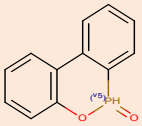
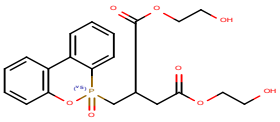
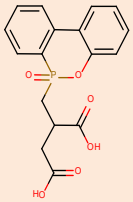
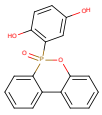
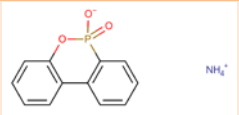
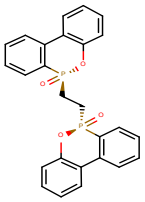
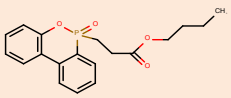
Assessment of regulatory needs

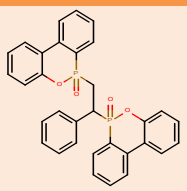
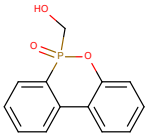
Authority: European Chemicals Agency (ECHA)

Group Name: Dibenzo oxaphosphorine oxide derivatives

Revision history

Version	*Date*	*Description*
1.0	15 December 2021	

EC / List number	CAS number	Substance name (substance name acronyms)	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
252-813-7	35948-25-5	6H-dibenz[c,e] [1,2]oxaphosphorin 6-oxide (DOPO)		Full, 100-1000 ton/y
264-313-6	63562-34-5	bis(2-hydroxyethyl) (6H-dibenz[c,e][1,2]oxaphosphorin-6-ylmethyl)succinate P-oxide		OSII or TII, not (publicly available)
426-480-5	63562-33-4	2-(10-oxo-10H-9-oxa-10-phosphaphenanthren-10-ylmethyl)succinic acid		Full, 1-10 ton/y
619-409-6	99208-50-1	1,4-Benzenediol, 2-(6-oxido-6H-dibenz[c,e][1,2]oxaphosphorin-6-yl)-		Full, not (publicly) available
700-893-3	-	ammonium 6H-dibenzo[c,e] [1,2]oxaphosphinin-6-olate 6-oxide		Full, not (publicly) available
-	-	6-oxo- 6H–Dibenz[c, e] [1, 2] oxaphosphorin 6-alkyl derivative		Full, not (publicly) available
805-659-5	848820-98-4	6H-Dibenz[c,e][1,2]oxaphosphorin-6-propanoic acid, butyl ester, 6-oxide		Full, not (publicly) available
815-096-7	1421927-53-8	EDA-DOPO	-	Full, not (publicly) available

EC / List number	CAS number	Substance name (substance name acronyms)	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)
823-458-0	-	6,6'-(1-phenylethane-1,2-diyl)bis(6H-dibenzo[c,e][1,2]oxaphosphinine) 6,6'-dioxide		Full, not (publicly) available
827-182-1	35948-26-6	6H-Dibenz(c,e)(1,2)oxaphosphorin-6-methanol 6-oxide		OSII or TII, not (publicly available)
947-340-4	-	Reaction product of 6H-dibenz[c,e][1,2]oxaphosphorin 6-oxide, itaconic acid and ethylene glycol	UVCB	Full, not (publicly) available

This table does not contain group members that are only notified under the CLP Regulation. 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.

Contents

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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 a 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, a 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[1].

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

Glossary

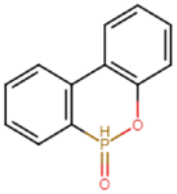
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate 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
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials

1 Overview of the group

The group Dibenzo oxaphosphorine oxide derivatives is one of several groups having flame retardant use in common.

ECHA has grouped together structurally similar substances based on the presence of the 6H-dibenz[c,e][1,2]oxaphosphorin 6-oxide (DOPO) moiety shown in the figure below. All the substances in the group contain one or two “DOPO” units in their structural formula.

The group is composed of eleven substances, ten well-defined and one UVCB (substance of unknown or variable composition, complex reaction products or biological materials).



