

ANNEX XV REPORT

AN ASSESSMENT OF WHETHER THE USE OF 1-BROMOPROPANE IN ARTICLES SHOULD BE RESTRICTED IN ACCORDANCE WITH ARTICLE 69(2) OF REACH

SUBSTANCE NAME: 1-bromopropane

IUPAC Name:	1-bromopropane,	
	n-propyl bromide	
EC NUMBER:	203-445-0	

CAS NUMBER: 106-94-5

CONTACT DETAILS:

EUROPEAN CHEMICALS AGENCY Telakkakatu 6, P.O. Box 400, 00121 Helsinki, Finland tel: +358-9-686180, www.echa.europa

VERSION NUMBER: 1.1

DATE: 21 February 2022

About the report

This draft report is prepared according to Article 69(2) of REACH Regulation (EC) No. 1907/2006, which, after the sunset date has passed for a substance included on the Authorisation List (Annex XIV), requires ECHA to consider if risks from the use of the substance in articles are adequately controlled and, if this is not the case, prepare an Annex XV restriction dossier.

In general, ECHA gathers information on potential risks to human health and/or the environment for identified uses of the substance in articles from various sources. Information is gathered (if available) from authorisations, recommendation for inclusion in Annex XIV and substance of very high concern (SVHC) identification. Uses identified in the REACH registrations and notifications in substances in articles, in accordance with article 7(2) of REACH¹ and the Waste Framework Directive (SCIP database),² are also investigated. Information on possible uses of the substance in articles that were not identified during the screening phase can be gathered through a subsequent call for evidence launched via ECHA's website.

In most cases, risks stemming from the incorporation of the substance into an article are not in the scope of this investigation as incorporation of a substance in articles has to be authorised, unless this use is exempted in accordance with Article 56(1) of REACH.³ The incorporation process carried out in third countries is outside the scope of EU legislation. However, it should be noted that articles if imported to the EU are within the scope of this investigation. The incorporation is regarded to cover two type of uses⁴:

a) The substance is incorporated into an article during its production, or

b) The substance, alone or in a mixture is incorporated into/onto an existing article (isolated or incorporated in a complex object) at a later stage (e.g., coatings, primers, adhesives, sealants) and become an integral part of the article (or of the complex object).

It is to be noted that there are several specific exemptions from the authorisation requirements⁵, while only few exemptions are envisaged in case of restrictions. These include manufacture and placing on the market or use of a substance in scientific research and development, risks to

¹ Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: <u>https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles</u>

² In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): <u>http://echa.europa.eu/scip</u>

³ Q&A ID: 0564: <u>https://echa.europa.eu/support/qas-support/qas</u> Note that ECHA will investigate for this report whether applications for authorisation/authorisation decisions cover the incorporation of the substance into an article.

⁴ <u>https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c</u>

⁵ <u>https://echa.europa.eu/documents/10162/13640/generic exemptions authorisation en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc</u>

human health of the use of the substance in cosmetic products and when a substance is used as an on-site isolated intermediate.

Contents

Α.	Conclu	clusions1		
	A.1	Conclusions based on the assessment1		
	A.2	Targeting2		
	A.3	Summary of the justification 2		
В.	. Information on hazard and risk			
	B.1	Identity of the substance and physical and chemical properties4		
	B.2	Manufacture and uses		
	B.3	Classification and labelling		
	B.4	Environmental fate properties		
	B.5	Human health hazard assessment9		
	B.6	Human health hazard assessment of physicochemical properties9		
	B.7	Environmental hazard assessment9		
	B.8	PBT and vPvB assessment		
	B.9	Exposure assessment		
	B.10 Summary of the existing legal requirements			
	B.11	Risk characterisation		
C.	Availa	Available information on alternatives12		
D.	Justification for action on a Community-wide basis			
E. mea	Justifi asure	cation why the proposed restriction is the most appropriate Community-wide 13		
F.	Socio-economic Assessment of Proposed Restriction			
G.	G. Stakeholder consultation			
н.	. Other information 13			
Ref	erences .			

A. Conclusions

A.1 Conclusions based on the assessment

1-bromopropane⁶ was included on the Candidate List (19 December 2012; ED/169/2012)⁷ and included into Annex XIV of REACH (entry #32, Commission Regulation (EU) No 2017/999)⁸ with a sunset date of 4 July 2020 due to its toxic to reproduction category 1B properties. According to REACH, ECHA needs to consider whether the use of the substance listed in the Annex XIV in articles poses a risk to human health or to the environment that is not adequately controlled. In such cases, ECHA prepares a restriction proposal.

