

Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name): 3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate

Chemical Group:

EC Number: 202-112-7

CAS Number: 91-97-4

Submitted by: FRANCE

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NOTE

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

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Confidential Justification for the selection of a candidate CoRAP substance

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1 IDENTITY OF THE SUBSTANCE

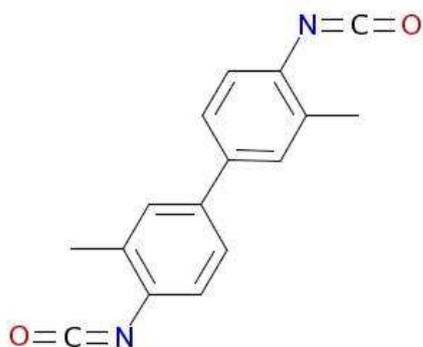
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate
EC number:	202-112-7
EC name:	3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate
CAS number (in the EC inventory):	91-97-4
CAS number:	91-97-4
CAS name:	o-Tolidine diisocyanate
IUPAC name:	1-isocyanato-4-(4-isocyanato-3-methyl-phenyl)-2-methyl-benzene
Index number in Annex VI of the CLP Regulation	Not listed
Molecular formula:	C ₁₆ H ₁₂ N ₂ O ₂
Molecular weight or molecular weight range:	264.28 g/mol
Synonyms:	TODI

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 in Annex VI

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

- Acute Tox. 4, H332: Harmful if inhaled
- Resp. Sens. 1, H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled
- Skin Sens. 1, H317: May cause an allergic skin reaction
- Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects

According to DSD criteria:

- Xn; R20 Harmful; Harmful by inhalation
- R42/43 May cause sensitisation by inhalation and skin contact
- N; R50/53 Dangerous for the environment; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

In addition are the following classification(s) included in the Classification and Labelling Inventory:

- Acute Tox. 4, H302: Harmful if swallowed
- Acute Tox. 4, H312: Harmful in contact with skin
- Skin Irrit. 2, H315: Causes skin irritation
- Eye Irrit. 2, H319: Causes serious eye irritation
- STOT SE 3, H335 : May cause respiratory irritation
- Muta. 2 – H341 : Suspected of causing genetic defects

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 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	<input type="checkbox"/> Exposure of sensitive population	<input type="checkbox"/> Aggregated tonnage
<input type="checkbox"/> Suspected Endocrine disruptor	<input type="checkbox"/> Other (provide further detail below)	

According to the registration data, no consumer exposure occurs. This is questionable and should be further assessed as the substance is used to manufacture paints, do-it-yourself products, household products (cleaning products), etc... The substance is already considered as Skin and Respiratory sensitizer by registration data because of structural similarities with already know sensitizers (i.e. MDI...) and according to the classifications included in the Classification and Labelling Inventory.

No Risk assessment is proposed for sensitisation endpoints. Mutagenicity should be further assessed as there are many positive studies in vitro and inappropriate in vivo study. Substance evaluation is recommended in order to get more information on uses/exposure and mutagenicity.

Also some risk management processes could be already launched: CLH on respiratory sensitizing properties. France is evaluating TODI in the framework of iPBT WG in order to clarify positive QSAR results about PBT/vPvB and to conclude if a substance evaluation is appropriate to clarify this concern.

3.3 Information on aggregated tonnage and uses

<input type="checkbox"/> 1 - 10 t	<input type="checkbox"/> 10 - 100 t	<input type="checkbox"/> 100 - 1000 t	<input type="checkbox"/> 1000 - 10,000 t	
<input type="checkbox"/> 10,000 - 100,000 t	<input type="checkbox"/> 100,000 - 1000,000 t	<input type="checkbox"/> > 1000,000 t	<input checked="" type="checkbox"/> Confidential	
<input checked="" type="checkbox"/> Industrial Use	<input checked="" type="checkbox"/> Professional Use	<input type="checkbox"/> Consumer Use	<input type="checkbox"/> Closed System	

3.4 Other completed/ongoing regulatory processes that may affect suitability for substance evaluation

<input type="checkbox"/> Compliance Check	<input type="checkbox"/> Annex VI (CLP)
<input type="checkbox"/> Testing Proposal(s)	<input type="checkbox"/> Annex XIV (Authorisation)
<input type="checkbox"/> Substance Identification Issues	<input type="checkbox"/> Annex XVII (Restriction)
<input type="checkbox"/> ESR Programme	<input type="checkbox"/> Other (provide further details below)

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 exposure
<input type="checkbox"/> Information on fate and behaviour	<input checked="" type="checkbox"/> Information on uses
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Other (provide further details below)
<input type="checkbox"/> Information on physico-chemical properties	

3.6 Potential follow-up and link to risk management

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