There are 18 registrations of which two are on-site isolated intermediate or transported isolated intermediate (OSII or TII) registrations. Based on information reported in the REACH registration dossiers, all substances of the group are used as flame retardants, as intermediates/precursors for flame retardants, or as intermediates. For four substances registrants mentioned use in articles, one of those substances is also indicated to be used in textile dyes, and impregnating products. The substances in articles are indicated to be used widely but with expected low release.

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 no need for regulatory risk management action at EU level

Based on currently available information, there is no need for further EU regulatory risk management for any of the substances in the group.

Based on ECHA's assessment of currently available hazard information, no carcinogenicity, mutagenicity, reproductive toxicity or endocrine disrupting (ED) hazards were identified for all substances in the group. These conclusions are based on data available in the registration dossiers for EC 252-813-7, List. No. 947-340-4 and substance X (two repeated dose toxicity studies and one screening study) which did not indicate a reproductive hazard or findings on reproductive organs. Also, the available data does not indicate a potential for ED (absence of effects in ED related organs). Available mutagenicity (*in vitro* genotoxicity) studies do not indicate genotoxicity.

Based on considerations of structural similarity and presence of common functional moiety the same conclusions have been extrapolated to other group members. However, uncertainty remains due to the presence of additional functional groups and the absence of systemic toxicity data in particular on those substances registered at low tonnage or as intermediates.

Two substances in the group have a harmonised/self-classification as skin sensitisers (EC 252-813-7, EC 426-480-5). Those substances have only industrial uses and therefore the existing harmonised/self-classification by registrants is considered as sufficient and should require adequate risk management measures to be in place according to workplace legislation. For the other susbtances the skin sensitisation hazard is inconclusive.

Based on ECHA's assessment of currently available hazard information, the substances in this group are unlikely to fulfil the PBT/vPvB screening criteria. Although the substances of this group may be partially degraded (e.g. by hydrolysis), none of them is rapidly mineralised. Therefore, those substances or some of their potential hydrolysis products are potentially persistent. Furthermore, there is no indication that the substances could be bioaccumulative.

There is currently no indication of high aquatic toxicity for any of the substances in this group. However, it is worth noting that there is only one long-term aquatic toxicity data (on Daphnia) available for the whole group (substance X).

Classification criteria for aquatic toxicity are met for List No. 805-659-5 (as Aquatic Chronic 3) and for List Nos. 947-340-4, 815-096-7 (as Aquatic Chronic 4), and substance X, however, there is no self-classification reported in the registration dossiers. Industry should update the registration dossiers with adequate classification and labelling information of the substances with aquatic toxicity, and inform accordingly the users of these substances (via safety data sheet update).

Compliance check (CCH) is proposed for EC 252-813-7, List Nos. 619-409-6, 823-458-0, 947-340-4, 815-096-7, and substance X for clarifying hazards.

All substances of the group are used as flame retardants. Information retrieved from the registration dossiers of that group are listing uses such as

- Formulation of resins
- Manufacture of expandable polymer-granulates

- Thermoplastic production used in automotive, construction, electronic and electrical component and electronic enclosures
- Manufacture of polymer foam-articles
- Impregnation of reinforced substrate (eg woven glass fiber) by the formulated resin.

Four substances (EC/List numbers 619-409-6, 700-893-3, 815-096-7, 947-340-4) were mentioned to be used in articles, one of those substances (List. No. 947-340-4) is also indicated to be used in textile dyes, and impregnating products. The substances in articles are indicated to be used widespread with low release.

Thus, a potential for exposure/release is expected mainly from the manufacturing/formulation of the polymers and from the unreacted substances or the break-down products from polymer degradation in the polymeric articles.

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 Roadmap[2] 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.