ECHA has gathered information on the uses of 1-bromopropane in articles from various sources. This includes information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV as well as uses identified in the REACH registrations. ECHA has not received any applications for authorisations for this substance. Notifications for substances in articles (in accordance with Article 7(2) of REACH)⁹ have not been received either. Submissions under the Waste Framework Directive¹⁰ are the only source that indicates that 1-bromopropane is used in imported articles, likely in quantities less than one tonne per year per supplier.

The call for evidence, which took place from 18 August 2021 to 29 September 2021, did not identify any new uses of the substance in articles placed on the EU market. One comment was received, from a Member State (Germany), which referred to studies identifying additional uses in articles internationally: as a solvent used in spray adhesives to fabricate foam products (e.g., polyurethane foam cushions), as an adhesive in laminates and in building and construction insulation material. There is no information that suggests that such articles containing 1-bromopropane are currently imported to the EU.

Following an assessment of the available evidence, ECHA considers that the uses of 1bromopropane in articles can potentially lead to human exposure to the substance. 1bromopropane is a reprotoxic substance; however, the information on the use and presence of the substance in articles is minimal. Therefore, taking into account the

⁶ Other substance names: 1-propyl bromide, propyl bromide, n-propyl bromide

⁷ <u>https://echa.europa.eu/documents/10162/322977d5-5c50-467b-a5aa-14dd621301af</u>

⁸ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0999&qid=1610546074272

⁹ Producers and importers have to notify ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met: i) the substance is present in their relevant articles above a concentration of 0.1% w/w; ii) the substance is present in these relevant articles in quantities totalling over 1 tonne per year. Companies have to notify no later than six months after the inclusion of the substance in the Candidate List. For further details see: https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles

¹⁰ In accordance with the Waste Framework Directive (WFD), companies supplying articles containing substances on the Candidate List in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA, from 5 January 2021. The information provided is included in the SCIP database, i.e., Substances of Concern In articles as such or in complex objects (Products): <u>https://echa.europa.eu/scip</u>

emerging priorities in the Restriction Roadmap,¹¹ ECHA will monitor for potential increased presence of the substance in articles via the SCIP (Substances of Concern In articles, in accordance with the Waste Framework Directive) and Substances in Articles notifications (in accordance with Article 7(2) of REACH) prior to considering further action under Article 69(2). The information in the SCIP database allows the users of the articles to assess the risk from their uses and take appropriate risk reduction measures, as information is available throughout the whole lifecycle of products and materials, including at the waste stage.

This final report, updated with information submitted during the call for evidence, was sent to CARACAL/Member States in December 2021 as an information document. One Member State Competent Authority provided comments of editorial nature.

A.2 Targeting

This report is targeted at the potential release of or exposure to 1-bromopropane from articles throughout its lifecycle (including the waste stage) and whether or not such use should be restricted. The report is focused on human health hazards due to which the substance is placed on the Annex XIV: toxic to reproduction. Other hazards are not taken into account in this report.

This targeting is based on the Article 69(2) of REACH Regulation that requires ECHA to consider if the use of the substance in articles poses a risk to human health or the environment that is not adequately controlled and prepare an Annex XV dossier for an appropriate restriction if this is the case. The incorporation of an Annex XIV substance into an article is a use which is subject to an authorisation requirement.¹²

A.3 Summary of the justification

A.3.1 Identified uses, hazard, exposure/emissions, and risk

Information on uses

ECHA did not receive any applications for authorisations for this substance. No registration dossiers or notifications for substances in articles under Article 7(2) of REACH identified the use of 1-bromopropane in articles. Searches in various other databases and the information submitted during the call for evidence revealed the following uses of the substance in articles internationally: as a solvent used in spray adhesives to fabricate foam products (e.g., polyurethane foam cushions), as an adhesive in laminates and in building and construction insulation material. There is no information that suggests that such articles containing 1-bromopropane are currently imported to the EU.

¹¹ To be proposed by the European Commission under the Chemical Strategy for Sustainability: <u>https://echa.europa.eu/hot-topics/chemicals-strategy-for-sustainability</u>

¹² Q&A ID No 564: <u>https://echa.europa.eu/support/qas-</u>

support/qas?p p id=journalqasearch WAR journalqaportlet&p p lifecycle=0&p p state=normal&p p mode=view&p _p col id=column-1&p p col pos=2&p p col count=3

A small number of submissions to the SCIP database revealed that the substance is present (likely in quantities of less than one tonne per supplier per year) in imported articles placed on the EU market.

