of the substance and on the potential for PBT properties, an exposure assessment is needed.

5.5 Potential follow-up and link to risk management

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

The potential regulatory outcome, following the clarification by SEV of the concern, could be to carry out an Annex XV for SVHC identification.