

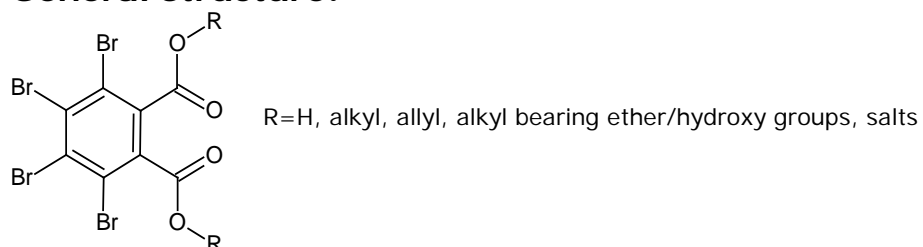
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 18.02.2022

Group Name: Brominated phthalates

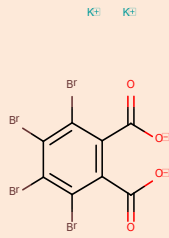
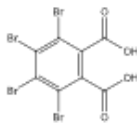
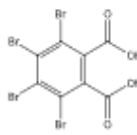
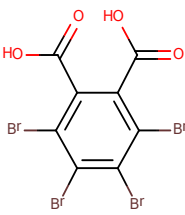
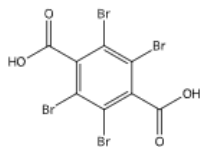
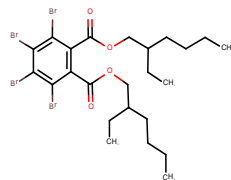
General structure:



Revision history

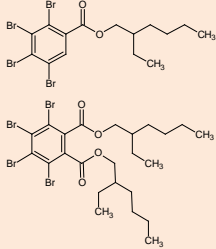
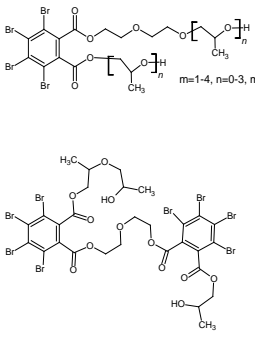
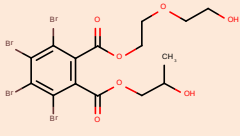
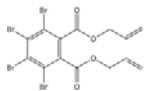
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Substances within this group:

EC/List number	CAS number	Substance name and Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
242-604-9	18824-74-3	dipotassium 3,4,5,6-tetrabromophthalate		Full, not (publicly) available
246-890-6	25357-79-3	disodium tetrabromophthalate	 <p>• 2 Na</p>	C&L notification
237-139-3	13654-74-5	aluminium tetrabromophthalate (3:2)	 <p>• 2/3 Al</p>	Not registered
634-371-0	13810-83-8	1,2-Benzenedicarboxylic acid, 3,4,5,6-tetrabromo-		Not registered
627-374-3	5411-70-1	tetrabromoterephthalic acid		C&L notification
247-426-5	26040-51-7	bis(2-ethylhexyl) tetrabromophthalate		Full, not (publicly) available

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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701-415-6	109230-28-6	No public or meaningful name is available		Not registered
701-414-0	56720-20-8	No public or meaningful name is available		Not registered
428-050-2	-	bis(2-ethylhexyl) 3,4,5,6-tetrabromophthalate ; reaction mass of: 2-ethylhexyl 2,3,4,5-tetrabromobenzoate		NONS
616-436-5	77098-07-8	Reaction products of 3,4,5,6-tetrabromobenzene-1,2-dicarboxylate with 2,2'-oxydiethanol and 2-epoxypropane	<p>UVCB, e.g.</p> 	Full, not (publicly) available
243-885-0	20566-35-2	2-(2-hydroxyethoxy)ethyl 2-hydroxypropyl 3,4,5,6-tetrabromophthalate		Not registered
256-433-2	49693-09-6	diallyl tetrabromophthalate		Not registered

This table contains also group members that are only notified under the CLP Regulation. However, the list is not necessarily exhaustive. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA, the Member States or other regulatory agencies may initiate at a later stage. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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 not part of the formal 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 website².

