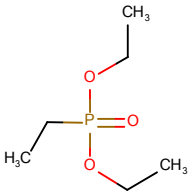
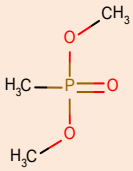
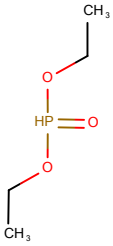
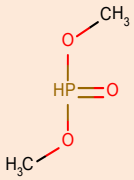
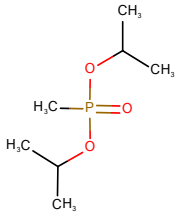
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

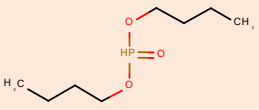
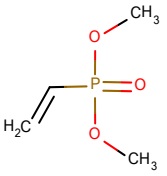
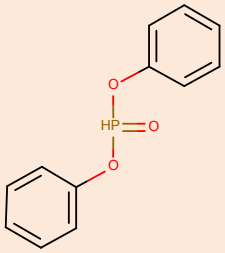
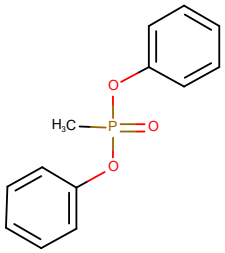
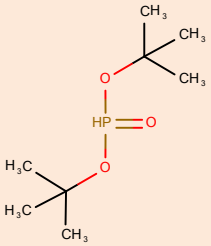
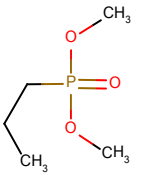
Group Name: Organic phosphonic acids, salts and esters

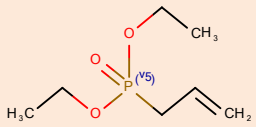
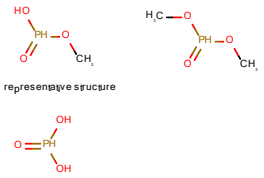
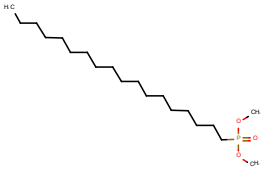
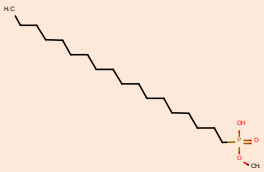
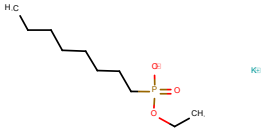
Revision history

Version	*Date*	*Description*
1.0	17 February 2022	

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]
Sub-group 1: Alkyl(<C8)diesters of hydrogenphosphonates and alkyl(<C8)phosphonates				
201-111-9	78-38-6	diethyl ethylphosphonate		Full, not (publicly) available
212-052-3	756-79-6	dimethyl methylphosphonate		TII or OSII, not (publicly) available
212-091-6	762-04-9	diethyl phosphonate		TII or OSII, not (publicly) available
212-783-8	868-85-9	dimethyl phosphonate		Full, not (publicly) available
215-896-0	1445-75-6	bis(1-methylethyl) methylphosphonate		C&L notified

[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

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]
217-316-1	1809-19-4	dibutyl phosphonate		Full, 100-1000
225-076-4	4645-32-3	dimethyl vinylphosphonate		TII or OSII, not (publicly) available
225-202-8	4712-55-4	diphenyl phosphonate		Full, 10-100,
231-388-1	7526-26-3	diphenyl methylphosphonate		Full, not (publicly) available
235-996-8	13086-84-5	bis(1,1-dimethylethyl) phosphonate		C&L notified
242-555-3	18755-43-6	dimethyl propylphosphonate		Full, not (publicly) available

