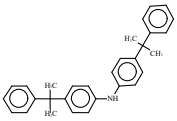
KEMI
Kemikalieinspektionen
Swedish Chemicals Agency

Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type
233-215-5	10081-67-1	4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl] aniline		FULL

Authority: Swedish Chemical Agency

Date: 19 March 2024

Revision history

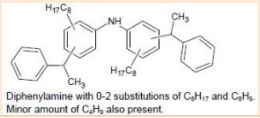
Version	*Date*

Cover Note

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

1. Background

1.1 Analogue substances

EC/List number	CAS RN	Public Substance name	Chemical structure
614-656-6	68608-79-7	Benzenamine, N-phenyl-, (tripropenyl) derivs.	uvcb
606-029-0	184378-08-3	Benzenamine, N-phenyl-, reaction products with isobutylene and ,4,4-trimethylpentene	uvcb
272-940-1	68921-45-9	Benzenamine, N-phenyl-, reaction products with styrene and 2,4,4-trimethylpentene	uvcb  Diphenylamine with 0-2 substitutions of C_8H_{17} and C_8H_8. Minor amount of C_8H_8 also present.
270-128-1	68411-46-1	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene	uvcb
701-385-4	-	Benzenamine, N-phenyl-, reaction products with 2,4,4-trimethylpentene; Reaction products of diphenylamine with nonene, branched	uvcb

1.2 Overview of ongoing or completed other REACH and CLP processes & other EU legislation

EC/ List number	Evaluation			CLH	Restriction	Authorisation
	CCH	TPE	Previously on CoRAP	Annex VI (CLP)	Annex XVII*	Candidate List/ Annex XIV
233-215-5	X	X	-	-	-	-

**Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40)*

EC/ List number	Other EU legislation	Previous legislation	Stockholm convention	Other
	PPP/ BPR	NONS/ RAR	POP	(e.g. UNEP)
233-215-5	-	-	-	-

2. Classification

You can find information on classification in the ECHA C&L Inventory database, which includes both harmonised classification (when available) and the notified self-classifications. (http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database].
The CLP Regulation and all published ATPs are available on ECHA website: http://echa.europa.eu/web/guest/regulations/clp/legislation .

EC/ List No	CAS RN	Public Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (877)
233-215-5	10081-67-1	4-(1-methyl-1-phenylethyl)-N-[4-(1-methyl-1-phenylethyl)phenyl]aniline		Skin. Sens. H317	Skin. Sens. H317 (180) Aquatic Chronic 4 H413 (187)

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers. Therefore the number may differ from the C&L inventory which displays number of notifiers.

3. Tonnage and uses

3.1 Aggregated Tonnage

EC/ List No	Aggregated tonnage (as per ECHA dissemination website*)[1][2]
233-215-5	Joint submission (7 active registrants) with aggregated tonnage ≥ 1 000 to < 10 000

** The total tonnage band has been calculated by excluding the intermediate uses,- See also the Manual for Dissemination and Confidentiality under REACH (section 2.6.11): https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0*

[1] The total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

[2] Substance Infocard on ECHA's dissemination website accessed on 13 October 2023. NB. REACH registration data on ECHA's webpage has not been updated since 19 May 2023.

3.2 Overview of the Uses

Main types of applications	EC 233-215-5 Key information
Industrial use	In processing aids at industrial sites, of substances in closed systems with minimal release and in the production of articles, such as; Formulation of mixtures and/or re-packaging. Use of lubricants and greases, heat transfer fluids, polymers, hydraulic fluids and metal working fluids. Manufacture of machinery and vehicles, plastic products, electrical, electronic and optical equipment and furniture
Professional use	Main exposure from: Lubricants and greases and hydraulic fluids Manufacture of machinery and vehicles In addition, some exposure from: Indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), Indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters), Outdoor use as processing aid Outdoor use in close systems with minimal release (e.g. hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids).
Consumer Use	Main exposure through use of lubricants and greases. In addition, some exposure from: Indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters), Indoor use as processing aid Outdoor use as processing aid Outdoor use in close systems with minimal release (e.g. hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids). Indirect exposure from articles especially when indoors
Article service life	Outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) Indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment). Use in complex articles, with no release intended: vehicles, machinery, mechanical appliances and electrical/electronic products (e.g. computers, cameras, lamps, refrigerators, washing machines) and electrical batteries and accumulators. Use in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones).
Intermediate use (if TII)	
Formulation	Manufacturing of the substance. Formulation of mixtures and formulation in materials; Lubricants and greases, metal working fluids, heat transfer fluids and polymers.

4. Justification for inclusion on the CoRAP

4.1 Legal basis

☒ Article 44(2)[3]

☐ Article 45(5)[4]

4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	☐ Carcinogenic ☐ Mutagenic ☐ Reproductive toxicant
Potential ED	☐ Human Health ☐ Environment
Suspected Sensitiser	☐ Respiratory ☐ Skin
Suspected PBT/ vPvB Suspected PMT/ vPvM	☒ Persistent ☒ Bioaccumulative ☐ Mobile ☒ Toxic (as defined in section 4.3 below) ☒ very Persistent ☒ very Bioaccumulative ☐ very Mobile
Other suspected human health hazard(s) (e.g. STOT RE)	☐ (as defined in section 4.3 below)
Other suspected environmental hazard(s)	☐ (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	☒
Consumer use	☒
Exposure of workers	☒
Exposure of sensitive populations	☒
Exposure of environment	☒
Cumulative exposure	☐
High RCR	☐
High (aggregated) tonnages	☒
Others (to be specified)	☐

[3] "The Agency shall use the criteria in paragraph 1 […]. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment."