Other uses, other than in articles, of 1-bromopropane are not relevant for this report.

Information on hazards

1-bromopropane is included in Annex XIV based on its toxic to reproduction category 1B, H360FD¹³ ("May damage fertility. Suspected of damaging the unborn child.") properties. Other endpoints are not relevant for this report.

Information on emissions/release/exposure

Only emissions and releases from articles are relevant for this report. Based on information from the SCIP database and historical uses of 1-bromopropane it appears that the substance may be present in some articles leading to a potential exposure of industrial, professional or consumer users of these articles.

Characterisation of risk

1-bromopropane was prioritised for Annex XIV listing due to its harmonised classification for reproductive toxicity (fertility and development) in category 1B (H360FD). In preparation for reviewing potential applications for authorisation, RAC prepared reference DNELs based on the reproductive toxicity of 1-bromopropane (see table 2). There are indications that 1-bromopropane is present in some imported articles, however exposure, including cumulative, to these articles is expected to be minimal. Therefore, before any further action on the substance is taken, ECHA will monitor the presence of the substance in articles via SCIP and SiA notifications for potential increased use (presence) and increased exposure to the substance in the EU.

A.3.2 Justification that action is required on a Union-wide basis

No restriction is proposed at present.

A.2.3 Justification that the proposed restriction is the most appropriate Union-wide measure

No restriction is proposed at present.

¹³ As reported in the Classification and Labelling Inventory in October 2021 (<u>https://echa.europa.eu/information-on-chemicals/cl-inventory-database/-/discli/details/111920</u>), although ECHA 2015 reports of "a mistake in the entry for the substance in the CLP Regulation (EC) No 1272/2008, Annex VI, part 3, Table 3.1, indicating its classification as 'Repr. 1B, H360FD". However, the correct hazard statement code is Repr. 1B, H360Fd."

B. Information on hazard and risk

B.1 Identity of the substance and physical and chemical properties

B.1.1 Name and other identifiers of the substance

1-bromopropane

Chemical name: 1-bromopropane; n-propyl bromide

EC Number: 203-445-0

CAS Number: 106-94-5

IUPAC Name: 1-bromopropane; n-propyl bromide

B.1.2 Composition of the substance(s)

1-bromopropane

Chemical name: 1-bromopropane; n-propyl bromide

EC Number: 203-445-0

CAS Number: 106-94-5

IUPAC Name: 1-bromopropane; n-propyl bromide

Molecular formula: C₃H₇Br

Structural formula: Br -

[−]CH₃

Molecular weight: 123.0 g/mol

Typical proportion %:

Concentration range %: 98-100%

B.1.3 Physicochemical properties

Table 1 provides certain physicochemical properties for 1-bromopropane. ECHA's dissemination site provides further information as provided by the registrants.

Table 1 Selected physicochemical properties					
REACH ref Annex	Property	Value			
VII, 7.1	Physical state at 20°C and 101.3 kPa	Liquid (100%)			
VII, 7.2	Melting / freezing point	-110 °C			
VII, 7.3	Boiling point	71 °C			
VII, 7.5	Vapour pressure	14.772 kPa at 20 °C			
VII, 7.7	Water solubility	2.45 - 2 450 mg/L at 20 °C			
VII, 7.8	Partition coefficient n-octanol/water (log value)	Log Kow (Log Pow): 2.1			
XI, 7.16	Dissociation constant				

Source: ECHA Substance brief profile for 1-bromopropane (ECHA, 2021)

P.O. Box 400, FI-00121 Helsinki, Finland | Tel. +358 9 686180 | echa.europa.eu

B.1.4 Justification for grouping

Not relevant.

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of a substance

1-bromopropane is registered under REACH for intermediate uses.¹⁴ Manufacturing and import of the substance may continue today for potentially any uses exempted from authorisation (as no applications for authorisation have been submitted to date) or for export. No information on exports is available.

B.2.2 Uses

Uses in articles

No registration dossiers identified the use of 1-bromopropane in articles. There are no applications for authorisation submitted to ECHA.¹⁵ Therefore, it can be concluded that the substance is used primarily as an intermediate in the EU, although it is possible that the substance is also used under conditions meeting exemptions from authorisation, such as for scientific research and development purposes.

