Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 21 January 2022

Group Name: Inorganic Bromide Salts

General structure:

Revision history

Version	*Date*	*Description*
1.0	29 September 2022	

Substances within this group:

EC/List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
231-599-9	7647-15-6	Sodium bromide		Full, 1000t/y
231-830-3	7758-02-3	Potassium bromide		Full, 100-1000t/y
232-164-6	7789-41-5	Calcium bromide		Full, 1000t/y
232-178-2	7789-60-8	Phosphorus tribromide		Full, Not (publicly) available
235-183-8	12124-97-9	Ammonium bromide		Full, Not (publicly) available

This table does not contain group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop a regulatory strategy for them.

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

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is voluntary, i.e., it is not part of the processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the bromide ion and cations of known and/or low toxicity.

The group consists of well-defined inorganic substances. The substances hydrolyse and in contact with water or biological fluids will release the corresponding cations (sodium, potassium, calcium, ammonium, phosphorus) and the anion bromide.

There has been no significant substance identity findings or impact of impurities in the hazard profiles for any of the substances in the group.

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g., substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. Harmonised classification and self-classifications reported by registrants are presented in Annex 1.

One group member (ammonium bromide, EC: 235-183-8) has been under CLH and a RAC opinion is available on ECHA website resulting in classification for Repr. 1B and STOT RE 1 (nervous system), STOT SE 3, Eye Irrit. 2. Ammonium bromide was originally included in the BPR Review Programme but is not anymore supported under the BPR. Phosphorus tribromide has a harmonized classification as Skin Corr. 1B and STOT SE 3.

The Swedish competent authority has submitted intentions for harmonised classification for Potassium Bromide (EC: 231-830-3), Sodium Bromide (EC: 231-599-9), Calcium Bromide (EC: 232-164-6) for Repr. 1B, STOT RE 1 (nervous system) and STOT SE 3.

Sodium bromide is used in industrial settings in drilling fluids by the oil drilling industry, in photochemical industry, as a processing aid, pH regulating agent, laboratory reagent and as adsorbent.

Calcium bromide is used at industrial settings in oil drilling fluids applications as a processing aid and as adsorbent for mercury at industrial setting.

Phosphorus tribromide is used only as intermediate and as laboratory chemical. Potassium Bromide has industrial uses (formulation stage) as process regulator for the manufacture of heat stabilisers and is also used in polymer preparation. It is used in photographic products both by professionals and consumers. Ammonium bromide has uses at industrial settings in wood, paint and washing and cleaning products as flame retardant but also intermediate uses. In addition, it is used as flame retardant in wood, paints and textiles and in photography by professionals, and photography applications by consumers.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – restriction/authorisation and/or OEL- for Reproductive toxicity hazards due to the potential for release/ exposure of Potassium Bromide (EC: 231-830-3), Ammonium bromide (EC: 235-183-8), Sodium Bromide (EC: 231-599-9), Calcium Bromide (EC: 232-164-6)

Ammonium bromide has been under CLH there is a RAC Opinion for harmonised classification as Repr.1B and STOT RE 1 (nervous system). These hazards should apply to all group members as they are based on the toxicity of the bromide ion.

No human health hazards have been identified for carcinogenicity, mutagenicity, skin sensitisation or environmental hazards for any of the group members.

Regarding endocrine disruption, there are indications in the registration dossiers, the CLH dossier and in the public domain that bromide has the potential for displacing iodine in the thyroid and cause endocrine (thyroid) effects that might be relevant for humans. A relevant substance, that is not a member of this group, DBNPA (2,2-dibromo-2-cyanoacetamide), EC: 233-539-7, is an active substance under the BPR has been assessed under the BPR Review programme[3,4]. Thyroid effects observed with DBNPA are attributed to bromide ion that is released upon metabolism. The BPC has concluded that the substance is an endocrine disruptor for human health and the environment due to the bromide ion. Based on the

[3] https://echa.europa.eu/documents/10162/085a4896-b067-bdbc-e38c-8f794e60e4f3

[4] https://echa.europa.eu/documents/10162/c984aeda-ac67-8be2-57f3-43c797cf293d

information available within the BPC opinion and the background documents there is currently no need to generate further data to clarify the concern for endocrine disruption and there is sufficient information to support this conclusion.