[4] "A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. […]".

4.3 Justification of the concern(s) – to be clarified under Substance evaluation

Existing data supporting the hazard-based concern and other relevant information to justify the inclusion in CoRAP

P/vP concern

The results in the registration dossier report half-lives from degradation studies in soil and sediments showing DT50 (12 °C) <180 d (days) and did not support the substance to be P. (Soil=26.6-102 d; Sediment/water total system=37.5-40.6d)

The registration dossier also reports that 3 specific degradation/transformation products were identified (OECD 307 and 308 studies). Based on QSAR predictions (BIOWIN) all three products are not ready biodegradable and potentially P or vP (run in EpiSuite using SMILES for the structures of the degradation/transformation products).

Based on this a P/vP concern remains and there is a need to further evaluate the persistence of the degradation/transformation products.

B/vB concern
Log Kow = 7.90 ± 1.22 (25°C, pH = 6.9)

QSAR predictions (BCFBAF, estimated logKow=8.51 (KowWin))
BCF= 455.2-2416 L/kg wet-wt L/kg ww
BAF = 9.586e+005

The substance screens as B/vB based on its Log Kow >4.5. An aqueous and dietary exposure test, OECD TG 305 was requested by ECHA, but has not been submitted.

The substance has LogKoa≥5 (QSAR:14,485) and LogKow≥2 (7.9) which indicates the potential to bioaccumulate in terrestrial food chains and air-breathing marine wildlife.
This is supported by monitoring data – the substance is found in liver in top predators such as seabirds and seals, and in seabird eggs in the Arctic:

- "Occurrence of substituted diphenylamine antioxidants and benzotriazole UV stabilizers in Arctic seabirds and seals." Z. Lu et al. / Science of the Total Environment 663 (2019) 950–957

- "Substituted diphenylamine antioxidants and benzotriazole UV stabilizers in blood plasma of fish, turtles, birds and dolphins from North America." Z. Lu et al. / Science of the Total Environment 647 (2019) 182–190

According to Lu et al 2017, the liver is a major tissue for accumulation in fish. Tissue-specific partition coefficients suggest that the substance tends to partition from plasma to liver and that the biliary excretion of these contaminants is a relatively minor pathway of elimination:

- "Tissue Distribution of Substituted Diphenylamine Antioxidants and Benzotriazole Ultraviolet Stabilizers in White Sucker (Catostomus commersonii) from an Urban Creek in Canada" Z. Lu et al. Environ. Sci. Technol. Lett. 2017, 4, 433−438

There are two scientific publications indicating that the substance can fulfill the B/vB criteria:

- "SUPPORTING INFORMATION FOR Distribution, Partitioning and Bioaccumulation of

Substituted Diphenylamine Antioxidants and Benzotriazole UV Stabilizers in an Urban Creek in Canada" Z. Lu et al. / Environ. Sci. Technol. 2016, 50, 9089−9097

- "Amino antioxidants: A review of their environmental behavior, human exposure, and aquatic toxicity" Jin et al. Chemosphere 317 (2023) 137913

If the transformation/degradation products are found to be persistent it can be relevant to study if they fulfill the criterion for B/vB. All three products have log Kow>5 and are potentially B or vB based on QSAR(BCFBAF) with BCF>2000 and/or BAF>5000 (run in EpiSuite using SMILES for the structures of the degradation/transformation products).

Ecotoxicity concern
Some CLP notifications self-classify the substance as Aquatic Chronic 4 ; H 413.

According to the registration dossier, the substance does not fulfill the criteria for T. The substance is poorly water soluble, and the test material does not display toxicity at the limit of solubility in water. No effect was detected up to the highest dose in the available experiments.

If the transformation/degradation products are found to be persistent it can be relevant to study if they fulfill the criterion for T. According to Jin et al. 2023, the metabolites of SDPAs can be significantly more toxic than the parent substance.

SDPA substances
The substance is mentioned in several scientific publications as belonging to the group Substituted diphenylamine antioxidants SDPAs – a substance group with a similar structure:

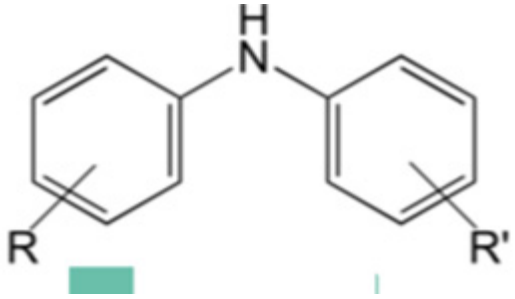


Figure of the basic structure for SDPA.

The analogue substances listed in table 1.1 is not an exhaustive list. More substances are identified for this group in the scientific literature. The group is of emerging environmental concern in the Arctic, according to the scientific literature.

The SDPA group has been previously screened in the COLLA project under ECHA[5].

[5] https://echa.europa.eu/documents/10162/13628/colla_pilot_project_report_en.pdf/0ba58a2e-675f-387e-4827-05aba076a0e0

Information to be potentially requested

Stepwise approach:
1. Screening test for degradation for the relevant metabolites.
2. Based on the results in 1) simulation degradation tests for the relevant metabolites.
3. Based on the results in 1) and 2) bioaccumulation tests for the metabolites.
4. Based on the results from 1)-3) toxicity test of the metabolites.

***Possible follow-up** (demonstrating the improvement of risk management measures)*

EC/ List number	Harmonised C&L	SVHC	Restriction	Authorisation	Other
233-215-5	☒	☒	☒	☒	☐