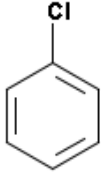


## Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y) <sup>1</sup>
203-628-5	108-90-7	Chlorobenzene		Full (10,000 – 100,000 t/y)

**Authority: the Netherlands**

**Date: 21 March 2023**

### Revision history

<i>Version</i>	<i>Date</i>

### Cover Note

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

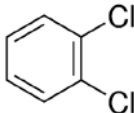
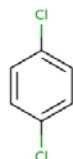
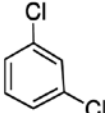
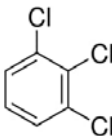
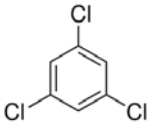
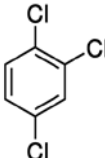
<sup>1</sup> Note that the total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

## 1. Background

### 1.1 Analogue substances

Chlorobenzene, hereinafter 'the Substance', is a chlorinated aromatic hydrocarbon, and part of a group of mono, di and tri chloro-benzenes. This group of substances is described in an Assessment of Regulatory Needs (ARN) from ECHA (dated 28 April 2022).

Analogue substances are indicated in the table below.

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type (t/y)
202-425-9	95-50-1	<b>1,2-dichlorobenzene</b>		Full, ≥ 10 000 to < 100 000 + TII
203-400-5	106-46-7	<b>1,4-dichlorobenzene</b>		Full, ≥ 10 000
208-792-1	541-73-1	<b>1,3-dichlorobenzene</b>		Full, ≥100 to <1000 + TII or OSII
201-757-1	87-61-6	<b>1,2,3-trichlorobenzene</b>		TII or OSII
203-608-6	108-70-3	<b>1,3,5-trichlorobenzene</b>		Full, ≥1 to <10
204-428-0	120-82-1	<b>1,2,4-trichlorobenzene</b>		TII or OSII
945-571-5	-	<b>Reaction mass of 1,2-dichlorobenzene, 1,3-dichlorobenzene and 1,4-dichlorobenzene</b>	-	TII or OSII

## 1.2 Overview of ongoing/ completed/ other 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
203-628-5	x			x		

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

In a compliance check (CCH) decision (1 July 2011), data related to uses and exposure assessment, waste management measures and PNECs were requested. The requests were met and the CCH is concluded.

A comprehensive CCH is currently under assessment.

## 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 (*)
203-628-5	108-90-7	Chlorobenzene	Flam. Liq. 3 Skin Irrit. 2 Acute Tox. 4 Aquatic Chronic 2	Flam. Liq. 3 Skin Irrit. 2 Acute Tox. 4 Aquatic Chronic 2	Flam. Liq. 3 (18) Skin Irrit. 2 (8) Acute Tox. 4 (4) Aquatic Chronic 2 (16) Eye Irrit. 2 (3) Ox. Sol. 1 (1) Acute Tox. 3 (2) Skin Corr. 1A (1) Skin Corr. 1B (1) Skin Sens. 1 (1) Resp. Sens. 1 (1) Muta. 1B (1) Carc. 1A (1) Repr. 2 (1) STOT RE1 (2) Aquatic Acute 1 (2) Aquatic Chronic 1 (2)

(\*) 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)* §
203-628-5	10,000 – 100,000 tpa

\* 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](https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0)

§ Confidential

#### 3.2 Overview of the Uses

Main types of applications	EC 203-628-5 Key information
Industrial use	Used in heat transfer fluids, pH regulators, water treatment products and laboratory chemicals. Used as intermediate in manufacture of another substance.
Professional use	Used in laboratory chemicals and heat transfer fluids. Also indoor use as processing aid and indoor use in close systems with minimal release (e.g. cooling liquids in refrigerators, oil-based electric heaters)
Consumer Use	
Article service life	
Intermediate use (if TII)	
Formulation	