There are no SiA notifications made under Article 7(2) for 1-bromopropane. A small number of submissions reporting 1-bromopropane containing articles were made to the SCIP database. The articles belong to the following categories:

- Components of dishwashing machines; machinery for cleaning, filling, closing, sealing, labelling and capsuling containers; packing or wrapping machinery and machinery for aerating beverages (CN¹⁶ chapter and heading: 8422)
- Spark-ignition reciprocating or rotary internal combustion piston engines (CN chapter and heading: 8407)
- Components and accessories of printing machinery such as printers, copying machines and facsimile machines, as well as typewriter and similar ribbons (CN chapters and headings: 8443 and 9612)¹⁷
- Self-adhesive paper or paperboard labels (CN chapter and heading: 4821)

¹⁴ ECHA dissemination site to be updated.

¹⁵ While there are no authorisations for the use of 1-bromopropane, several applications have been submitted to ECHA for the use of trichloroethylene for vapour degreasing and surface cleaning, which appear similar to the uses of 1-bromopropane. It should be recalled that one of the reasons for the prioritisation of 1-bromopropane was due to it being a substitute for trichloroethylene for degreasing and surface cleaning (ECHA 2015).

¹⁶ Combined Nomenclature

¹⁷ Printer cartridges and printing ribbons are regarded as a combination of articles (object functioning as a container) and a mixture (the toner or ink), according to Annex 3 of the "<u>Guidance on requirements for substances in articles</u>". Therefore, if 1-bromopropane is present in the ink or toner incorporated in such objects, and since those objects are not considered as articles under REACH, they are not covered by the scope of Article 69(2).

- Plastic tubes, pipes, hoses, plates, sheets, film, foil, tape, strip, and other articles, including self-adhesive (CN chapter and heading: 3917, 3919, 3920, 3921)
- Telephone sets, components of electrical resistors, electronic bases (e.g. boards, panels) (CN chapters and headings: 8517, 8533, 8537)
- Articles of base metal (CN chapters: 72, 73, 76, 83).

The SCIP database reports that these articles are primarily made of the following materials: rubber, elastomers, plastic and polymers (e.g., polypropylene and polyethylene) and other materials such as ceramic.

From the data submitted to the SCIP database, it seems that the presence of 1bromopropane results from the use or incorporation of the following types of mixtures containing 1-bromopropane in their composition, during the production or assembling of the articles or complex objects listed above:

- coatings and inks (European product categorisation system (EuPCS) code: PC-INK-3);
- lubricants, greases, release agents (EuPCS code: PC-TEC-11);
- adhesives and sealants (EuPCS code: PC-ADH-7).

The submissions to the SCIP database suggest that 1-bromopropane may be present in articles (in a concentration above 0.1% w/w) placed on the EU market, namely in imported articles. SCIP however does not contain information on the function of 1-bromopropane in these articles or complex objects, neither about the tonnage of the substance present, and it is unclear whether the submission was made as a result of tests that demonstrated the presence of the substance in the article or a knowledge of the production process. If 1-bromopropane was applied to the articles or complex objects for the purpose of cleaning and degreasing, during the prioritisation it was stated that there was no indication that the substance would be present in the final articles given its function (ECHA 2015). (See section on Other identified uses below.) No additional information was received during the call for evidence to help clarify the function and the presence of 1-bromopropane in these articles.

Other identified uses

Based on the information gathered during the SVHC listing and recommendation for the inclusion of substances in Annex XIV, and uses identified in the REACH registrations, the uses of 1-bromopropane include:

a) uses at industrial sites (formulation and use) as well as by professional workers as a solvent in mixtures for vapour degreasing and surface cleaning: Examples of these uses include the degreasing and surface cleaning of metal parts and printed circuit boards in sectors such as the aerospace and defence industries as well as dry cleaning.¹⁸ Given the technical function of the substance, during the prioritisation it

¹⁸ The following sectors of end use are referenced in the registration dossiers: SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys); SU 12: Manufacture of plastics products, including compounding and conversion; SU 15: Manufacture of fabricated metal products, except machinery and equipment; SU 16: Manufacture of computer, electronic and optical products, electrical equipment; SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment; as well as specifically for surface cleaning, SU 0: Other: Surface cleaning, Surface degreasing

was stated that there was no indication that the substance would be present in the final articles. The tonnage of 1-bromopropane subject to authorisation was estimated in the range of 1 000 - <10 000 tonnes per year, although industry questioned this estimate during the consultations for SVHC identification (ECHA 2015). No applications for authorisation have been submitted to date. Therefore, it can be concluded that 1-bromopropane is no longer used for these in the EU.