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]
619-646-5	1067-87-4	Phosphonic acid, P-2-propen-1-yl-, diethyl ester		Full, not (publicly) available
909-044-3		Reaction mass of dimethyl phosphonate and methyl hydrogenphosphonate and phosphonic acid		TII or OSII, not (publicly) available
Sub-group 2: Alkyl esters of alkyl(≥C8)phosphonates				
246-904-0	25371-54-4	dimethyl octadecylphosphonate		Full, not (publicly) available
246-905-6	25371-55-5	methyl hydrogen octadecylphosphonate		Full, not (publicly) available
268-740-9	68134-28-1	potassium ethyl octylphosphonate		C&L notified

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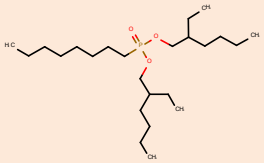
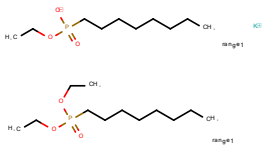
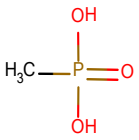
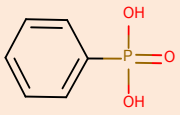
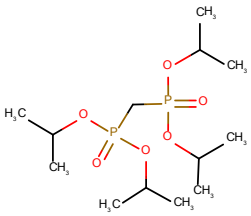
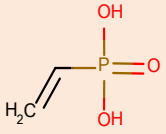
417-170-0	52894-02-7	bis(2-ethylhexyl)octylphosphonate		Full, not (publicly) available
939-595-5		Reaction mass of diethyl octylphosphonate and potassium ethyl octylphosphonate		Full, not (publicly) available
Sub-group 3: other phosphonates				
213-607-2	993-13-5	methylphosphonic acid		Full, not (publicly) available
216-388-1	1571-33-1	phenylphosphonic acid		Full, 1-10
216-765-0	1660-95-3	tetraisopropyl methylenebisphosphonate		TII or OSII, not (publicly) available
217-123-2	1746-03-8	vinylphosphonic acid		Full, not (publicly) available

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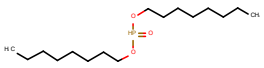
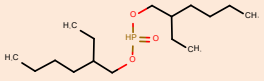
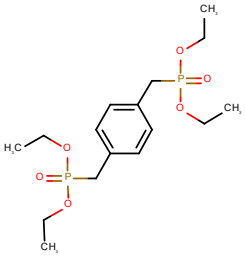
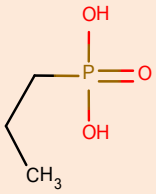
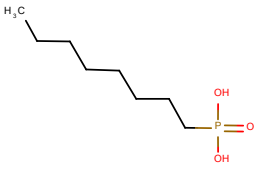
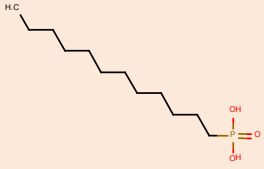
217-315-6	1809-14-9	dioctyl phosphonate		Full, not (publicly) available
222-904-6	3658-48-8	bis(2-ethylhexyl) phosphonate		Full, not (publicly) available
224-902-0	4546-04-7	tetraethyl [1,4-phenylenebis(methylene)]bisphosphonate		TII or OSII, not (publicly) available
225-121-8	4672-38-2	propylphosphonic acid		TII or OSII, not (publicly) available
225-218-5	4724-48-5	octylphosphonic acid		Full, 100-1000,
225-897-8	5137-70-2	dodecylphosphonic acid		Full, not (publicly) available

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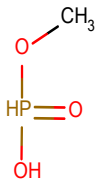
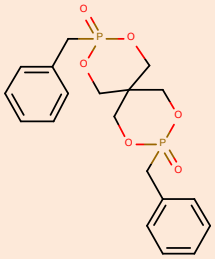
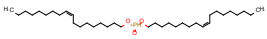
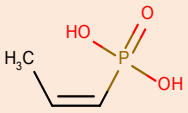
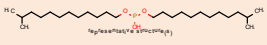
237-027-4	13590-71-1	methyl hydrogenphosphonate		C&L notified
243-869-3	20544-37-0	3,9-dibenzyl-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane 3,9-dioxide		Full, not (publicly) available
246-608-1	25088-57-7	(Z,Z)-di-9-octadecenyl phosphonate		Full, not (publicly) available
246-928-1	25383-06-6	cis-propenylphosphonic acid		TII or OSII, not (publicly) available
254-320-2	39148-24-8	aluminium triethyl triphosphonate	No Structure	C&L notified
275-063-2	70955-74-7	diisotridecyl phosphonate		Full, not (publicly) available

