

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	N,N-dicyclohexylbenzothiazole-2-sulphenamide
Chemical Group:	Benzothiazole
EC Number:	225-625-8
CAS Number:	4979-32-2
Submitted by:	Germany
Published:	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	3
1.1	Name and other identifiers of the substance	3
2	CLASSIFICATION AND LABELLING	4
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	4
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	6
3.5	Information to be requested to clarify the suspected risk	6
3.6	Potential follow-up and link to risk management	7

1 IDENTITY OF THE SUBSTANCE

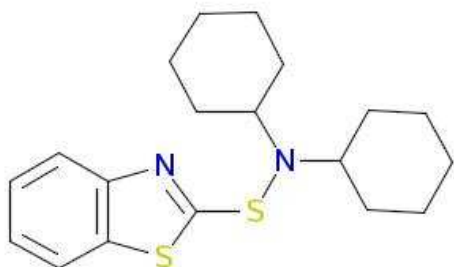
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	N,N-dicyclohexyl-2-Benzothiazolesulfenamide
EC number:	225-625-8
EC name:	N,N-dicyclohexyl-2-Benzothiazolesulfenamide
CAS number (in the EC inventory):	4979-32-2
CAS number:	4979-32-2
CAS name:	2-Benzothiazolesulfenamide, <i>N,N</i> -dicyclohexyl-
IUPAC name:	N-(1,3-Benzothiazol-2-yl-sulfanyl)-N-benzyl-1-phenylmethanamine
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	C ₁₉ H ₂₆ N ₂ S ₂
Molecular weight or molecular weight range:	346.5531
Synonyms:	N,N-dicyclohexylbenzothiazole-2-sulphenamide

Type of substance Mono-constituent Multi-constituent UVCB

Structural formula:



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Not listed.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classification and labeling according to CLP;

- Skin Sens. 1; H317: May cause an allergic skin reaction.
- Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

Classification and labeling according to 67/548/EEC (DSD);

- R43 May cause sensitisation by skin contact.
- N; R50 Dangerous for the environment; Very toxic to aquatic organisms.
- R53 May cause long-term adverse effects in the aquatic environment.

Classifications given in Classification and labelling Inventory are consistent with self classification from the registrants and additionally include:

- Acute Tox. 4; H302: Harmful if swallowed.
- 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 4; H413: May cause long lasting harmful effects to aquatic life

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 checked="" 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 checked="" type="checkbox"/> (Suspected) PBT/vPvB	<input type="checkbox"/> Exposure of sensitive populations	<input checked="" type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected endocrine disruptor	<input checked="" type="checkbox"/> Other (provide further details below)	

In the registration dossier the registrants assess the BCF of DCBS of being larger than 5000 and consequently DCBS is "vB".

Based on the results of two screening tests in which no or only negligible biodegradation was observed the registrants assess DCBS as "Not Readily Biodegradable". But the registrants provide no further testing of the biodegradation. This raises the suspicion of DCBS also being "vP". Due to the hydrolysis testing demonstrating the ability for hydrolysis under specific conditions, one might assess that the persistence in a water-sediment-simulation test would be below the vP-trigger. However, with regard to the physico-chemical properties it is reasonable to expect persistence in sediment and especially in soil to be very high. DCBS strongly adsorbs to sediment and soil. It is known, that hydrolysis can be inhibited by adsorption of the substance (Boethling et al. 2009) causing persistency. Because DCBS decomposes during vulcanization the persistence of the transformation products is of particular interest.

Further grounds for concern:

- High exposure to workers. Also consumer exposure possible.
- Based on read across approach with the structure analogues: CBS, TBBS and MBS a skin sensitizing potential of DCBS in humans is suggested.
- Overall picture of toxicity to reproduction that is observed at relatively higher doses (476 mg/kg bw) in a non-guideline study.
- In a non-guideline study sarcomas observed at the port of entrance (subcutaneous application). However, no clear evidence of carcinogenicity based on the absence of genotoxic potential in vivo and no observation of pre-neoplastic lesions in an oral repeated dose toxicity study (subchronic).

3.3 Information on aggregated tonnage and uses

<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 - 50,000 tpa	<input checked="" type="checkbox"/> 1000 + tpa
<input type="checkbox"/> 100,000 - 1000,000 tpa	<input type="checkbox"/> > 1000,000 tpa	

Confidential

Note: There is additional tonnage band which is confidential.

<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
<p>The use of DCBS is assessed as wide dispersive use. http://apps.echa.europa.eu/registered/data/dossiers/DISS-9eba1307-5d61-3c51-e044-00144f67d031/AGGR-99c9030b-4209-4ad1-811f-62a42df137b3_DISS-9eba1307-5d61-3c51-e044-00144f67d031.html#section_3_5</p>			

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 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)	
-	

3.5 Information to be requested to clarify the suspected risk

<input checked="" type="checkbox"/> Information on toxicological properties	<input checked="" type="checkbox"/> Information on physico-chemical properties
<input checked="" 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 type="checkbox"/> Other (provide further details below)	
<p>There is a need to evaluate the endpoint persistence. This should be done for DCBS as well as for the transformation products (metabolites). As the substance is Not Readily Biodegradable, a water sediment simulation test is required due to Annex IX, which is missing until now. However, we also see the need to assess the persistency in soil as well.</p> <p>Further informations requests:</p> <ul style="list-style-type: none"> • More detailed exposure data because of the skin sensitization potential. • According to OECD SIDS (JP): "The chemical possesses a hazard for human health (repeated dose toxicity). An exposure assessment and, if necessary risk assessments for workers and consumers should be performed taking into account possible breakdown products." → Possible need of toxicokinetic information. • Possibly confirmatory information on sensitization endpoint. • Clarification of the available reproductive toxicity data in terms of Classification and labelling. 	

3.6 Potential follow-up and link to risk management

<input type="checkbox"/> Restriction	<input checked="" type="checkbox"/> Harmonised C&L	<input checked="" type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
<p>Up to now there is a strong suspicion for DCBS and its transformation products (metabolites) to be vP when evaluated with respect to Annex XIII. Consequently, an identification as SVHC and additional regulatory action might be appropriate. The German Federal Environment Agency (UBA) considers preparing an Annex XV dossier for identification as a substance of very high concern.</p> <p>For the toxicological endpoints the follow-up will depend on the information potentially to be requested.</p>			