However, a number of uncertainties regarding the setting of a threshold for these ED properties as well as the natural occurrence and essentiality of bromide have been highlighted within the BPC opinion for DBNPA which are also relevant for the current group members. At this stage no further action is proposed for the inorganic bromides members of this group in relation to their endocrine disruption potential. Further work might be needed to examine overall contribution of exposure to bromide from various sources/releases to cover other substances that are bromide salts and a potential need for risk management for the endocrine disruptive properties for human health and environment.

No environmental hazards apart from endocrine disruption potential has been identified for any of the group members.

The current regulatory strategy is based on the reproductive toxicity hazard identified: as a first step group members Potassium Bromide (EC: 231-830-3), Sodium Bromide (EC: 231-599-9), Calcium Bromide (EC: 232-164-6) should be classified for Reproductive toxicity (Repr. 1B) and STOT RE 1 (nervous system) (covered by current intention for CLH by SE).

It is noted that a generic CLH proposal for these hazards for bromide salts would be beneficial to cover in general all substances that are simple salts and release bromide ion in contact with water.

Consumer uses of potassium bromide and ammonium bromide in photography application would be restricted following CLH, via entries 28-30 of Annex XVII, therefore no specific action is proposed.

For the professional uses of potassium bromide and ammonium bromide a restriction should be proposed. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures. In addition, professional users may be self-employed and therefore not covered by the abovementioned OSH legislation for workers. Consumers may be co-exposed to the substances used. Therefore, a **specific restriction for the substances used by professionals** is suggested after the CLH. The choice of the restriction for professional uses over other regulatory management options (e.g. authorisation) is in line with the policy recently proposed by the European Commission[5] under the Chemical Strategy for Sustainability that expresses the need to extend *the level of protection granted under REACH to consumers also to* professional user.
The available information from the registration dossiers does not allow at this stage to make assumptions if the substances can be released from (treated) articles. During the restriction, it can be further explored if there is remaining risk from the articles (photography, treated articles with ammonium bromide) and if restriction should also be considered to cover imported articles.

For the industrial uses of sodium bromide, calcium bromide and potassium bromide the potential for actual exposure might be low due to the technical functions and/or

[5] European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, 14.10.20 Ref to paragraph 2.2.1, https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

existing control measures. However due to the hazard (Repr. 1B) identified an OEL can be considered following CLH to ensure adequate control measures.

For the industrial uses of ammonium bromide, due to specific industrial applications in treated articles, the exposure potential might be high for specific steps in the process. An OEL and/or authorisation need to be considered as subsequent risk management steps following CLH.

There are no EU OELs established for any of the substances in the group.

Based on currently available information, there is no need for (further) EU regulatory risk management for Phosphorus Tribromide (EC: 232-178-2) due to low exposure potential.

No action is proposed for phosphorus tribromide as it is used as intermediate and in laboratory chemicals resulting in low potential for exposure. Phosphorus tribromide hydrolyses and release phosphonic acid and hydrogen bromide, which in turn would release bromide ion which is the moiety of concern for systemic toxicity assessment. The current intention for CLH for the other group members does not cover a proposal for a generic entry to cover bromide salts. If in the future such a generic CLH is proposed this can cover substances like phosphorus tribromide.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
235-183-8 Ammonium bromide **231-830-3 Potassium bromide**	Known or potential hazard for reproductive toxicity, ED and STOT RE	No hazard or unlikely hazard for aquatic toxicity Known or potential hazard for ED	Both substances have professional and consumer uses in photographic products Ammonium bromide has industrial uses as flame retardant in wood, paint and washing and cleaning products	Need for EU RRM: Restriction Justification: Potential widespread use and exposure due to professional uses in photography Need for EU RRM: OEL/ Authorisation Justification: For ammonium bromide due to uses a flame retardant and treated articles there is potential for exposure	**First step:** CLH for potassium bromide **Next steps (if hazard confirmed):** Restriction (for professional/consumer uses) OEL and/or Authorisation (for Industrial uses)