- b) use at industrial sites as an intermediate: Eight registrants have identified this use. According to the registration dossiers, the sector most commonly referenced for intermediate use is manufacture of fine chemicals (with product category "intermediate" and/or "pharmaceuticals"). Some of the reported intermediate uses during the SVHC identification of 1-bromopropane include the manufacture of pharmaceutical products such as anticonvulsant and mood-stabilizing medicines for the treatment of epilepsy, amongst others. The substance is reported as fully consumed during the manufacturing process and not expected to be present in the final article (ECHA 2015).
- c) laboratory uses: the consultation for identification of 1-bromopropane as an SVHC showed that the substance may also be used in some laboratory analyses. This use may fall outside the scope of authorisation due to the generic exemption on scientific research and development (ECHA 2015), provided that the conditions for this exemption are met.

During the consultation on the Member State Committee opinion document on the Sixth Recommendation for Amendment of Annex XIV of REACH, stakeholders confirmed that there are no known consumer uses of 1-bromopropane.

Other sources of information on uses:

IARC 2018 reports 1-bromopropane used internationally as a solvent for fats, waxes and resins and is primarily used as a chemical intermediate in the production of pesticides, quaternary ammonium compounds, flavours and fragrances, and pharmaceuticals in closed processes. 1-bromopropane is a solvent that is used in spray adhesives to fabricate polyurethane foam cushions, as a vapour degreasing agent and as a cleaning solvent for metals, plastics, optical and electronic components, and for dry cleaning fabrics. In the mid-to-late 1990s, 1-bromopropane was introduced as a nontoxic, fast-drying solvent that does not leave surface residue for cleaning metals, plastics, and optical, electrical and electronic components. It was marketed as a substitute solvent for ozone-depleting and other solvents such as trichloroethylene, tetrachloroethylene (perchloroethylene) and methylene chloride (IARC 2018).

US EPA reports that 1-bromopropane is used as an aerosol solvent in asphalt, aircraft, and synthetic fibre manufacturing, as a vapor and immersion degreaser in metals, metal products, plastics, optics, and electronics manufacturing, and as a cleaning solvent for dry cleaning. In addition, 1-bromopropane can be used as an adhesive in laminates and foam products, and as a chemical intermediate in pharmaceuticals, pesticides, quaternary ammonium compounds, flavours, and fragrances. A variety of consumer and commercial products use 1-bromopropane as adhesives and sealants, in furniture care products, in dry cleaning, spot cleaning and other liquid, spray, and aerosol cleaners, and in automotive care products (US EPA 2015). The substance is also reported to be used as an adhesive in building and construction insulation material, such as THERMAXTM brand insulation manufactured by Dow Chemical. THERMAXTM is a polyisocyanurate rigid board insulation for interior and exterior applications, and can be

used on walls, ceilings, roofs, and crawl spaces in commercial and residential buildings. According to EPA's Use Dossier, 1-BP is present at less than 5 percent concentration in the THERMAXTM brand insulation manufactured by Dow Chemical (US EPA 2020).

There is no information that these uses internationally result in imported articles containing 1-bromopropane in the EU.

Searches in various other databases did not reveal any information of the presence of 1-bromopropane in articles.¹⁹

B.2.3 Uses advised against by the registrants

There are no uses advised against in REACH registrations.

B.2.4 Description of targeting

This Article 69(2) review report is targeted on the potential release of 1-bromopropane from articles and exposure of 1-bromopropane when used in articles and whether or not such use should be restricted. Furthermore, targeting is based on the hazard for which the substance was included on Annex XIV, i.e., toxic to reproduction.

B.3 Classification and labelling

Classification according to CLP

1-bromopropane

Flam. Liq. 2 H225; Skin Irrit. 2 H315; Eye Irrit. 2 H319; STOT SE 3 H335, H336; STOT RE 2 H373; Repro 1B H360FD.

Some registrants have also self-classified the substance as Carc.2 H35120 and Aquatic Chronic 3 H412.

Classification according to the Classification and Labelling Inventory

There have been 41 notifications to the C&L inventory for 1-bromopropane most of them reproducing the harmonised classification, although there is some variation in the reported affected organs under STOT SE 3 and STOT RE 2. One notification was also received for Ozone 1 H420.

B.4 Environmental fate properties

Not relevant as the reason for inclusion in Annex XIV is risks to human health due to its harmonised classification for reproductive toxicity.

