MINISTERIO
DE SANIDAD, CONSUMO
Y BIENESTAR SOCIAL

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	2-Bromo-3,3,3-trifluoroprop-1-ene
EC Number:	627-872-0
CAS Number:	1514-82-5
Authority:	Ministry of Health, Consumer Affairs and Social Welfare. Spain
Date:	19/03/2019

Cover 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

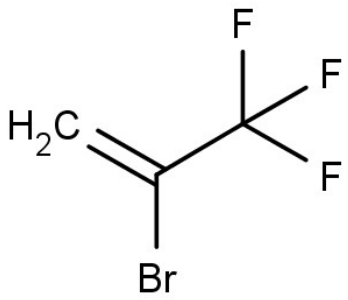
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	2-bromo-3,3,3-trifluoroprop-1-ene
IUPAC name (public):	2-Bromo-3,3,3-trifluoroprop-1-ene
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$C_3H_2BrF_3$
Molecular weight or molecular weight range:	174.947
Synonyms:	*2-BTP* *AAWG Agent #873* *Agent 873* *BTP* *Halotron BrX* *NMERI Agent #873* *Propene, 2-bromo-3,3,3-trifluro- 2-Bromo-3,3,3-trifluoropropene 3,3,3-Trifluoro-2-bromopropene* *Halon 1323 NSC 117350* *2-bromo-3,3,3-trifluoroprop-1-ene*

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

Structural formula:



1.2 Similar substances/grouping possibilities

Not applicable.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	☐ Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	☐ Compliance check
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restriction	☐ Annex XVII[1]
CLH	☐ 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 67/548/EEC (NONS)	
	☐ Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☐ Other (provide further details below)	
Further details		

[1] Please specify the relevant entry.

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

No harmonised classification is available.

3.1.2 Self classification

- In the registration:

  STOT SE 3 (H335: May cause respiratory irritation)

  STOT SE 3 (H336: May cause drowsiness or dizziness)

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

  Not classified

  Flam. Liq. 1 (H224: Extremely flammable liquid and vapour)

  Self-react. F (H242: Heating may cause a fire)

  Acute Tox. 4 (H302: Harmful if swallowed)

  Acute Tox. 4 (H312: Harmful in contact with skin)

  Acute Tox. 4 (H332: Harmful if inhaled)

  Muta. 2 (H341: Suspected of causing genetic defects)

  H319: Causes serious eye irritation

  H315: Causes skin irritation

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

Currently, there is no proposal for harmonised classification for the substance 2-bromo-3,3,3-trifluoroprop-1-ene.

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

4.1 Tonnage and registration status

Table: Tonnage and registration status

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
A single registration as individual submission.		

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

4.2 Overview of uses

The substance is described to be used at industrial sites for refilling and maintenance of fire extinguishers and it may be used by consumers in case of their emergency discharge, in both indoors and outdoors situations.

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	
Formulation	

[2] *The dissemination site was accessed July 2017.*

Uses at industrial sites	Refilling and maintenance of extinguisher systems ERC7: Use of functional fluid at industrial site PROC1: Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions PROC9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) SU10: Formulation (mixing) of preparations and/or re-packaging (exclusing alloys)
Uses by professional workers	
Consumer Uses	End user exposure (emergency discharge of fire extinguishers) (indoors) End user exposure (emergency discharge of fire extinguishers) (outdoors) PC0: Other: Fire extinguishant ERC9a: Widespread use of functional fluid (indoor) ERC9b: Widespread use of functional fluid (outdoor)
Article service life	

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

In a GLP reproduction/developmental toxicity screening test (OECD TG 421) performed in SD rats by inhalation at doses of 50, 100, 175 and 10000 ppm, higher mean pre-coital interval and longer mean gestation length were observed in parental females at 175 ppm. In F1 animals, lower postnatal survival was noted from birth to PND 4 in the group dosed with 175 ppm. Pups that were found dead showed an increased incidence of interventricular septal defect at 175 ppm, considered test substance-related and adverse.

Another GLP screening study in SD rats (OECD TG 421) by inhalation at concentrations of 198, 505, 2900 ppm, showed clinical signs such us underactivity, unresponsiveness, piloerection and partially close eyelids, lower bodyweight gain and food intake (for males throughout the treatment period and for females mainly during gestation) at the two highest doses tested. In relation to reproductive effects, parental animals showed longer oestrus cycles (6 days or longer), extended duration of gestation (only one female littering) and longer pre-coital intervals in mid and high doses (505 and 2900 ppm). At 2900 ppm, effects on sperm analysis (reduction in motility, velocity, sperm count in the cauda epididimys and abnormal sperm) were observed. Reduced sperm velocity and abnormal sperm were also observed at 505 ppm. In the low dose (198 ppm) effects such as a slightly lower sperm count noted in the vaginal smear on the day of mating and an increase in abnormal sperm were reported. In addition, lower implantations counts and decreases in prostate, seminal vesicles and pituitary weights were observed at all dose levels tested. In the F1 animals, post-implantation survival and birth viability leading to reduction in the litter size were observed at all doses tested.

These findings raised concern that the substance might be a reproductive toxicant and a potential endocrine disruptor (due to effects observed in endocrine parameters such as oestrus cyclicity, gestation length and sperm parameters).

Taking into account this information, further investigations might be needed and these concerns should be clarified under SEV.

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)
Further information might be needed to investigate and clarify the concerns.	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☒ Authorisation	☐ Other (provide further details)
Depending on the outcome of the substance evaluation, it might be necessary to put forward a proposal for harmonized classification or inclusion on the candidate list.			