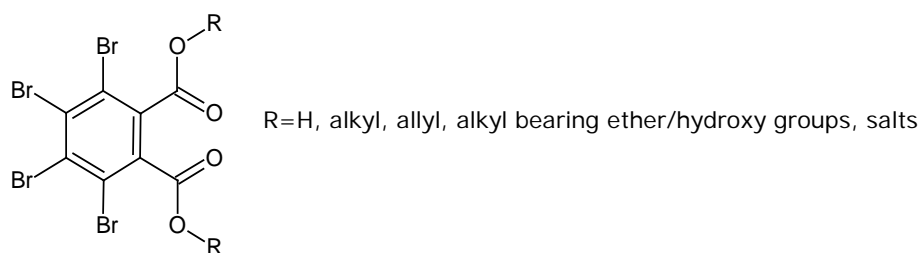
² <https://echa.europa.eu/understanding-assessment-regulatory-needs>

Glossary

ARN	Assessment of Regulatory Needs
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 tetrabromophthalate moiety shown in the figure below.



The group is composed of 12 brominated flame retardants, among which 3 are fully registered and 1 is a NONS. The group includes:

- tetrabromophthalic acid and its potassium, sodium and aluminium salts
- esters of tetrabromophthalic acid including linear and branched esters, allyl and esters bearing ether and hydroxy groups.

Tetrabromoterephthalic acid has also been included to the group although it has a structure where the carboxylate groups are bound to the aromatic ring in para- (1,4-) and not in ortho- (1,2-) position like is the case for the other 11 members of the group.

The regulatory needs for other brominated flame retardants are assessed in other groups such as "Brominated flame retardants related substances (small groups)".

Based on information reported in the REACH registration dossiers, the substances of this group are mainly used in industrial settings as flame retardants and in one case (EC 247-426-5) also as plasticiser in formulation of flame retardant mixtures, polyurethane foam production for insulation, production of adhesives, coatings and paints, polymer preparation and compounds. Professional use (spray foam, application of reactive sealants and adhesives for tile bonding) and article service life (rubber and other) are reported only for EC 247-426-5. The presence in the final articles of residual amounts of EC 242-604-9 used in textile dyes and impregnating product cannot be excluded. Overall, potential for exposure and release to the environment cannot be excluded during industrial and professional uses, and from the use of articles.

Bis(2-ethylhexyl) tetrabromophthalate (EC 247-426-5), following substance evaluation performed by the Swedish Chemicals Agency (KEMI, 2020)³, has been considered to fulfil the REACH Annex XIII criteria as being vPvB. An RMOA from the same authority concluded that it is appropriate to identify the substance as an SVHC.

³ [Substance evaluation conclusion](#)

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 hazard 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 (no) 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 for vPvB hazard due to the potential for release of EC 247-426-5, EC 428-050-2, EC 616-436-5 and EC 242-604-9.

Based on ECHA's assessment of currently available information, all the substances in the group are potential vPvB, in some cases to be clarified through data generation. The outcome of a substance evaluation confirmed that EC 247-426-5 fulfils the criteria for vPvB based on a weight of evidence approach including all available information (i.e. QSAR-predictions, laboratory studies, monitoring data)⁴. Since EC 428-050-2 contains EC 247-426-5 as a constituent largely above the regulatory limit of 0.1% w/w, it can also be considered to have vPvB properties. Based on this, should the hazard for EC 247-426-5 be confirmed via SVHC identification and inclusion in the candidate list, the manufacturer or importer of EC 428-050-2 will have the obligation to recommend downstream risk management measures which minimise exposures and emissions to humans and the environment, throughout the lifecycle of the substance that results from manufacture or identified uses.

EC 616-436-5 and EC 242-604-9 are suspected to have vPvB properties, pending confirmatory data generation. Should the hazard be confirmed, its confirmation via SVHC identification and inclusion in the candidate list will be pursued.

For the reasons above, the first step of the regulatory risk management action proposed is the confirmation of vPvB hazard via SVHC identification and inclusion

⁴ Sweden also concluded that EC 247-426-5 has a potential for long-range transport.

in the candidate list for EC 247-426-5. This will automatically trigger supply chain communication obligations for both EC 247-426-5 and EC 428-050-2.