EC/ List number	Human Health Hazard	Environmental Hazard	Relevant use (s) & exposure potential	Last foreseen action	Action
252-813-7	Known or potential hazard for for skin sensitisation	No hazard or unlikely hazard	Use as flame retardant in polymerisation processes at industrial sites. Potential for exposure for workers, potential for release and exposure for consumers from articles.	**Currently no need for EU RRM** <u>Justification</u> Overall, no or unlikely hazard that would lead to concern for the reported uses. Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to	CCH
Substance X 815-096-7 947-340-4	No hazard or unlikely hazard	Known or likely hazard for aquatic toxicity	Formulation and use as flame retardant in polymerisation processes at industrial sites, and/or by professionals (List No. 947-340-4, substance X) and/or inclusion in articles (List Nos. 815-096-7,		

[2] https://ec.europa.eu/docsroom/documents/49734

EC/ List number	Human Health Hazard	Environmental Hazard	Relevant use (s) & exposure potential	Last foreseen action	Action
			947-340-4). Potential for exposure for workers, potential for release and exposure for consumers from articles.	ensure safe use at the workplace.	
619-409-6 823-458-0	Inconclusive hazard	Inconclusive hazard	Use as flame retardant in polymerisation processes at industrial sites (List Nos. 619-409-6, 823-458-0), and inclusion in articles (List No. 619-409-6) Potential for exposure for workers, potential for release and exposure for consumers from articles.		
426-480-5	Known or potential hazard for skin sensitisation	Known or likely hazard for aquatic toxicity	Use as flame retardant in polymerisation processes at industrial sites and as intermediate. Potential for exposure for workers, potential for release and exposure for consumers from articles.		No action
700-893-3 805-659-5	No hazard or unlikely hazard	No hazard or unlikely hazard	Manufacture only (List No. 805-659-5); Use as flame retardant in polymerisation processes at industrial sites and inclusion in articles (List no. 700-893-3).		

EC/ List number	Human Health Hazard	Environmental Hazard	Relevant use (s) & exposure potential	Last foreseen action	Action
			Potential for exposure for workers, potential for release and exposure for consumers from articles.		
264-313-6 827-182-1	Inconclusive hazard	No hazard or unlikely hazard	Intermediates (EC 264-313-6, List No. 827-182-1); Use as flame retardant in polymerisation processes at industrial sites (EC 264-313-6). Potential for exposure for workers, potential for release and exposure for consumers from articles.		

Annex 1: Overview of classifications

Data extracted on 18 May 2021.

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
252-813-7	**35948-25-5**	6H-dibenz[c,e] [1,2]oxaphosphorin 6-oxide (DOPO)		Skin Sens. 1B H317	Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Irrit. 2 H319
426-480-5	**63562-33-4**	2-(10-oxo-10H-9-oxa-10-phosphaphenanthren-10-ylmethyl)succinic acid	Skin Sens 1 H317 Aquatic Chronic 3 H412	Aquatic Chronic 3 H412 Skin Sens. 1 H317	
805-659-5	848820-98-4	6H-Dibenz[c,e][1,2]oxaphosphorin-6-propanoic acid, butyl ester, 6-oxide		*Acute Tox. 4 H302 Skin Irrit. 2 H315*	
827-182-1	35948-26-6	6H-Dibenz(c,e)(1,2)oxaphosphorin-6-methanol 6-oxide			*Eye Irrit. 2 H319* *Skin Irrit. 2 H315*

(*) 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 18 May 2021.

Main types of applications structured by product or article types	EC 252-813-7	EC 264-313-6	EC 426-480-5	EC 619-409-6	EC 700-893-3	Substance x	EC 805-659-5[1)]	EC 815-096-7	EC 823-458-0[2)]	EC 827-182-1	EC 947-340-4
PC 1: Adhesives, sealants						I					
PC 19: Intermed.	I	I	I							I	F, I, P
PC 21: Lab. Chem.	I										F, I, P
PC 32: Polymer preparations and compounds	I	I	I	I, C, A	F, I, A	F, I, P		F, I, A			F, I, P ,A
PC 34: Textile dyes, and impregnating products											F, I, P
PC 35: Washing and cleaning 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.
1) only manufacture of the substance (1-10 ton/y)
2) ERC4: Use of non-reactive processing aid at industrial site (no inclusion into or onto article)

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

Data extracted on 22 June 2021.

There are no relevant completed or ongoing regulatory risk management activities for any of the substances.