baua:
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, reaction products with aniline hydrochloride and nitrobenzene
EC Number:	309-912-6
CAS Number:	101357-15-7
Authority:	DE 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, reaction products with aniline hydrochloride and nitrobenzene
IUPAC name (public):	Benzenamine, reaction products with aniline hydrochloride and nitrobenzene
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	not applicable, UVCB substance containing numerous chemical species
Molecular weight or molecular weight range:	-
Synonyms:	-

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

Structural formula:

Other relevant information about substance composition

Constituents:
- 5,9,18-triphenyl-9,18-dihydropyrazino[2,3-b:5,6-b']diphenazin-5-ium
- 5,12-diphenyl-5,12-dihydroquinoxalino[2,3-b]phenazine
- (3Z,10E)-N,12-diphenyl-3,10-bis(phenylimino)-10,12-dihydro-3H-quinoxalino[2,3-b]phenoxazin-9-amine
- (Z)-N,9,16-triphenyl-9,9a,13a,16-tetrahydro-3H-pyrazino[2,3-b:5,6-b']diphenoxazin-3-imine
- N,5,12-triphenyl-5,12-dihydroquinoxalino[2,3-b]phenazin-2-amine
- (Z)-N,7,14-triphenyl-7,13a,14,18-tetrahydropyrazino[2,3-b:5,6-b']diphenazin-2(9aH)-imine
- N,5,12-triphenyl-5,7,12,14-tetrahydroquinoxalino[2,3-b]phenazin-2-amine
- N,7,9,14-tetraphenyl-7,9,14,18-tetrahydropyrazino[2,3-b:5,6-b']diphenazin-2-amine
- 5,7,16,22-tetraphenyl-5,7,9,11,16,18,20,22-octahydroquinoxalino[2,3-b]quinoxalino[2´,3´:6,7]quinoxalino[2,3-i]phenazine
- diphenylamine
- aniline

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[1]
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)	

[1] Please specify the relevant entry.

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: Self-heat. 2 H252

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory: STOT RE 2 H373 (blood system, oral), Aquatic Chronic 3 H412 (Both classifications are affected by impurities/additives.), Aquatic Chronic 2 H411, Skin Sens 1 H317, Acute Tox.4 H302, H312, H332, Carc 2 H351.

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[2]

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

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

4.2 Review of uses

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	
Formulation	Refer the dissemination site
Uses at industrial sites	Refer the dissemination site
Uses by professional workers	Refer the dissemination site
Consumer Uses	Wide dispersive indoor use resulting in inclusion into or onto a matrix (ERC 8c): Use of toner cartridges by consumers Wide dispersive indoor use resulting in inclusion into or onto a matrix (ERC 8c): Consumer use of permanent markers, stamp ink and ink-ribbons
Article service life	Wide dispersive outdoor use of long-life articles and materials with low release (ERC 10a); Wide dispersive indoor use of long-life articles and materials with low release (ERC 11a): Use of plastic articles

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[3] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[3]	☐ 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)

[3] 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 (> 2.2) is in the range of the screening criterion for bioaccumulation The BCF in a fish test ranged from 25-164 for the UVCB in the lower test item concentration. However, one not identified constituent (Peak 3) achieved a BCF of up to 1850. The available data on bioconcentration in fish requires a further evaluation, considering the low water solubility of the substance.

In the same test, an LC_{50} of ≥ 200 mg/L was determined for *Oryzias latipes*. Other tests with fish resulted in an LC_{50} > 2.0 mg/L (nominal); a short-term test with *Daphnia* resulted an LC_{50} > 2.2 mg/L (nominal). In a 21-day test with *Daphnia*, both immobilisation EC_{50} (mean measured) and reproduction EC_{50} were > 0.021 mg/L. LOEC and NOEC were 0.021 mg/L. These ecotoxicity tests need re-assessment with regard to the low water solubility of the substance.

Due to the registered uses of the substance which point towards a wide dispersive use, significant environmental exposure has to be assumed. Therefore, the suspected PBT/vPvB status needs further assessment.

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.