SVHC identification as vPvB will trigger supply chain communication but will not be sufficient to limit possible releases of the substances in the environment. A group restriction is seen as the most appropriate option to address potential releases to the environment of the substances in the group for which vPvB hazard will be confirmed. The conclusion is mainly built upon the information on industrial, widespread professional uses and article service life reported for EC 247-426-5. In addition, the production of articles and possible presence in articles of residual amounts of EC 242-604-9 used in textile dyes and impregnating products and related exposure and release to the environment is also considered. The other registered substance (EC 616-436-5), which is reported by registrants as being used as flame retardant only in industrial setting in polymers is also considered having the same regulatory need to limit releases in the environment.

Professional use is typically widespread with relatively low levels of operational controls and risk management measures. Professional uses are mainly non-contained and non-automated. Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by industrial and professional workers is suggested after SVHC identification, with the aim to minimize as much as possible the releases to the environment. Moreover, restricting substances in articles used by professionals or consumers (reported for EC 274-426-9 and assumed for EC 242-604-9) is proposed as potential for exposure and release to the environment from articles cannot be excluded.

The use of PBT and vPvB substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability⁵.

The current proposal will be revisited, preferably based on further assessment when developing a restriction on mixtures and articles used by professionals and consumers which should also support clarifying what are those industrial uses in need for EU RRM action. Authorisation route can also be considered for industrial uses not in scope of the anticipated restriction.

Based on currently available information, there is no need for EU regulatory risk management for all the other, non-registered substances in the group.

The substances EC/List 701-415-6, 701-414-0 and 256-433-2 are structurally related to EC 247-426-5, so they are suspected to have vPvB properties as well, but there is currently not sufficient evidence to confirm. These substances are neither registered nor notified in the Classification and Labelling inventory, therefore there is no possibility to request further information. Similarly, the other five non-registered substances are either structurally related to EC 616-436-5 or to EC 242-604-9, so they are also suspected to have vPvB properties but for the time being there is no possibility to generate data to confirm the hazard.

For the reasons above, no action is currently foreseen for these substances.

Should the hazards for substances EC 616-436-5 and EC 242-604-9 be confirmed, it will be considered at that stage whether read across could be applied to the other

⁵ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

similar substances and whether any other regulatory follow-up actions will be needed.

Similarly, if the registration status of these substances changes, data generation and potentially follow up actions will be re-considered when the assessment will be revisited.

All the confirmed vPvB substances of the group will follow the same regulatory route, with restriction being the last foreseen action.

Additional considerations

There is very limited, inconclusive information related to potential reproductive toxicity and ED properties of the substances. The available data indicate some ED activity *in vitro* for EC 247-426-9, however as also concluded under substance evaluation, potential ED properties cannot be confirmed by the currently available *in vivo* data (KEMI, 2020)³. The available *in vivo* data indicate that EC 247-426-9 has a very low absorption, much lower than DEHP, very low to no toxicity in repeated dose studies and the developmental toxicity study. In addition, based on the available data, significant debromination *in vivo* is not expected. No reproductive toxicity study addressing fertility is available for any of the substances. Based on structural similarity and in the absence of adequate data, potential ED properties cannot be excluded also for other substances in the group, in particular the diesters. However, it is considered that clarification of potential ED properties would not significantly impact the RRM, if the substances will be confirmed as vPvB.

Two substances are (self)classified as Skin Sens. 1 (EC 428-050-2 and EC 242-604-9). In this respect, for industrial and professional uses, sufficient and consistent classification by registrants should limit the exposure and trigger adequate risk management measures according to workplace legislation. Based on structural similarity and lack of adequate data, potential (low potency) skin sensitisation cannot be excluded also for other substances in the group. However, it is considered that clarification of potential skin sensitisation properties would not significantly impact the RRM, if the substance will be confirmed as vPvB.

Restriction based on vPvB hazard will allow for sufficient controls and serve as driver for substitution. Therefore, it is considered that there is little benefit of additional concern clarification (ED and Skin Sens.) since in practice exposure to workers and consumers are likely to be addressed.

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.

As indicated in the Restrictions Roadmap⁶ ECHA will prepare an overall strategy on flame retardants by 2022, which will support the Commission when it decides to request ECHA to prepare (a) restriction dossier(s). The substances in scope are in principle all flame retardants, and there will be particular focus on brominated flame retardants and their prioritisation for restrictions.

