Justification for the selection of a candidate CoRAP substance

Substance Name (Public Name):	mixture of two components: 1. N-(1,3-dimethylbutyl)-N´-phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)-N4-(4-(1-methyl-1-phenylethyl)phenyl)benzene-1,4-diamine
Chemical Group:	organic
EC Number:	448-020-2
CAS Number:	NA
Submitted by:	Centre for Chemical Substances and Preparations, Slovakia
Published:	20/03/2013

Contents

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

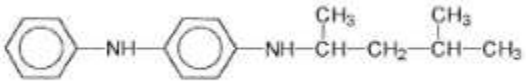
Table 1: Substance identity

Public Name:	Mixture of two components: 1. N-(1, 3-dimethylbutyl)-N´-phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)-N4-(4-(1-methyl-1-phenylethyl)phenyl)benzene-1,4-diamine
EC number:	448-020-2
EC name:	
CAS number (in the EC inventory):	NA
CAS number:	NA
CAS name:	NA
IUPAC name:	mixture of two components: 1. N-(1,3-dimethylbutyl)-N´-phenyl-p-phenylenediamine 2. N1-(1,3-dimethylbutyl)-N4-(4-(1-methyl-1-phenylethyl)phenyl)benzene-1,4-diamine
Index number in Annex VI of the CLP Regulation	-
Molecular formula:	1. C18H24N2 2. C27H34N2
Molecular weight or molecular weight range:	268,4 - 386,6
Synonyms:	N-1,3-dimethylbutyl-N'-phenyl-p-phenylenediamine, reaction products with 2-phenylpropene Dusantox L

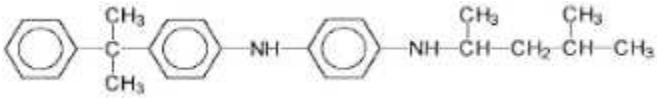
Type of substance ☐ Mono-constituent ☒ Multi-constituent ☐ UVCB

Structural formula:

1. N-(1,3-dimethylbutyl)-N´-phenyl-p-phenylenediamine



2. N1-(1,3-dimethylbutyl)-N4-(4-(1-methyl-1-phenylethyl)phenyl)benzene-1,4-diamine



2 CLASSIFICATION AND LABELLING

2.1 Harmonised Classification in Annex VI of the CLP

None listed.

2.2 Proposal for Harmonised Classification in Annex VI of the CLP

None proposed.

2.3 Self classification

The registration data includes the following self classification:

According to CLP criteria:

Skin Sens. 1 (H317 May cause an allergic skin reaction)
Repr. 1B (H360: May damage fertility or the unborn child)
STOT Rep. Exp. 1 (H372: Causes damage to liver through prolonged or repeated exposure by oral route)
Aquatic Chronic 2 (H411 Toxic to aquatic life with long lasting effects)

According to DSD criteria:

R43 May cause sensitisation by skin contact.
Repr. Cat. 3; R62 Possible risk of impaired fertility
Repr. Cat. 2; R61 May cause harm to the unborn child.
T; R48/25 Danger of serious damage to health by prolonged exposure if swallowed.
N; R51-53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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)	

Dusantox L belongs to notified new substances. The risk assessment for tonnage level 100 - 1000 tpa for human health part was not finalized for this substance as two important studies (90 day repeat dose toxicity study and developmental toxicity study) were missing. These studies were submitted to ECHA by the registrant additionally. In the update of the registration dossier the registrant reconsidered the classification for repeat dose toxicity and for reprotoxicity of the substance and submitted new CSR.

Based on new modification and data in the dossier SK CA would like to consider the possibility to prepare Annex VI dossier for harmonised classification for reprotoxicity endpoint. Futhermore, the PBT assessment reveals that the substance is a potential PBT/vPvB. The registrant also indicated that it is difficult to draw conclusion on PBT/vPvB assessment. It is indicated that most probably the P criterion is satisfied rather than by degradation product than by the parent compound. This issue has not been further clarified.

3.3 Information on aggregated tonnage and uses

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

Please provide further details

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

Dusantox L is an effective stabilizer of synthetic styrene-butadiene and polyisoprene rubber and also an antidegradant for dry rubber compounds.

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)	
Please provide further details	

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)	
Information for better characterisation of P and B properties would be requested.	

3.6 Potential follow-up and link to risk management

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