



Justification Document for the Selection of a CoRAP Substance

EC/List number	CAS RN	Public Substance name	Chemical structure	Registration type
204-278-6	118-79-6	2,4,6-tribromophenol		Full, Intermediate

Authority: FRANCE

Date: 19 March 2024

Revision history

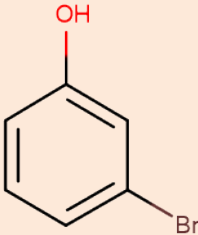
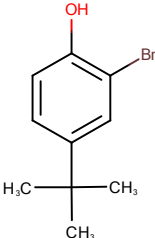
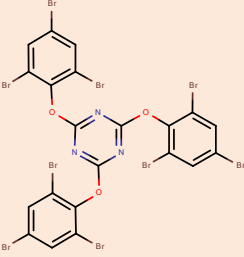
Version	Date

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
209-706-5	591-20-8	3-bromophenol	
218-602-9	2198-66-5	2-bromo-4-tert-butylphenol	
426-040-2	25713-60-4	2,4,6-tris(2,4,6-tribromophenoxy)-1,3,5-triazine	
443-430-8	-	FIREGUARD FG-1500	Confidential

Part of subgroup 1 of the GMT 271
<https://echa.europa.eu/fr/assessment-regulatory-needs/-dislist/details/0b0236e18630928d>

ECHA has grouped together structurally similar substances which are brominated aliphatic and aromatic compounds. Based on the hazard and use screening, ECHA has published an Assessment of Regulatory Needs (ARN) on a group of Brominated cycloalkanes, alcohols, phosphates, triazine triones, diphenyl ethers and diphenyl alkyls (flame retardants related substances) in 2021¹ supplemented in 2023 with a strategy for flame retardants².

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
204-278-6	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)

¹ <https://echa.europa.eu/documents/10162/fc17a901-2fbf-015f-712c-7ec81135eb32>

² <https://echa.europa.eu/documents/10162/188bf877-aeb0-144f-c19b-143e10466e12>

JUSTIFICATION DOCUMENT FOR THE SELECTION OF A CORAP SUBSTANCE

#2,4,6-tribromophenol was included on the 2012 CoRAP but was concluded without any data requests due to inactivation of all the registrations at that time. The conclusion is published here: <https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e18071f2ba>
 Since then, new registrations have been submitted.

EC/ List number	Other EU legislation PPP/ BPR	Previous legislation NONS/ RAR	Stockholm convention POP	Other (e.g. UNEP)
204-278-6	-	-	-	-

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 (*)
204-278-6	118-79-6	2,4,6-tribromophenol	none	Acute Tox. 4 ; H302 Eye Irrit. 2; H319 Skin Sens. 1; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410	[165 notifiers]: Skin Sens. 1; H317 Eye Irrit. 2; H319 Aquatic Acute 1; H400 [6 notifiers]: Acute Tox. 4 ; H302 Skin Sens. 1; H317 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 [2 notifiers]: Acute Tox. 3; H301 Acute Tox. 4 ; H312 Skin Irrit. 2 ; H315 Eye Irrit. 2; H319 Acute Tox. 4 ; H332 STOT SE 3 (respiratory sytem) (inhalation) ; H335 Aquatic Chronic 2 ; H411 [2 notifiers]: Acute Tox. 3; H301 [1 notifier]: Skin Sens. 1; H317 Eye Irrit. 2; H319 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 [1 notifier]: Acute Tox. 4; H302 Skin Sens. 1; H317 Eye Irrit. 2; H319 Repr. 2 H361

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					<p>STOT SE 2; H371 (other:Nervous S...) STOT SE 2; H371 (Nervous System) STOT RE 2; H373 (Liver, Kidney) STOT RE 2; H373 (other:Liver, Ki...) Aquatic Acute 1; H400 Aquatic Chronic 1; H410</p> <p>[1 notifier:] Not classified</p>
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() 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*) ³⁴
204-278-6	≥ 100 to < 1000 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

3.2 Overview of the Uses

The substance is mainly used as a flame retardant in thermoplastic polyester and epoxy resins, in acrylonitrile-butadiene-styrene resins, in phenolic resins and polystyrene (SFT, 2009). Information in the registration dossiers indicates industrial use in polymers and used as a chain ending agent in a polymer.

Main types of applications	EC 204-278-6 Key information
Industrial use	X
Professional use	
Consumer Use	
Article service life	X
Intermediate use (if TII)	
Formulation	

³ The total aggregated tonnage band may be available on ECHA's webpage at <https://echa.europa.eu/information-on-chemicals/registered-substances>

⁴ Substance Infocard on ECHA's dissemination website accessed on 25 September 2023. NB. REACH registration data on ECHA's webpage has not been updated since 19 May 2023.

