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):	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene
EC Number:	270-128-1
CAS Number:	68411-46-1
Authority:	German MSCA
Date:	22/03/2016

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: Other Substance identifiers

EC name (public):	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene
IUPAC name (public):	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	UVCB substance containing numerous chemical species
Molecular weight or molecular weight range:	281.44 - 505.88 g/mol
Synonyms:	-

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

Structural formula:

Other relevant information about substance composition

Constituents:
- Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene
- 4-tert-Butyldiphenylamine
- Benzenamine, 4-(1,1,3,3-tetramethylbutyl)-N-[4-(1,1,3,3-tetramethylbutyl)phenyl]-

1.2 Similar substances/grouping possibilities

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2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☒ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L	☐ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	

Other processes / EU legislation	☐ Other (provide further details below)

A compliance check was conducted and the decision was adopted in 2013 where clarification *on substance identity* was requested*.*

Currently, the evaluation of testing proposals for a two-generation study and a sub-chronic toxicity (90-day) oral study is ongoing.

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: Aquatic Chronic 3 (H412)

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

  STOT RE 2 H373 (liver)

  Eye Irrit. 2 H319

  Aquatic Chronic 2 H411

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 USES[1]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per 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

4.2 Overview of uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Article service life	☐ Closed system

Part 2:

	Use(s) **(antioxidant and radical scavenger; lubricant additive)**
Uses as intermediate	-
Formulation	Formulation of preparations (ERC 2): Industrial formulation of additives (stabiliser) for adhesives and sealants; Feeding and mixing of additives (stabiliser) for production of masterbatches and compounds; Handling and dilution of metalworking fluid concentrates; Industrial formulation of lubricant additives, lubricants and greases; Use of additive in polyurethane application
Uses at industrial sites	Industrial use of processing aids in processes and products, not becoming part of articles (ERC 4): Use of lubricants in high energy/high temperature open processes (e.g. metal forming); Open application of lubricant to work pieces or equipment by dipping, brushing or spraying; General industrial use of lubricants and greases in vehicles or machinery; Industrial use as stabiliser resulting in inclusion into or onto a matrix

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

	(closed/semi-open/open ERC 5): Use of masterbatches or compounds in foam production; Direct use of additives at coverter's facilities (open processes); Feeding and mixing of masterbatches for conversion (manufacture of plastics); Use in the polymerisation or polycondensation process; Use in production of compounds
Uses by professional workers	Wide dispersive indoor/outdoor use of processing aids in open systems/ resulting in inclusion into or onto a matrix (ERC 8a, 8c, 8d, 8f): Use as additive for adhesives and sealants; Use of lubricants and greases in high/low energy open systems; Application of lubricant to work pieces or equipment by dipping, brushing or spraying; Use of additive in polyurethane application; Wide dispersive indoor/outdoor use in closed systems (ERC 9a, 9b): General professional use of lubricants and greases in vehicles or machinery
Consumer Uses	Wide dispersive indoor/outdoor use of processing aids in open systems (ERC 8a, 8d): Consumer application of lubricants and greases by dipping, brushing or spraying; Wide dispersive indoor/outdoor use in closed systems (ERC 9a, 9b): General use of lubricants and greases in vehicles or machinery
Article service life	Subsequent service life relevant for these uses: no; Wide dispersive indoor/outdoor use of long-life articles and materials with low release (ERC 10a, 11a); Industrial processing of articles with abrasive techniques (low release; ERC 12a)

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[2] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[2]	☐ 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)

[2] 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

The substance is not readily biodegreadable. The available data do not allow assessing degradation in environmental compartments. Therefore, the substance is considered to be potentially persistent.

The log P_{ow} of the substance is in the range of the screening criterion for bioaccumulation. The available data on bioconcentration in fish require further evaluation.

5.4 Preliminary indication of information that may need to be requested t 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.

Further evaluation and, if necessary, further testing is required to clarify whether the substance is bioaccumulative or very bioaccumulative.

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.