			Potassium Bromide has industrial uses (formulation stage) as process regulator for the manufacture of heat stabilisers and is also used in polymer preparation	For potassium bromide exposure potential cannot be excluded but might be low to the technical function and uses	
231-599-9 Sodium Bromide **232-164-6 Calcium Bromide**	Known or potential hazard for reproductive toxicity, ED and STOT RE	No hazard or unlikely hazard for aquatic toxicity Known or potential hazard for ED	Drilling fluids by the oil drilling industry, photochemical industry, as a processing aid, pH regulating agent. Some exposure potential might occur.	Need for EU RRM: OEL Justification: To ensure adequate control measures for cases where exposure cannot be strictly controlled	**First step:** CLH **Next steps (if hazard confirmed):** OEL
232-178-2 Phosphorus Tribromide	Known or potential hazard for reproductive toxicity, ED and STOT RE	No hazard or unlikely hazard for aquatic toxicity Known or potential hazard for ED	Intermediate and Laboratory reagent	Currently no need for EU RRM Justification: Low exposure potential due to uses	**First step:** No action

Annex 1: Harmonised classifications and self-classifications reported by registrants

Data consulted on 27/10/2021

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
231-599-9	7647-15-6	Sodium bromide	-	-
231-830-3	7758-02-3	Potassium bromide	-	Eye Irrit. 2 H319
232-164-6	7789-41-5	Calcium bromide	-	Eye Damage 1 H318
232-178-2	7789-60-8	Phosphorus tribromide	Skin Corr. 1B H314 STOT SE 3 H335	Skin Corr. 1B H314 STOT Single Exp. 3 H335, affected organs: respiratory system STOT Single Exp. 3 H335, affected organs: respiratory tract [intermediate (active)]
235-183-8	12124-97-9	Ammonium bromide	RAC Opinion adopted in 08/10/ 2020: Repr. 1B H360FD Lact. H362 Eye Irrit. 2 H319 STOT SE 3 H336 STOT RE 1H372 (nervous system)	Repr. 2 H361 Eye Irrit. 2 H319 STOT Rep. Exp. 2 H373, affected organs: central nervous system STOT Single Exp. 3 H336, affected organs: central nervous system

Annex 2: Overview of uses based on information available in registration dossiers

Data consulted on 27/10/2021

Main types of applications structured by product or article types	EC/ List 231-599-9	EC/ List 231-830-3	EC/ List 232-164-6	EC/ List 232-178-2	EC/ List 235-183-8
Manufacture and preparation of fine and oilfield chemicals, Water treatment chemicals	F,I				
Intermediate, Laboratory chemicals,	F,I	F,I		I	F, I
Photographic products		F, I, **P, C, A**			I, **P, C, A**
Polymers		I, **A**			
Heat Stabiliser		F			
Oil drilling fluids			F,I, A		
Mercury adsorption			I		
Paints, textiles, wood, washing and cleaning products					**I, P, A**

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data consulted: 09/11/2021

EC/List number	RMOA	Authorisation		Restriction	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
235-183-8					RAC Opinion adopted in 08/10/ 2020	

The Swedish competent authority has submitted intentions for harmonised classification for Potassium Bromide (EC: 231-830-3), Sodium Bromide (EC: 231-599-9), Calcium Bromide (EC: 232-164-6) for Repr. 1B, STOT RE 1 (nervous system) and STOT SE 3.