¹⁹ Danish Chemicals in Consumer Products Database, Consumer Product Information Database (USA & Canada); OECD Global Products Recall; Children's Safe Product Act Reported Data; Crest search engine; ChemSec Sinlist; Comparative Toxicogenomics Database; International Agency of Research on Cancer (IARC) monographs; California Department of Pesticide Regulation; Pesticide info.org

²⁰ 1-Bromopropane has been classified as "reasonably anticipated to be a human carcinogen" by the National Toxicology Program and in 2015, the US EPA added the substance to the Toxic Release Inventory (TRI) Program (US EPA 2015). According to IARC 2018, there is sufficient evidence in experimental animals for the carcinogenicity of 1-bromopropane and their overall conclusion is that 1-Bromopropane is possibly carcinogenic to humans (Group 2B).

B.5 Human health hazard assessment

1-bromopropane was prioritised for Annex XIV listing due to its harmonised classification for reproductive toxicity (fertility and development) in category 1B (H360FD). In preparation for reviewing potential applications for authorisation, RAC prepared reference DNELs based on the reproductive toxicity of 1-bromopropane. These are presented in the table 2 below:

Table 2 Reference DNELs for 1-bromopropane for reproductive toxicity endpoint						
General population						
Inhalation (24hrs)	Dermal	Oral				
1.1 mg/m3	3.2 mg/kg bw/d	0.32 mg/kg bw/d				
Workers						
Inhalation (8hrs)	Dermal					
6.2 mg/m ₃	9 mg/kg bw/d					

Source: ECHA 2016

Other human health endpoints are not relevant for this report, although a potential future restriction work may include other endpoints on the request of the European Commission.

B.6 Human health hazard assessment of physicochemical properties

Not relevant.

B.7 Environmental hazard assessment

Not relevant.

B.8 PBT and vPvB assessment

Not relevant.

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

For this report only releases from articles and exposure of a substance when used in articles are relevant.

1-bromopropane has been identified to be present in articles placed on the EU market solely in submissions in the SCIP database. Based on this information, it can be expected that the substance can lead to exposure of industrial, professional and consumer users of the articles.

The type of exposure anticipated from articles include dermal as a result of direct contact with the article as well as inhalation due to evaporation of the substance after its application on the articles. The magnitude of exposure depends on a variety of factors including the concentration of the substance in products used, use patterns (including frequency, duration, amount of product used, room of use, and local ventilation), and application methods. Depending on the articles to which the substance is applied, oral exposure due to mouthing of the articles may also be relevant.

It is anticipated that the amount of 1-bromopropane in the final articles is relatively low. Uses of 1-bromopropane in articles such as commercial and consumer uses of insulation material as building and construction materials in the form of rigid board insulation for interior applications²¹ were not found to lead to unreasonable risk to consumers and bystanders (US EPA 2020). However, most industrial, professional and consumer uses of 1-bromopropane for cleaning and degreasing were found likely to present an unreasonable risk of injury to health (US EPA 2020).²² IARC 2018 summarises exposure to workers in foam-fabricating plants assembling seat cushions using 1-bromopropane, are subject to authorisation (and no applications for authorisation have been received to date) or restricted in the EU under entry 30 of Annex XVII of REACH.

In summary, although there are indications that 1-bromopropane can be contained in imported articles, it is expected that exposure to those articles, including cumulative exposure, would be low. Therefore, before any further action on the substance is taken, ECHA will monitor the presence of the substance in articles via SCIP and SiA notifications for increased use (presence) and potential exposure. The information in the SCIP database allows the users of the articles to assess the risk from their uses and take appropriate risk reduction measures, as information is available throughout the whole lifecycle of products and materials, including at the waste stage.

B.10 Summary of the existing legal requirements

REACH

REACH has several requirements for substances on the Candidate List including notification of its presence in Articles if greater than 0.1% by weight and 1 tonne per year (Article 7(2)) and that suppliers must inform their customers on request if an article

²¹ The product evaluated is assumed to contain 0.5 percent by weight of 1-bromopropane (US EPA 2020).

²² EPA has determined that the following conditions of use of 1-1-bromopropane present an unreasonable risk of injury: Processing: incorporation into formulation, mixture, or reaction products; Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaser -open-top, inline vapor degreaser); Industrial and commercial use as solvent for cleaning and degreasing in vapor degreaser (batch vapor degreaserclosed-loop); Industrial and commercial use as solvent for cleaning and degreasing in cold cleaners; Industrial and commercial use as solvent in aerosol spray degreaser/cleaner; Industrial and commercial use in adhesives and sealants; Industrial and commercial use in dry cleaning solvents, spot cleaners and stain removers; Industrial and commercial use in liquid cleaners (e.g., coin and scissor cleaner) and liquid spray/aerosol cleaners; Other industrial and commercial uses: arts, crafts, hobby materials (adhesive accelerant), automotive care products (engine degreaser, brake cleaner, refrigerant flush), anti-adhesive agents (mold cleaning and release product), electronic and electronic products and metal products, functional fluids (close/open-systems) -refrigerant/cutting oils, asphalt extraction, laboratory chemicals, and temperature indicator -coatings; Consumer use as solvent in aerosol spray degreasers/cleaners; Consumer use in spot cleaners and stain removers; Consumer use in liquid cleaner (e.g., coin and scissor cleaner); Consumer use in liquid spray/aerosol cleaners; Consumer use in arts, crafts, hobby materials (adhesive accelerant); Consumer use in automotive care products (refrigerant flush); Consumer use in anti-adhesive agents (mold cleaning and release product) (US EPA 2020).

