

## **Justification for the selection of a candidate CoRAP substance**

<b>Substance Name (Public Name):</b>	tert-butyl perbenzoate
<b>Chemical Group:</b>	perbenzoate
<b>EC Number:</b>	210-382-2
<b>CAS Number:</b>	614-45-9
<b>Submitted by:</b>	Italy
<b>Published:</b>	20/03/2013

### **NOTE**

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

## Contents

1	IDENTITY OF THE SUBSTANCE	
1.1	Name and other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING	
2.1	Harmonised Classification in Annex VI of the CLP	4
2.2	Proposal for Harmonised Classification in Annex VI of the CLP	4
2.3	Self classification	4
3	JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE	
3.1	Legal basis for the proposal	4
3.2	Grounds for concern	5
3.3	Information on aggregated tonnage and uses	5
3.4	Other completed/ongoing regulatory processes that may affect suitability for substance evaluation	6
3.5	Information to be requested to clarify the suspected risk	6
3.6	Potential follow-up and link to risk management	6

## 1 IDENTITY OF THE SUBSTANCE

### 1.1 Name and other identifiers of the substance

Table 1: Substance identity

<b>Public Name:</b>	tert-butyl perbenzoate
<b>EC number:</b>	210-382-2
<b>EC name:</b>	tert-butyl perbenzoate
<b>CAS number (in the EC inventory):</b>	614-45-9
<b>CAS number:</b>	614-45-9
<b>CAS name:</b>	Benzenecarboperoxoic acid, 1,1-dimethylethyl ester
<b>IUPAC name:</b>	tert-butyl benzenecarboperoxoate
<b>Index number in Annex VI of the CLP Regulation</b>	The harmonized classification is not available
<b>Molecular formula:</b>	$C_6H_5COOOC(CH_3)_3$
<b>Molecular weight or molecular weight range:</b>	194.23
<b>Synonyms:</b>	

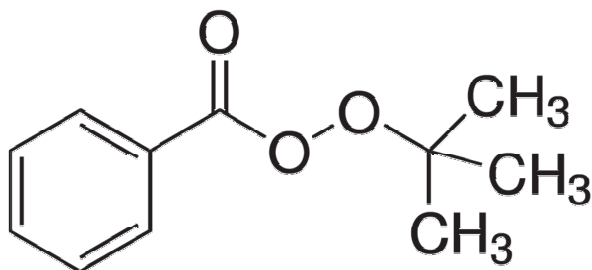
**Type of substance**

Mono-constituent

Multi-constituent

UVCB

**Structural formula:**



## 2 CLASSIFICATION AND LABELLING

### 2.1 Harmonised Classification in Annex VI of the CLP

No harmonized classification.

### 2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None.

### 2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

Org. Perox. C, H242: Heating may cause a fire  
Acute Tox.4, H332: Harmful if inhaled  
Skin Irrit. 2, H315: Causes skin irritation  
Skin Sens. 1, H317: May cause an allergic skin reaction.

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

According to DSD criteria:

E; R2 Risk of explosion by shock, friction, fire or other sources of ignition.  
R7 May cause fire.  
Xn; R20 Harmful by inhalation.  
Xi; R38 Irritating to skin.  
R43 May cause sensitisation by skin contact.  
N; R50 Dangerous for the environment; Very toxic to aquatic organisms.

In addition are the following classifications included in the Classification and labeling inventory:

Org. Perox. A; H240: Heating may cause an explosion.

Org. Perox. B; H241: Heating may cause a fire or explosion.

Ox.Liq. 3; H272; May intensify fire; oxidizer.

Acute Tox 4; H302: Harmful if swallowed.

## 3 JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

### 3.1 Legal basis for the proposal

- Article 44(1) (refined prioritisation criteria for substance evaluation)
- Article 45(5) (Member State priority)

### 3.2 Grounds for concern

<input type="checkbox"/> (Suspected) CMR	<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Cumulative exposure
<input checked="" type="checkbox"/> (Suspected) Sensitiser	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> High RCR
<input type="checkbox"/> (Suspected) PBT	<input type="checkbox"/> Exposure of sensitive populations	<input type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input type="checkbox"/> Other (provide further details below)	

The test results for sensitization showed debated results (modified guinea pig test was negative and LLNA test was positive). Further evaluation of the available sensitisation data is required, with possible need for additional testing.

No data on carcinogenicity are available for this substance (according to Annex IX of Reach regulation). In particular the genotoxicity in vitro data were positive while the genotox in vivo was negative, in this condition more data should not be requested. Moreover the toolbox profiler by Benigni Bossa doesn't alert for carcinogenicity while Oncologic tool reveal a moderate concern for carcinogenicity. This concern was presumably based on the chemical class of perbenzoate, the organic peroxide that are strong oxidizing agents able to induce the formation of free radicals.

The available information on repeated dose toxicity didn't support the request of further study on carcinogenesis at this stage that have to be performed at the next tonnage level.

### 3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 + tpa
<input type="checkbox"/> 100 - 1000 tpa	<input type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa
<input checked="" type="checkbox"/> 100+ tpa	<input type="checkbox"/> 100,000 - 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa

Confidential

There is a confidentiality claim for one tonnage band.

The overall tonnage is 100+ tpa.

<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
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The following consumer uses are disseminated on ECHA website:

PC 1: Adhesives, sealants  
 PC 3: Air care products  
 PC 8: Biocidal products (e.g. disinfectants, pest control)  
 PC 9a: Coatings and paints, thinners, paint removes  
 PC 9b: Fillers, putties, plasters, modelling clay  
 PC 9c: Finger paints  
 PC 18: Ink and toners  
 PC 31: Polishes and wax blends  
 PC 35: Washing and cleaning products (including solvent based products)  
 PC 39: Cosmetics, personal care products

ERC 8b/8e: Wide dispersive indoor/outdoor use of reactive substances in open systems

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

<input type="checkbox"/> Compliance check	<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
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Annex XVII (Restriction)	
<p>There is testing proposal for the following end-points;</p> <ul style="list-style-type: none"> <li>• Viscosity</li> <li>• Long-term tox. fish</li> <li>• Long-term tox. aquatic invert.</li> <li>• Develop. Tox. / teratogen.</li> </ul>	

### 3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input checked="" type="checkbox"/> Other (provide further details below)	
<p>All the possible exposure scenarios should be evaluated in order to characterise the risk of sensitization. A need for additional testing may be possible.</p>	

### 3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<i>Please provide further details</i>			