4. Justification for inclusion on the CoRAP

4.1 Legal basis

Article 44(2)⁵

Article 45(5)⁶

4.2 Identification of initial grounds of concern

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

⁵ "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."

⁶ "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

2,4,6-tribromophenol was evaluated by Norway in 2012 under Substance Evaluation, but the evaluation was terminated in 2016 with several open concerns due to the substance no longer having active registrations. The eMSCA concluded that further information would have been necessary to clarify the concerns regarding suspected PBT/vPvB, reproductive toxicity and endocrine disruption properties.

New registrations occurred in 2018 and some concerns still need to be further investigated:

- The substance 2,4,6-tribromophenol may be reprotoxic and neurotoxic because of the potential release of bromide ion which can cause adverse effects on development, on or via lactation and narcotic effects. Ammonium bromide is classified as Repro. 1B, H360 FD and H362; STOT SE 3, H336 and STOT RE 1, H372. According to the RAC opinion (ECHA, 2020) comparison of the available data on the various bromide salts has shown that the bromide ion is the relevant ion for determination of the toxicological profile with simple cations such as potassium, sodium or ammonium having little or no influence on the bromide ion properties.
- Based on the results of the screening study conducted according to the OECD TG 422, effects were seen on liver and kidney, a decrease of thymus weight, atrophy of thymus and hypertrophy of adrenals (STOT RE) were observed which are indicative of potential ED properties. *In vitro* tests also confirmed the concern.
- Results from *in silico*, *in vitro* and *in vivo* studies suggest that 2,4,6-tribromophenol may interact with the endocrine system through multiple modes of action (MoA). 2,4,6-tribromophenol seems to produce adverse effects such as reduction of oocyte development, reduction of fertilization success and fecundity, and shift in male ratios of zebrafish being suggestive of an ED MoA (Norwegian Environmental Agency, 2016).
- *In vitro* studies indicate a potential for endocrine disruption that is relevant for humans (Norwegian Environmental Agency, 2016).
- QSAR estimates based on BIOWIN predict that 2,4,6-tribromophenol is not readily biodegradable and no biodegradation of 2,4,6-TBP was observed in (non-guideline) screening studies (Norwegian Environmental Agency, 2016). Therefore 2,4,6-TBP screens as (v)P. The mean half-life of 2,4,6-tribromophenol in soil was 7 days in a OECD TG 307, indicating non-persistence in the tested soils. No simulation test in water or sediment are available for the substance.
- 2,4,6-tribromophenol is ionisable with a reported pKa of 6.08. It has a water solubility of 59 mg/L at 25 °C. The Log Koc has been measured in an OECD TG 106 study in three different soils having pHs in the range 4.6-5.8. The Log Koc was 3.01-3.75. The lower value is close to the classification threshold for M of Log Koc = 3. Since the substance is ionisable, further investigation of the Log Koc in more alkaline soils where the anionic form would dominate may be needed.
- 2,4,6-tribromophenol is acutely very toxic to aquatic organisms, and is self-classified as Aquatic Acute 1 and Aquatic Chronic 1. The lowest NOEC is from an OECD TG 211 *Daphnia magna* reproduction test with a NOEC 0.025 mg/L for survival. This does not meet the T criterion. However, the reproductive toxicity in mammals and endocrine disrupting effects still needs to be investigated and are

also relevant for the T criterion.

References:

SFT, 2009. Current state of knowledge and monitoring requirements - Emerging "new" brominated flame retardants in flame retarded products and the environment (TA-2462/2009)

Norwegian Environmental Agency. 2016. Substance Evaluation Conclusion as required by REACH Article 48 and Evaluation Report for 2,4,6-tribromophenol. EC No 204-278-6, CAS No 118-79-6.

<https://echa.europa.eu/documents/10162/fd19d44e-7365-c189-d263-d3b0f4cc7dd9>

ECHA, 2020. Committee for Risk Assessment RAC Opinion proposing harmonised classification and labelling at EU level of Ammonium bromide. CLH-O-0000006899-51-01/F. Adopted on 8 October 2020

<https://echa.europa.eu/documents/10162/61e8d5d7-2ebd-fd02-a9c5-89671c2aef3b>

Information to be potentially requested

Further tests may be required to elucidate concern on ED properties for human health and environment, PMT properties as well as reprotoxic properties such as for instance an EOGRTS, a long term toxicity study in fish or a surface water simulation test OECD 308 including identification of environmental degradation products.

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

EC/ List number	Harmonised C&L	SVHC	Restriction	Authorisation	Other
204-278-6	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>