contains more than 0.1% by weight of 1-bromopropane (Article 33(b)). To date, no notifications have been submitted to ECHA for 1-bromopropane in articles.

The entry in Annex XIV for 1-bromopropane set a latest application date of 4 January 2019 and a sunset date of 4 July 2020. No applications for authorisation have been submitted to ECHA to date.

Due to its harmonised classification of Repro 1B, 1-bromopropane is restricted (see entry 30 of Annex XVII of REACH) for supply to the general public as a substance, constituent of a substance or in mixtures, when the concentration exceeds relevant concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Other legislation than REACH:

- Worker protection

Chemical Agents Directive (CAD), Art. 2(b)(i) - Hazardous Agents: The harmonised classification of 1-bromopropane (Table 3 of Annex VI of CLP Regulation) and its other properties of concern trigger obligations for employers to determine whether 1-bromopropane is present in workplaces, and if so, assess health and safety risks under Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directives within the meaning of Article 16(1) of Directive 89/391/EEC). Employers must take the necessary preventive measures to eliminate or reduce risks to the minimum. The legislation provides for indicative occupational exposure limit (OEL) values to be established (ECHA 2021). No OEL value has been set for 1-bromopropane.

Protection of pregnant and breastfeeding women: The substance is included in Annexes I and II of Directive 92/85/EEC on Pregnant Workers, 28 November 1992 (updated by table 3 of Annex VI to CLP, 5 Oct 2018) which establish a partial list of substances that may cause adverse health effect for either mother or child to which pregnant workers and workers who have recently given birth or are breastfeeding may not be exposed (ECHA 2021).

Protection of young people at work: 1-bromopropane is included in the non-exhaustive list of banned biological and chemical agents, in accordance with Article 7 and points 2 and 3 of the Annex to Directive 94/33/EC, to which young persons (under 18 years of age) may not be exposed at the workplace (ECHA 2021).

Workplace signage: EU Directive 92/58/EEC on the minimum requirements for the provision of safety and/or health signs at work, ensures that proper signage is posted in areas where hazards cannot be avoided or reduced. According to the directive, storage areas and containers containing chemical substances or mixtures that are classified as hazardous according to the CLP Regulation must be marked and/or labelled. The relevant signs for 1-bromopropane are flame, health hazard and exclamation point (ECHA 2021).

- Cosmetic products

The use of 1-bromopropane is prohibited in all cosmetics products by Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products. The substance is included in Annex II: Prohibited substances similar to other CMRs (ECHA 2021).

- EU Ecolabel Regulation

As 1-bromopropane is included on Table 3 of Annex VI of the CLP Regulation and in the REACH SVHC list, the EU Ecolabel cannot be awarded to goods containing the substance on its own or in mixture meeting the classification criteria for toxic, hazardous to the environment, or CMR according to the CLP regulation (ECHA 2021).

- Toy Safety

Under the <u>Toy Safety Directive (2009/48/EC</u>) reprotoxic substances are not allowed in the accessible parts of toys beyond the concentration limits set in the <u>Regulation on</u> <u>Classification, Labelling and Packaging of substances and mixtures</u>, or unless they are considered safe following a rigorous scientific evaluation.

- Waste Framework Directive (WFD)

1-bromopropane is included in Annex II of the Directive due to its harmonised classification under the CLP Regulation. The revised WFD (July 2018) gave ECHA the task to develop a database with information on articles containing SVHCs on the Candidate List. Companies supplying articles containing these substances in a concentration above 0.1% w/w on the EU market have to submit information on these articles to ECHA from 5 January 2021. The SCIP database (for information on Substances of Concern In articles as such or in complex objects (Products) established under the WFD) complements the existing information requirements for the presence of hazardous substances in articles under REACH (ECHA 2021). A small number of submissions to the SCIP database revealed that the substance is present (likely in quantities of less than one tonne per supplier per year) in imported articles placed on the EU market.

