Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	**bis(nonylphenyl)amine**
EC Number:	**253-249-4**
CAS Number:	**36878-20-3**
Authority:	**FR 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 1: Other Substance identifiers

EC name (public):	Bis(nonylphenyl)amine
IUPAC name (public):	Reaction products of Benzeneamine, N-phenyl- with nonene (branched)
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{30}H_{47}N$
Molecular weight or molecular weight range:	169.0 — 547.0
Synonyms:	Benzenamine, ar-nonyl-N-(nonylphenyl)-

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

Structural formula:

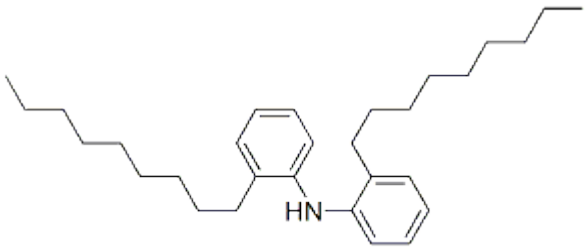
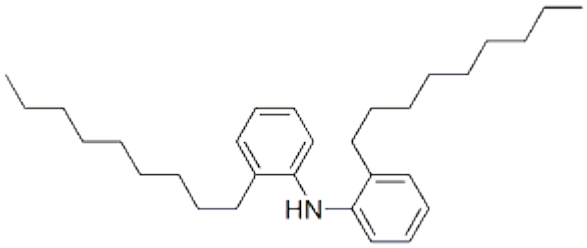


Table 2: Constituent

EC number:	253-249-4
EC name (public):	bis(nonylphenyl)amine
CAS number:	36878-20-3
CAS name (public):	
IUPAC name (public):	Reaction products of Benzeneamine, N-phenyl- with nonene (branched)
Index number in Annex VI of the CLP Regulation:	
Molecular formula:	$C_{30}H_{47}N$
Molecular weight or molecular weight range:	169.0 — 547.0
Synonyms:	*Benzenamine, ar-nonyl-N-(nonylphenyl)*

Structural formula:



1.2 Similar substances/grouping possibilities

Chemical name	Benzeneamine, N-phenyl-, reaction products with	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene	Mono-nonyldiphenylamine	Dioctyldiphenyl amine
	Target chemical / analogue	Source chemical	Source chemical	Source chemical
CAS no	36878-20-3	68411-46-1	27177-41-9	101-67-7
EC No	253-249-4	270-128-1		

There is a self-classification of susbtance CAS# 68411-46-1 as Eye Irrit. 2, STOT RE 2, Aquatic Chronic 3 or 2.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table 3: 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
	Restric -tion	☐ 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.

After the examination of the TPE a repeated dose toxicity study was requested (90d, OECD 408) by January 2013. This repeated dose toxicity study is available. The study is well conducted. Effects on liver, thyroid and body weight were identified. The liver was the target organ.

Additionally a CCH have been completed in December 2013 requesting a prenatal developmental toxicity study (OECD 414) by 13 December 2014. This study is available and well conducted. No teratogenic or embryotoxic hazards were identified.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No existing harmonised classification

3.1.2 Self classification

- In the registration:

Aquatic Chronic 4 M factor=0

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

Aquatic chronic 3, H412

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Not applicable

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table 4: Tonnage and registration status

[2] *Please provide here the date when the dissemination site was accessed.*

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
Joint submission		

4.2 Overview of uses

Table 5: Uses

Part 1:

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

Part 2:

	Use(s)
Formulation	Handling and dilution of metalworking fluid concentrates Industrial formulation of lubricant additives, lubricants and greases. Includes material transfers, mixing, large and small scale packing, sampling, maintenance and associated laboratory activities
Uses at industrial sites	Use of lubricants in open high temperature processes, e.g. quenching fluids, glass release agents General industrial use of lubricants and greases in vehicles or machinery. Includes filling and draining of containers and enclosed machinery (including engines) Use of lubricants in high energy open processes, e.g. in high speed machinery such as metal rolling / forming or metalworking fluids for machining and grinding Use of lubricants and greases in open systems. Application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat), e.g. mould releases, corrosion protection, slideways General industrial use lubricants and greases in vehicles and machinery
Uses by professional workers	Use of lubricants in high energy open processes, e.g. in high speed machinery such as metal rolling / forming or metalworking fluids for machining and grinding General professional use of lubricants and greases in vehicles or machinery. Includes filling and draining of containers and enclosed machinery (including engines) Use of lubricants and greases in open systems. Application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat), e.g. mould releases, corrosion protection, slideways Lubricant applications by dipping, brushing or spraying Lubricants in high energy processes General professional use of lubricants and greases in vehicles or machinery
Consumer Uses	General consumer use of lubricants and greases in vehicles or machinery. Includes filling and draining of containers and enclosed machinery (including engines) Use of lubricants and greases in open systems. Application of lubricant to work pieces or equipment by dipping, brushing or spraying (without exposure to heat), e.g. mould releases, corrosion protection, slideways) Lubricant applications by dipping, brushing or spraying General consumer use of lubricants in vehicles or machinery Consumer use of lubricants in open systems

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[1] ☐ C ☒ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ 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

According to uses and high tonnage, the read across proposed in the dossier must be evaluated, particulary for genotoxicity. The justification for the read-across should be redrafted.

Among all tests identified for the assessment of genotoxicity one the different substances used for read-across, one test for CAS 101-67-7 (DNA damage and repair assay, unscheduled DNA synthesis in mammalian cells in vitro) is positive without metabolic activation. Because of these equivocal results, further assessment is justified.

Concerning environement, despite the substance is an UVCB, no accurate information dealing with identity are provided and it is therefore not possible to state on the PBT status of the components of the substance. In a read across approach, bis(nonylphenyl)amine is considered as P/vP on the basis of a ready biodegradation test carried out with another substance. Nevertheless, because of structural differences between the two substances, biodegradation of bis(nonylphenyl)amine leading to metabolites of concern cannot be completely excluded. According to QSAR, bis(nonylphenyl)amine should not fulfill B/vB criterion. However, component with shorter carbon chain length could have bioaccumulation potential which should be assessed. At last, aquatic toxicity tests have been carried out through the water accommodated fraction and showed no adverse effects on organisms. However, when performed, analytical monitoring do not detect any substance in water. It is therefore not possible to state that organisms have been exposed to the substance.

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

Substance identity linked to PBT properties

Despite the substance is an UVCB, no accurate information dealing with identity are provided and it is therefore not possible to state on the PBT status of the components of the substance. P criterion is assessed through a read across with a worst case substance (branched carbon chain) and QSARs indicate higher biodegradation potential for linear chain, which could lead to the formation of metabolite of concern. Although QSARs support that bis(nonylphenyl)amine should not be B, they also indicate that phenyl amine with with shorter chain length could have B or even vB potential. At last, analyticial monitoring in the aquatic toxicity test do not allow to state that orgasnims have been exposed to the substance. Therefore, the identity of the substance should first be clarified. Second, the PBT/vPvB criteria should be assessed for each component.

5.5. Potential follow-up and link to risk management

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