Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	bis(α,α-dimethylbenzyl) peroxide
Chemical Group:	
EC Number:	201-279-3
CAS Number:	80-43-3
Submitted by:	Norway
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

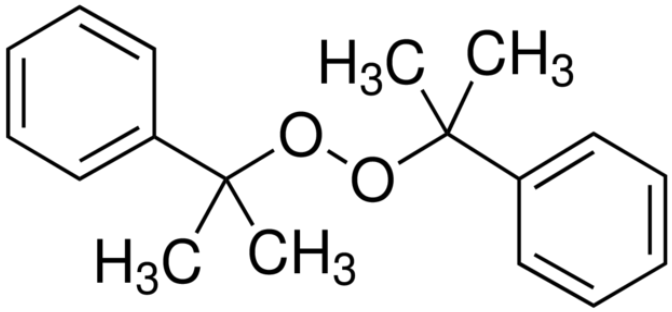
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	bis(α,α-dimethylbenzyl) peroxide
IUPAC name:	1,1'-(dioxydipropane-2,2-diyl)dibenzene
Index number in Annex VI of the CLP Regulation	617-006-00-X
Molecular formula:	C18H22O2
Molecular weight or molecular weight range:	270.3661
Synonyms/Trade names:	Peroxide, bis(.alpha.,.alpha.-dimethylbenzyl) Peroxide, bis(1-methyl-1-phenylethyl) dicumyl peroxide cumene peroxide diisopropylbenzene peroxide

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

Structural formula:



1.2 Similar substances/grouping possibilities

Not assessed yet

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

CLP criteria:

Org. Perox. F; H242: Heating may cause a fire.

Skin Irrit.2; H315: Causes skin irritation.

Eye Irrit. 2; H319: Causes serious eye irritation.

Aquatic chronic 2; H411: Toxic to aquatic life with long lasting effects

DSD criteria:

O; R7 - May cause fire

Xi, R36/38 - Irritating to eyes and skin

N; R51/53 Dangerous for the environment; Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

2.2 Self classification

2.2.1 Self classification(s) proposed by the registrant(s)

None, as the registrants follow the harmonised classification in Annex VI.

2.2.2 Self classification(s) in the C&L Inventory

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

Aquatic Acute 1; H400: Very toxic to aquatic life.

The same notification has also included labelling with H410 (Very toxic to aquatic life with long lasting effects) but not included the human health harmonised classifications.

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

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
1000 + tpa		☐ Confidential

High total amount of registered substance in nordic countries (up to 1031 t in 2011), Spin database.

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

Identified uses based on dissiminated information from registrations (ECHA):

Manufacture of organic peroxides

Formulation of the substance

Formulation and (re)packing of organic peroxides and mixtures

Industrial formulation of organic peroxides in materials (covers use of organic peroxide as a flame retardant synergist) (eg. wdk, PEST, FECC, ETRMA)

Industrial use of bis(a,a-dimethyl benzyl peroxide)

Industrial use of organic peroxides in the polymer industry

Industrial use of organic peroxides in non-polymer industries

Industrial use of organic peroxide as a flame retardant synergist

Use of organic peroxides in the Chemical Distribution Sector (eg. FECC)

Other Industrial uses of organic peroxides (eg. AISE, COLIPA)

Industrial use of organic peroxides as polymerization initiators, crosslinking agents or curing agents (eg. wdk, SRM, PEST, EPDLA, PPRM, ETRMA, UPR, CEPE, FEICA, EFCC)

Production of compounds and use as cross-linking agent for the manufacture of rubber products

Professional indoor use of organic peroxides in non-polymer applications

Professional outdoor use of organic peroxides in non-polymer applications

Professional indoor use of organic peroxides

Professional outdoor use of organic peroxides

Consumer indoor use of organic peroxides in non-polymer applications

Consumer outdoor use of organic peroxides in non-polymer applications

Consumer use of organic peroxide as a flame retatrdant synergist (indoor and outdoor)

Consumer indoor use of organic peroxides (Adhesives, sealants, Air care products, Biocidal products, Coatings and paints, thinners, paint removes, Fillers, putties, plasters, modelling clay, Finger paints, Ink and toners, Polishes and wax blends, Washing and cleaning products, Cosmetics, personal care products)

Consumer outdoor use of organic peroxides

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

P: No experimental data on abiotic degradation are available. Existing screening tests on biodegradation show conflicting results but demonstrate that the substance is not readily biodegradable. Several structurally related compounds have also been shown to be not readily biodegradable. Biodegradation tests in soil and simulation tests in water, sediment, soil have been waived. Given the low water solubility and the high log Koc of 3.98 of bis(α,α-dimethylbenzyl) peroxide, sediment and soil may be an important matrix for the substance.

B: With a log Kow of 5.6 the screening criterion for B is met. Only one BCF test in fish is available and its experimental design appears to have limitations.
Low biodegradation, low mobility, high sorption in soil/sediment and slightly high BCF of bis(α,α-dimethylbenzyl) peroxide indicate potential for bioaccumulation for soil living organisms.

T: The lowest NOEC reported was 0.117 mg/L in a Daphnia magna reproduction test and hence this would suggest that bis(α,α-dimethylbenzyl) peroxide would not meet the T criteria. However, there are no chronic fish toxicity data which is a data requirement and may result in a lower NOEC. Testing proposals are pending for sub-chronic and reproductive toxicity, see point 4.4, therefore no conclusion possible at the moment.

HH: The outcome of the pre-natal developmental toxicity test and the 90day oral subchronic oral toxicity will decide the need for further tests to be performed on reproductive toxicity and carcinogenicity.

Exposure:The registered substance is in wide dispersive use including use by consumers. RCRs close to 1 have been identified. Exposure estimation seems to be of very general character.

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)	

The registered substance is classified according to annex VI, see section 2.1.

A final descision issued by ECHA after examination of a testing proposal requests by 18 July 2014 a

- reproductive toxicity (pre-natal developmental toxicity) test

- sub-chronic toxicity (90-day): oral

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)

-Further tests to investigate the environmental fate of the substance.

-Further tests to investigate long term toxicity to aquatic organisms.

-More information on exposure to clarify potential risk.

-More information on toxicological properties may need to be requested after examination of the pre-natal developmental test and the sub-chronic toxicity test (90-day, oral)

4.6 Potential follow-up and link to risk management

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

Depends on the outcome of the substance evaluation process.