B.11 Risk characterisation

Although there are indications that 1-bromopropane can be contained in imported articles, it is expected that exposure to those articles, including cumulative exposure, would be low. Therefore, before any further action on the substance, ECHA will monitor the presence of the substance in articles via SCIP and SiA notifications.

C. Available information on alternatives

During the consultations for the identification and prioritisation of 1-bromopropane a number of alternatives were identified. Several of these alternatives have comparable concerns to human health and potentially have several disadvantages in comparison to 1-bromopropane: trichloroethylene (EC 201-167-4),²³ dichloromethane (methylene chloride, EC 200-839-9);²⁴ HFC/HFE solvents all based on Trans 1,2-dichloroethylene

²³ On Annex XIV

²⁴ The substance has harmonised classification of Carc 2 and is under assessment for ED properties.

(tDCE, EC 208-750-2) structurally similar to trichloroethylene;²⁵ and tetrachloroethylene (perchloroethylene, EC 204-825-9)²⁶ (ECHA 2012).

No further assessment of these or other alternatives is undertaken at this stage as no restriction is proposed at present.

D. Justification for action on a Community-wide basis

Not relevant, as no restriction is proposed at present.

E. Justification why the proposed restriction is the most appropriate Community-wide measure

Not relevant, as no restriction is proposed at present.

F. Socio-economic Assessment of Proposed Restriction

Not relevant, as no restriction is proposed at present.

G. Stakeholder consultation

The Annex XV screening report was subject to a call for evidence from 18 August 2021 to 29 September 2021. A comment was received from one Member State (Germany), providing references to certain studies identifying additional uses in articles internationally: as a solvent used in spray adhesives to fabricate foam products (e.g., polyurethane foam cushions), as an adhesive in laminates and in building and construction insulation material.

H. Other information

Not relevant.

²⁵ The substance is not registered. It has harmonised classification for Flam liq 2, Acute tox 4, and Aquatic chronic 3.

²⁶ The substance has harmonised classification for Carc 2 and Aquatic chronic 2.

References

- Applications for authorisation none submitted: <u>https://echa.europa.eu/applications-for-authorisation-previous-consultations</u>
- ECHA (2012) Member State Committee support document for identification of 1bromopropane as a substance of very high concern. Available at: <u>https://echa.europa.eu/candidate-list-table/-</u> /dislist/details/0b0236e1807dbbed
- ECHA (2015) Background document for 1-bromopropane document developed in the context of ECHA's Sixth Recommendation for the inclusion of substances in Annex XIV. Available at https://echa.europa.eu/documents/10162/381015b7-2bd1-4a34-935d-692416f3fa11
- ECHA (2016)Applications for authorisation: Establishing reference DNELs for 1-
bromopropane.Availableat:
at:
https://echa.europa.eu/documents/10162/21961120/1-
Bromopropane.pdf/f7d46cbc-f9c8-b1ca-26ab-60a047e97276
- ECHA (2021)ECHA dissemination database. Substance infocard: 1-bromopropane
Available at: <a href="https://echa.europa.eu/substance-information/-
/substanceinfo/100.003.133? disssubsinfo WAR disssubsinfoportlet bac
kURL=https%3A%2F%2Fecha.europa.eu%2Fhome%3Fp p id%3Ddisssi
mplesearchhomepage WAR disssearchportlet%26p p lifecycle%3D0%2
6p p state%3Dnormal%26p p mode%3Dview%26p p col id%3Dcolum
n-
1%26p p col count%3D2%26 disssimplesearchhomepage WAR dissse
archportlet sessionCriteriaId%3D
- IARC (2018) Some Industrial Chemicals, IARC Monographs on the Evaluation of Carcinogenic Risks to Humans Volume 115, International Agency for Research on Cancer, World Health Organisation, 2018. Available at: https://publications.iarc.fr/563
- US EPA (2015) Addition of 1-Bromopropane to the Toxic Release Inventory (TRI) Program. United States Environmental Protection Agency. 2015. Available at: <u>https://www.epa.gov/toxics-release-inventory-tri-program/addition-1-bromopropane</u>
- US EPA (2020) Risk Evaluation for 1-Bromopropane. United States Environmental Protection Agency. August 20202. Available at: <u>https://www.epa.gov/sites/default/files/2020-</u> <u>08/documents/risk evaluation for 1-bromopropane n-</u> <u>propyl bromide.pdf</u>