

Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide
Chemical Group:	Peroxide
EC Number:	229-782-3
CAS Number:	6731-36-8
Submitted by:	Germany
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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 1: Substance identity

EC name:	di-tert-butyl 3,3,5-trimethylcyclohexylidene diperoxide
IUPAC name:	1,1-bis(tert-butylidioxy)-3,3,5-trimethylcyclohexane
Index number in Annex VI of the CLP Regulation	none
Molecular formula:	C ₁₇ H ₃₄ O ₄
Molecular weight or molecular weight range:	302.45 g/mol
Synonyms/Trade names:	Trigonox 29

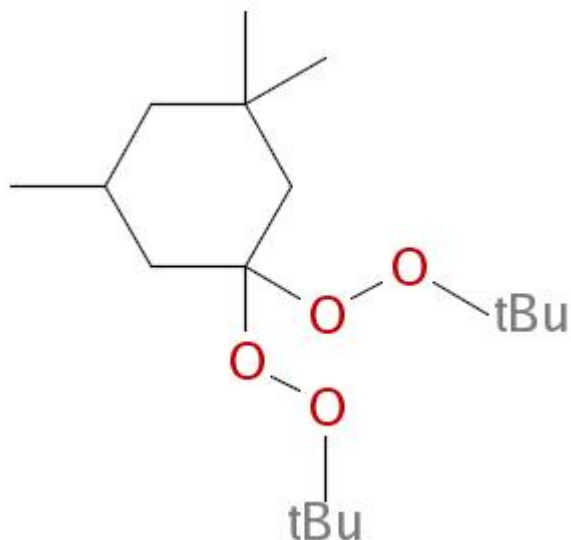
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

None

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not included in Annex VI of Regulation (EC) No 1272/2008.

2.2 Self classification

- In the registration:
 - Org. Perox. Type B, H241: Heating may cause a fire or explosion.
 - Aquatic Chronic 4, H413: May cause long lasting harmful effects to aquatic life.
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
 - Not classified
 - Flam. Liq. 3, H226 – Flammable liquid and vapour
 - Org. Perox. C, H242 – Heating may cause fire
 - Asp. Tox. 1, H304 – May be fatal if swallowed and enters airways
 - Skin irrit. 2, H315 – Causes skin irritation
 - Eye irrit. 2, H319 – Causes serious eye irritation
 - STOT SE 3, H335 – May cause respiratory irritation
 - Aquatic Acute 1, H400 – Very toxic to aquatic life
 - Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

3 INFORMATION ON AGGREGATED TONNAGE AND USES

From ECHA dissemination site			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input type="checkbox"/> 100 – 1000 tpa	
<input type="checkbox"/> 1000 – 10,000 tpa	<input type="checkbox"/> 10,000 – 100,000 tpa	<input type="checkbox"/> 100,000 – 1,000,000 tpa	
<input type="checkbox"/> 1,000,000 – 10,000,000 tpa	<input type="checkbox"/> 10,000,000 – 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa	
<input checked="" type="checkbox"/> 100 + tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input checked="" type="checkbox"/> Confidential	
One registrant in the joint submission has claimed the tonnage confidential.			
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Closed System
<p>A wide range of uses is given in the registration dossiers, including use as a polymer additive and as adhesive or sealant and wide dispersive use in consumer products:</p> <p>Air care products, Biocidal products (e.g. disinfectants, pest control), 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</p>			

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
<p>1,1-bis(tert-butyldioxy)-3,3,5-trimethylcyclohexane fulfils the screening criteria for persistence or very high persistence (P/vP), bioaccumulation or very high bioaccumulation (B/vB) and toxicity (T) as described in the ECHA "Guidance on information requirements and chemical safety assessment", chapter R.11.</p> <p>According to the data provided in the chemical safety report of the registration dossiers, the substance is not readily biodegradable and thus fulfils the P/vP screening criterion. A non-standard simulation study on degradation in a water/sediment system is available, however, this study is considered inappropriate for a definitive assessment on environmental half-life values.</p> <p>The B/vB screening criterion is also considered to be fulfilled: The partition coefficient n-octanol/water given is around 7. Furthermore, the Japanese Ministry of International Trade and Industry (MITI) lists the substance as highly bioaccumulative, with measured BCF values in carp ranging from 3500 to 13200. According to these experimental results, the substance also fulfils the vB criterion as laid down in Annex XIII of the REACH regulation.</p> <p>The T screening criterion is considered to be fulfilled, as preliminary results from a study currently being performed by the registrant indicate the substance is potentially toxic to Daphnia.</p>		

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

4.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance check, Final decision	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC
<input checked="" type="checkbox"/> Testing proposal	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC
<input type="checkbox"/> Annex VI (CLP)	<input type="checkbox"/> Plant Protection Products Regulation 91/414/EEC
<input type="checkbox"/> Annex XV (SVHC)	<input type="checkbox"/> Biocidal Products Directive 98/8/EEC ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>The testing proposal Decision of 05/07/2012 has been published. The DL was 07/01/2014 for updating the dossier with the results of the four tests (according to OECD 114, 414, 211 and 225).</p> <p>The dossier was updated and is currently under evaluation by ECHA.</p>	

4.5 Preliminary indication of information that may need to be requested to clarify the concern

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
<p>Based on a preliminary examination of the available data, simulation studies on biodegradation are required to derive reliable half life values for sediment, water and soil. The registrant has proposed to conduct a test on the long-term toxicity of the substance to aquatic invertebrates. Depending on the outcome, further data on ecotoxicity may be needed to conclude whether the T criterion is fulfilled. Additionally, a detailed evaluation of the available data may lead to further information requirements.</p>	

4.6 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Depending on the outcome of the substance evaluation, an analysis of Risk Management Options shall be carried out to identify appropriate risk management measures. If the substance is confirmed to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB), it may be proposed for inclusion in the Candidate List and subsequent inclusion in Annex XIV of REACH.</p>			