Justification for the selection of a substance for CoRAP inclusion

- Update -

Substance Name (Public Name):	(1-methyl ethyl)-1,1'-biphenyl
Chemical Group:	
EC Number:	247-156-8
CAS Number:	25640-78-2
Submitted by:	Germany
Date:	17/03/2015 22/03/2016 (1. updated version) 21/03/2017 (2. updated version)

Note

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

Contents

1 IDENTITY OF THE SUBSTANCE

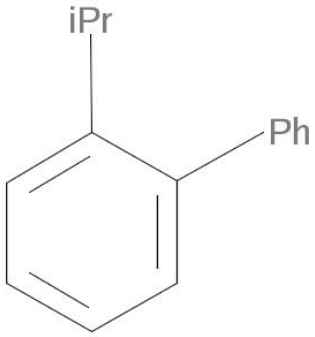
1.1 Other identifiers of the substance

Table 1: Substance identity

EC name:	(1-methyl ethyl)-1,1'-biphenyl
IUPAC name:	(1-methyl ethyl)-1,1'-biphenyl
Index number in Annex VI of the CLP Regulation	
Molecular formula:	$C_{15}H_{16}$
Molecular weight or molecular weight range:	196.29 g·mol^{-1}
Synonyms/Trade names:	

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

Structural formula: (only the *ortho*-isomer of the three possible *ortho*-, *meta*- and *para*-isomers is depicted)



1.2 Similar substances/grouping possibilities

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2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

The substance is not listed in Annex VI CLP.

2.2 Self classification

- In the registration:

Eye Irrit. 2	H319: Causes serious eye irritation.
Asp. Tox. 1	H304: May be fatal if swallowed and enters airways.
Aquatic Acute 1	H400: Very toxic to aquatic life.
Aquatic Chronic 2	H411: Toxic to aquatic life with long lasting effects.

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

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2.3 Proposal for Harmonised Classification in Annex VI of the CLP

There is currently no proposal registered or under consideration.

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

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

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

The disseminated tonnage is lower than overall tonnage. The relevance of this is under verification.

The substance is used in coatings and adhesives. The use includes wide dispersive indoor and outdoor use resulting in inclusion into or onto a matrix. Article service life – consumers: Wide dispersive indoor and outdoor use of long-life articles and materials with low release.

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)	

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 ☐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)

The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII, i.e.

P/vP criterion

Screening tests on ready biodegradability and on inherent biodegradability are available. However, the results of these tests are contradictory and available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent.

B/vB criterion

The substance has a log Pow > 4.5. Measured BCF indicating that the substance is bioaccumulative and potentially very bioaccumulative. The registrant regards the substance to fulfill the B, but not the vB criterion.

T criterion

Data on long-term aquatic ecotoxicity for fish are available, but are regarded as not reliable by the registrant. For aquatic invertebrates, a read across approach to a structurally related substance is applied. The available data on toxicity require further evaluation.

Environmental exposure

The use includes wide dispersive indoor and outdoor use resulting in inclusion into or onto a matrix. The likelihood of environmental exposure needs to be assessed.

[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

5.4 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)

Further information on biodegradation is required to clarify whether the substance is persistent or very persistent.
Also further evaluation is necessary to check the validity of the BCF values and to decide whether the substance fulfills the B/vB criterion and also information on aquatic ecotoxicity might be required to clarify whether the substance is toxic.

5.5 Potential follow-up and link to risk management

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

If the substance is identified as a PBT/vPvB substance, an analysis of risk management options will be carried out, taking into account information on use and exposure. Potential options are the inclusion in the Candidate List with or without Authorisation, but also Restriction.