The overall strategy on flame retardants may bring new perspectives and may result in a need to revise some of the conclusions in this ARN.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
247-426-5 428-050-2 (NONS)	Known or potential hazard for skin sensitisation for EC 428-050-2 and 242-604-9	Known or potential hazard for PBT/vPvB	Potential for exposure and release to the environment due to <ul style="list-style-type: none"> Industrial, widespread professional uses as flame retardant 	Need for EU RRM: Restriction <u>Justification:</u> Restriction with the aim to minimise	First step: SVHC identification only for EC 247-426-5 Next steps (if hazard confirmed): Restriction

⁶ <https://ec.europa.eu/docsroom/documents/49734>

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<p>616-436-5 242-604-9</p>			<p>and plasticiser in adhesives, coatings and paints, fillers, polymers, and article service life for EC 247-426-5</p> <ul style="list-style-type: none"> • Mainly industrial uses as flame retardant <ul style="list-style-type: none"> • in textile dyes and impregnating products, where article service life can be assumed for EC 242-604-9; • in polymers for EC 616-436-5. 	<p>releases to the environment.</p> <p>Releases to the environment from consumer and widespread professional uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Potential releases to the environment from articles cannot be excluded. Industrial uses to be considered as part of the restriction.</p> <p>Potential for regrettable substitution justifies the group restriction.</p>	<p>First step:</p> <ul style="list-style-type: none"> • Await results from ongoing CCH (EC 616-436-5) • CCH for EC 242-604-9 <p>Next steps (if hazard confirmed): SVHC identification Restriction</p>
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701-415-6*	No hazard or unlikely hazard	Known or potential hazard for PBT/vPvB	No information is available	<p>No need for EU RRM</p> <p><u>Justification:</u> Not registered, thus currently no data generation is possible to clarify the hazards. Actions (including data generation) will be re-considered when the assessment will be revisited, following clarification of the hazards for EC 616-436-5 and 242-604-9 and/or change in the registration status of the substances.</p>	No action
701-414-0*					
256-433-2*					
243-885-0*					
246-890-6*					
237-139-3*					
634-371-0*					
627-374-3*					

*Not registered

Annex 1: Harmonised and self-classifications

Data extracted on 17/11/2021

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
242-604-9	18824 -74-3	Dipotassium 3,4,5,6- tetrabromophthalat e	-	Skin Irrit. 2 H315 Eye Damage 1 H318 Skin Sens. 1 H317	
243-885-0	20566 -35-2	2-(2- hydroxyethoxy)eth yl 2-hydroxypropyl 3,4,5,6- tetrabromophthalat e	-	-	Aquatic Chronic 3 H412[3 out of 4]
247-426-5	26040 -51-7	Bis(2-ethylhexyl) tetrabromophthalat e	-		Eye Irrit. 2 H319[3 out of 4]
428-050-2	-	bis(2-ethylhexyl) 3,4,5,6- tetrabromophthalat e; reaction mass of: 2-ethylhexyl 2,3,4,5- tetrabromobenzoat e	607-588-00-3 NONS Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1		Skin Sens. 1 H317[1 out of 1] Aquatic Acute 1 H400[1 out of 1]
616-436-5	77098 -07-8	Reaction products of 3,4,5,6- tetrabromobenzene -1,2-dicarboxylate with 2,2'-oxy- diethanol and 2- epoxypropane	-		Aquatic Chronic 3 H412[1 out of 2]
634-371-0	13810 -83-8	1,2- Benzenedicarboxyli c acid, 3,4,5,6- tetrabromo-	-		Eye Irrit. 2 H319[2 out of 2] Skin Irrit. 2 H315[2 out of 2] STOT Single Exp. 3 H335, affected organs: [1 out of 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.

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

Data extracted on 5/11/2021

Main types of applications structured by product or article types	EC 242-604-9	EC 247-426-5	EC 616-436-5
PC 1: Adhesives, sealants		F, I, P	
PC 9a: Coatings and paints, thinners, paint removes		I	
PC 9b: Fillers, putties, plasters, modelling clay		P	
PC 19: Intermediate			I
PC 21: Laboratory chemicals		P	
PC 32: Polymer preparations and compounds		F, I, P, A	F, I
PC 34: Textile dyes, and impregnating products	I		

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 extracted on 17/09/2021

EC number	RMOA	Authorisation		Restriction		CLH	Actions not under REACH/CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)		
247-426-5	YES						

No relevant completed or ongoing regulatory risk management activities for any of the other substances.