



Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]
EC Number:	225-935-3
CAS Number:	5160-02-1
Authority:	DE MSCA
Date:	22/03/2016

Note

This document has been prepared by the evaluating Member State(s) 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):	bariumbis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]
IUPAC name (public):	bariumbis{5-chloro-2-[(2-hydroxy-1-naphthyl)diazenyl]-4-methylbenzenesulfonate}
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{17}H_{13}ClN_2O_4SBa_{0.5}$
Molecular weight or molecular weight range:	888.9 g/mol
Synonyms:	CI 15585

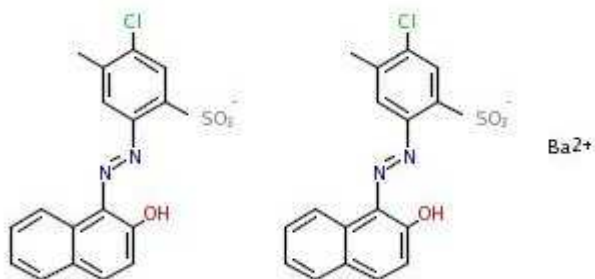
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input type="checkbox"/> Compliance check, Final decision
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
	Restriction	<input type="checkbox"/> Annex XVII
Harmonised C&L	<input type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes / EU legislation	<input checked="" type="checkbox"/> Other (provide further details below)	

Cosmetic Product Regulation No. 1223/2009, Annex II (LIST OF SUBSTANCES PROHIBITED IN COSMETIC PRODUCTS, Ref.-Nr. 397): Colouring agent CI 15585 is included in list of prohibited substances.

COMMISSION DIRECTIVE 2006/15/EC („indicative occupational exposure limit values“) Generic groups name: Barium compounds, IOEL for Barium (soluble compounds): 0.5mg/m³

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available.

3.1.2 Self classification

- In the registration: not classified
- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory: Acute Tox 4 H302, Acute Tox 4 H332, Acute Tox 3 H301, Skin Sens 1 H317.

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, no proposal for harmonized classification and labeling is available.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES¹

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input checked="" 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 type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential

4.2 Overview of uses

Table: Uses

Part 1:

<input type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

	Use(s)
Formulation	Ind. Formulation of non-solid preparations containing pigment (incl. inks, paints), PROC: 5,8b,9,14 Ind. Formulation of solid preparations containing pigment (incl. plastics) PROC: 5,8b,9,14, 24
Uses at industrial sites	Ind. Use of pigment preparations resulting in incl. into a matrix (incl. ink and paint) PROC: 5,6,7,8a,10,13,14,21 Ind. Use of pigment preparations resulting in inclusion into a matrix (incl. plastics) PROC: 5,8a,14,24

¹ Data taken from ECHA dissemination site (accessed in May 2015)

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	Ind. Use of pigment preparations resulting in inclusion into a matrix (incl. inks and paints) 5,6,7,8a,10,13,14,21 Ind removal of matrix (e.g. abrasion) PROC: 24
Uses by professional workers	Wide spread indoor/outdoor use (prof.) resulting in inclusion into a matrix PROC: 5,8a,10,11,13,19 Prof. removal of matrix, outdoor (e.g. abrasion) PROC: 24
Consumer Uses	Widespread dispersive indoor and outdoor use (consumer) resulting in inclusion into or onto a matrix, removal of matrix indoor and outdoor (e.g. abrasion), consumer indoor and outdoor use of pigmented articles with low release PC 0, 9a, 18, 32.
Article service life	Removal of matrix (e.g. abrasion) indoor and outdoor; consumer indoor and outdoor use of coloured articles AC 01, 1, 7, 8, 11, 13.

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ² <input checked="" 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 ²	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ²	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input checked="" type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" 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)
Indicative trigger of concern is CMR. A study with the substance in rats showed an increase of sarcomas in the spleen of male rats. For the workplace there are several ES described with PROCS indicating potential high exposure.		

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

<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 checked="" type="checkbox"/> Information on exposure
<input 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)
The evaluation will show if further information on the toxicological properties and exposure for the uses of the substance is necessary.	

5.5 Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
A possible follow-up of the evaluation process is the preparation of a proposal for harmonized classification and labeling.			