Justification Document for the Selection of a CoRAP Substance

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

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

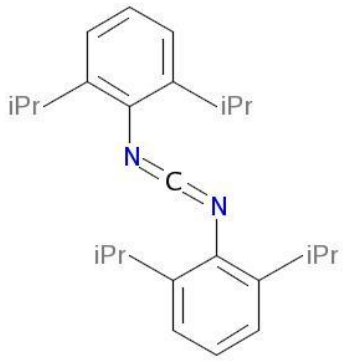
1.1 Other identifiers of the substance

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:



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
	Authorisation	☐ 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)	

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

  STOT Rep. Exp. 2 H373 (heart, white blood cells, lymphoid organs, gastro-intestinal tract, kidneys and female genital tract)

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

  STOT SE 3 H335 (na)(Inhalation)

  Aquatic Chronic 4 H413

  Skin Irrit. 2 H315

  Eye Irrit. 2 H319

  Acute Tox. 2 H310

  Acute Tox. 3 H301

  Acute Tox. 4 H332

  Not Classified

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

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

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).

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

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

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	
Formulation	Industrial formulation of preparations Industrial formulation of lubrificant
Uses at industrial sites	Industrial use in polymerisation process Industrial use in thermoplast and in masterbatch Industrial use in PU-based adhesives Industrial use of lubricants
Uses by professional workers	Professional use in PU-based adhesives Professional use of lubricants - indoor Professional use of lubricants - outdoor
Consumer Uses	
Article service life	service life (worker at industrial site)

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

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 category 2) 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

The substance is not classified for the environment under CLP and so no environmental risk assessment was performed by the Registrants neither in the CSR, nor in the IUCLID dossiers. Consequently, all identified uses of the substance are assessed by the Registrants as safe for the environment.

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.

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 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 of the concern, could be to carry out an Annex XV for SVHC identification.