## 4. Justification for inclusion on the CoRAP

### 4.1 Legal basis

- Article 44(2)<sup>2</sup>  
 Article 45(5)<sup>3</sup>

### 4.2 Identification of initial grounds of concern

Hazard-based concerns	
Suspected CMR	<input type="checkbox"/> Carcinogenic <input checked="" type="checkbox"/> Mutagenic <input checked="" type="checkbox"/> Reproductive toxicant
Potential ED	<input checked="" type="checkbox"/> Human Health <input type="checkbox"/> Environment
Suspected Sensitiser	<input type="checkbox"/> Respiratory <input type="checkbox"/> Skin
Specific target organ toxicity – repeated (STOT RE)	<input type="checkbox"/> (as defined in section 4.3 below)
Suspected PBT/ vPvB Suspected PMT/ vPvM	<input type="checkbox"/> Persistent <input type="checkbox"/> Bioaccumulative <input type="checkbox"/> Mobile <input type="checkbox"/> Toxic (as defined in section 4.3 below) <input type="checkbox"/> very Persistent <input type="checkbox"/> very Bioaccumulative <input type="checkbox"/> very Mobile
Other human health hazard(s)	<input type="checkbox"/> (as defined in section 4.3 below)
Other environmental hazard(s)	<input type="checkbox"/> (as defined in section 4.3 below)
Exposure/ risk-based concerns	
Wide dispersive use	<input checked="" type="checkbox"/>
Consumer use	<input type="checkbox"/>
Exposure of workers	<input checked="" type="checkbox"/>
Exposure of sensitive populations	<input type="checkbox"/>
Exposure of environment	<input type="checkbox"/>
Cumulative exposure	<input type="checkbox"/>
High RCR	<input type="checkbox"/>
High (aggregated) tonnages	<input checked="" type="checkbox"/>
Others (to be specified)	<input type="checkbox"/>

<sup>2</sup> “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.”

<sup>3</sup> “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*

Based on currently available information, there is a need for data on the potential reproductive toxicity and ED. The available registration information indicates potential for reproductive toxicity and ED due to findings in available studies showing adverse effects of bilateral degeneration of the testicular germinal epithelium. In addition, effects on spleen, thymus and bone marrow were seen in a 90-day repeated dose toxicity study, which may trigger further investigation of developmental immunotoxicity. Toxcast assays give positive results for RXR (retinoid X receptor) antagonism, and therefore also indicates potential ED properties.

Moreover, the potential of the Substance to cause DNA damage should be further investigated. An OECD TG 476 (In Vitro Mammalian Cell Gene Mutation Test) study showed positive results, but results from an in vivo single cell gel electrophoresis assay were ambiguous. The genotoxic potential of the Substance needs further investigation, also taking into account the neoplastic nodules found in the livers of male rats in a chronic toxicity study.

Chlorobenzene is an Annex X substance which finds industrial uses as an intermediate, solvent and heat transferring agent and also professional use as a heat transferring agent.

To clarify human health hazards and any remaining uncertainties regarding endocrine disrupting properties of the substance, substance evaluation is proposed. SEv will focus on reproductive parameters, ED parameters and the potential to cause DNA damage. Additional information needs regarding STOT RE may be considered.

#### *Other relevant information to justify the inclusion in CoRAP*

#### *Information to be potentially requested*

The current information suggests potential reprotoxic properties and potential ED properties, but the data are insufficient to conclude on these endpoints. Further toxicological data may be needed to clarify the concerns for reproductive toxicity and ED.

The genotoxic potential of the Substance will be assessed in the evaluation. Based on the outcome of the assessment, it will be concluded if additional genotoxicity data are needed, e.g. a Comet assay.

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

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

EC/ List number	Harmonised C&L	Restriction	Authorisation	Other
203-628-5	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

If the Substance will be identified as toxic for reproduction and/or ED, it may lead to harmonized classification for these endpoints. The European Commission intends to introduce a new hazard class for endocrine disruptors to the CLP Regulation 1272/2008. Harmonised classification as an endocrine disruptor to the human health and/or environment may, in future, be an additional regulatory risk management measure which could be taken for the Substance. Depending on this classification, the Substance may be identified as a SVHC, with restriction or authorization as potential follow-up.