

**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
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Note

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

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1 IDENTITY OF THE SUBSTANCE

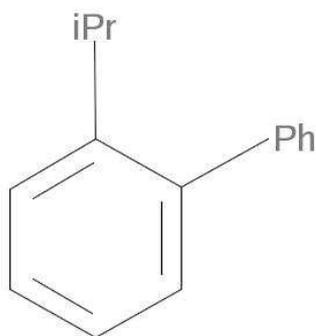
1.1 Other identifiers of the substance

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			
<input type="checkbox"/> 1 – 10 tpa	<input type="checkbox"/> 10 – 100 tpa	<input checked="" type="checkbox"/> 100 – 1000 tpa	
<input 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	
<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input checked="" type="checkbox"/> Consumer use	<input type="checkbox"/> Closed System
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

<input type="checkbox"/> Compliance check, Final decision	<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 ; Biocidal Product Regulation (Regulation (EU) 528/2012)
<input type="checkbox"/> Annex XIV (Authorisation)	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> 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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input 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 ¹	
<input type="checkbox"/> PBT/vPvB	<input checked="" type="checkbox"/> Suspected PBT/vPvB ¹	<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 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)
<p>The substance is fulfilling the screening criteria for persistence and bioaccumulation as defined in Annex XIII, i.e.</p> <p>P/vP criterion</p> <p>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.</p> <p>B/vB criterion</p> <p>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.</p> <p>T criterion</p> <p>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.</p> <p>Environmental exposure</p> <p>The substance has a relatively high tonnage (100-1000t/a). 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.</p>		

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

<input type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input checked="" type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input checked="" 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)

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

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