Justification for the selection of a substance for CoRAP inclusion

Substance Name (Public Name):	4,4'-(1,3-phenylene-bis(1-methylethylidene))bisphenol
Chemical Group:	bisphenol
EC Number:	428-970-4
CAS Number:	13595-25-0
Submitted by:	Belgium
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

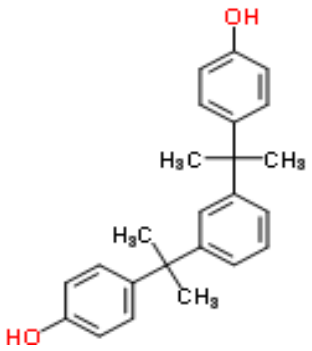
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	NA
IUPAC name:	4,4'-(1,3-phenylene-bis(1-methylethylidene)) bisphenol
Index number in Annex VI of the CLP Regulation	604-079-00-8
Molecular formula:	$C_{24}H_{26}O_2$
Molecular weight or molecular weight range:	346.46 g/mol
Synonyms/Trade names:	CAS name = phenol, 4,4'-[1,3-phenylenebis(1-methylethylidene)]bis- Bisphenol-M

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

Structural formula:



1.2 Similar substances/grouping possibilities

NA

2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

Repr. 2; H361f: Suspected of damaging fertility.

Skin Sens. 1; H317: May cause an allergic skin reaction.

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

Signal word: Warning Pictograms: GHS08, GHS09

2.2 Self classification

- In the registration

  Same as the harmonised

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

  Same as the harmonised

2.3 Proposal for Harmonised Classification in Annex VI of the CLP

NA

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
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☒ Confidential
There is also one NONS registration with confidential tonnage.		

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

Industrial uses:

Polymerisation (used in closed process)

Article service life: Plastic articles

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

Persistency:

In a ready biodegradability test, 30.7% degradation is seen after 28 days. The substance is not readily biodegradable.

No further testing available.

Bioaccumulation:

Log Kow value close to the cut-off value, namely 4.3. However, QSAR data provide higher LogKow values.

No further testing available.

Toxicity:

The T criterion is fulfilled given that the substance is classified as Toxic for Reproduction Category 2.

Other:

The substance belongs to the bisphenol group, so some further assessment to clarify the similarities (possible ED properties) might be initiated if warranted.

Exposure:

Potential exposure related to the plastic articles should be further clarified.

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)	

Information on other completed/ongoing regulatory processes was not found.

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)

This substance is considered to be a potential PBT substance. The definitive T-criterion is met. Screening data for P do not allow to draw a conclusion. Experimental screening data for B indicate that the value is close to the cut-off value and QSAR predictions even show values fulfilling the cut-off.

It is not clear whether the plastic articles create exposure to the environment or to consumers.

4.6 Potential follow-up and link to risk management

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

Depending on the outcome of the evaluation any of the above mentioned RMMs could be initiated if warranted.