Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs.
Chemical Group:	Aromatic Amines
EC Number:	273-227-8
CAS Number:	68953-84-4
Submitted by:	Germany
Version:	01/07/2013

NOTE

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

Please note that this justification document explains the grounds of the initial concerns that triggered the inclusion of the substance in the CoRAP for further clarification under substance evaluation. The justification document is based on a preliminary screening of the substance and is without prejudice to the outcome of the substance evaluation.

Contents

1 IDENTITY OF THE SUBSTANCE

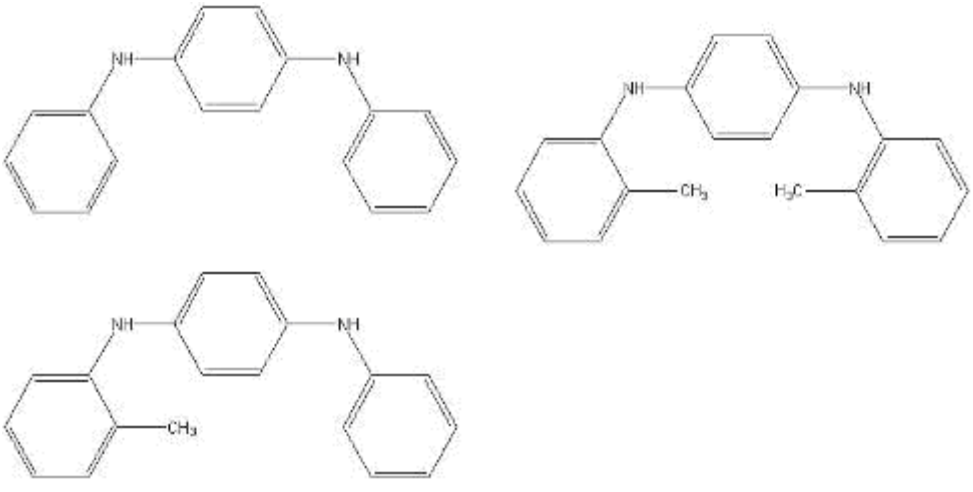
1.1 Name and other identifiers of the substance

Table 1: Substance identity

Public Name:	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs.
EC number:	273-227-8
EC name:	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs.
CAS number (in the EC inventory):	68953-84-4
CAS number:	68953-84-4
CAS name:	1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs.
IUPAC name:	Reaction mass of N-phenyl,N'-o-tolyl-phenylene diamine, N,N'-diphenyl-p-phenylene diamine and N,N'-di-o-tolyl-phenylene diamine
Index number in Annex VI of the CLP Regulation	
Molecular formula:	Not available
Molecular weight or molecular weight range:	260.3 – 288.39
Synonyms:	

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.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

Classification and labelling according to CLP;

- Skin Sens. 1B; H317: May cause an allergic skin reaction.
- Aquatic Acute 1; H400: Very toxic to aquatic life.
- Aquatic Chronic 1; H410: Very toxic to aquatic life with long lasting effects.

Classifications given in classification and labelling inventory additionally include:

- Resp. Sens. 1; H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Eye Irrit. 2; H319: Causes serious eye irritation.

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

☐ (Suspected) CMR	☒ Wide dispersive use	☐ Cumulative exposure
☐ (Suspected) Sensitiser	☒ Consumer use	☐ High RCR
☒ (Suspected) PBT	☐ Exposure of sensitive populations	☒Aggregated tonnage
☐ Suspected endocrine disruptor	☐ Other (provide further details below)	

1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs. (BENPAT) is suspected to be of very high concern due to its PBT properties. These properties were identified during a PBT QSAR screening of substances registered in 2010 and following data research to selected substances carried out by the German Federal Environment Agency (UBA). Due to the suspected PBT properties of BENPAT, the German CA prepared an Annex XV dossier for identification as a substance of very high concern. In January 2013 new information became available which now questions current P and B assessment. Having evaluated the corresponding test protocols it still remains unclear whether all criteria are fulfilled and further information is needed. Therefore BENPAT is proposed for the Community Rolling Action Plan in order to gain additional data in a substance evaluation.

Based on a screening of substances registered in 2012, 1,4-Benzenediamine, N,N'-mixed phenyl and tolyl derivs. (BENPAT) fulfills the PBT screening criteria according to annex XIII section 3.1 of the REACH regulation. There is a concern that BENPAT might fulfill the PBT criteria according to annex XIII section 1.1 of the REACH regulation and consequently should be identified as SVHC substance by a more in-depth evaluation.

The registration dossier contains data showing that BENPAT is not readily biodegradable. In addition to this, the production volume per year is exceeding the 1000 tons-level. Consequently, according to Annex IX of the REACH regulation, simulation tests on degradation in the different media are necessary. New data became available in January 2013. Newly gathered information consists of three degradation studies and one bioaccumulation study. Their significance is unclear.

Thus the German CA considers a substance evaluation of BENPAT necessary to verify whether these data may change the PBT assessment and to gain additional data, if required for completing the assessment.

3.3 Information on aggregated tonnage and uses

☐ 1 – 10 tpa	☐ 10 – 100 tpa	☐ 100 – 1000 tpa
☒ 1000 – 10,000 tpa	☐ 10,000 – 50,000 tpa	☐ 50,000 – 100,000 tpa
☐ 100,000 – 500,000 tpa	☐ 500,000 – 1000,000 tpa	☐ > 1000,000 tpa
☐ Confidential		

BENPAT has been registered for a tonnage band >1000 t/a. Between 1000 and 10.000 t tonnes of BENPAT were imported in 2010. BENPAT has been identified as a high production volume (HPV) chemical on the lists from the following organisations: the European Commission Joint Research Centre (ESIS) and the Organisation for Economic Co-operation and Development (OECD Environment, 2009).

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

BENPAT is released onto streets, roads and associated soil nearby and into roadway run-off water as a result of consumer or commercial use of products such as tyres. The majority of BENPAT in commercial/consumer products is estimated to be recycled. Therefore the release by use as synthetic turf fields and playgrounds of recycled tired rubber material might be an additional source. Apart from recycling BENPAT may also be disposed of in landfills and is as destined for incineration. Releases of BENPAT estimated from industrial activities or uses to wastewater and landfill and air are estimated to be low (ECHA 2012).

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

☐ Compliance check	☐ 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
☐ Annex XIV (Authorisation)	☐ Other (provide further details below)
☐ Annex XVII (Restriction)	

3.5 Information to be requested to clarify the suspected risk

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☐ Information on exposure
☐ Information on ecotoxicological properties	☐ Information on uses
☐ Other (provide further details below)	

There is a need to re-evaluate the PBT endpoints of BENPAT. New studies on biodegradation and bioaccumulation became available in January 2013. Their significance is unclear. A substance evaluation of BENPAT is necessary to evaluate these data and to gain additional data, if required for completing the PBT assessment.

3.6 Potential follow-up and link to risk management

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

Follow-up regulatory action will depend mainly on additional information about persistence. Considering all available and additionally requested information, the PBT properties of BENPAT need to be evaluated with respect to Annex XIII. Depending on the outcome of this evaluation, an identification as SVHC (Inclusion in the Candidate List) and additional regulatory action might be appropriate.