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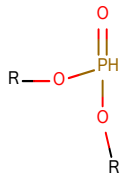
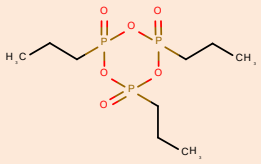
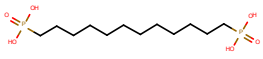
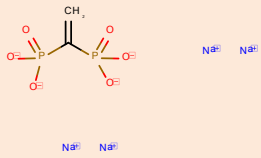
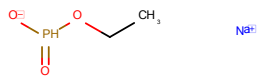
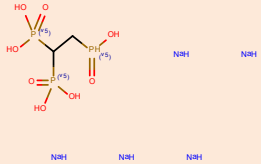
300-326-6	93925-25-8	Phosphonic acid, mixed C12-20-alkyl and C14-18-unsatd. alkyl derivs.		Full, not (publicly) available
422-210-5	68957-94-8	2,4,6-tri-n-propyl-2,4,6-trioxo-1,3,5,2,4,6-trioxatriphosphorinane		Full, not (publicly) available
435-710-3	7450-59-1	Phosphonic acid, P,P'-1,12-dodecanediylbis-		Full, not (publicly) available
443-520-7		[TETRASODIUM ETHYLENE 1,1-DIPHOSPHONATE]		Full, not (publicly) available
444-960-2	39148-16-8	[Phosphonic acid, monoethyl ester, sodium salt]		Full, not (publicly) available
618-709-4	912335-51-4	[Phosphonic acid, [2-(hydroxyphosphinyl) ethylidene] bis-, pentasodium salt]		TII or OSII, not (publicly) available

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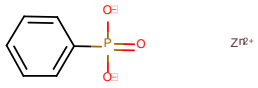
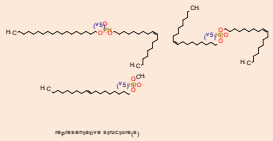
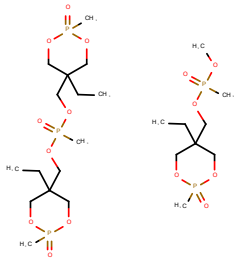
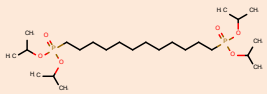
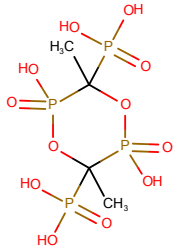
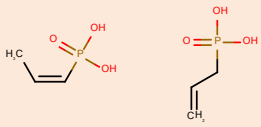
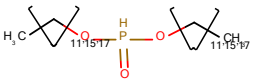
696-577-7	34335-10-9	Phosphonic acid, P-phenyl-, zinc salt (1:1)		Full, not (publicly) available
701-298-1		Dialkyl C18 and C18-unsaturated phosphonates		Full, 10-100,
915-680-2		Reaction mass of phosphonic acid, methyl-, bis[(5-ethyl-2-methyl-2,2-dioxido-1,3,2-dioxaphosphorinan-5-yl)methyl] ester with (5-ethyl-2-methyl-2-oxido-1,3,2-dioxaphosphorinan-5-yl)methyl methyl methylphosphonate		Full, 100-1000,
919-645-2	1161072-80-5	Phosphine oxide, 1,1'-(1,12-dodecanediyl)bis[1,1-bis(1-methylethyl)-		TII or OSII , not (publicly) available
921-798-5		2,5-dihydroxy-3,6-dimethyl-3,6-bis(dihydroxyphosphinyl)-1,4,2,5-dioxadiphosphorane-2,5-dioxide		TII or OSII , not (publicly) available

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]
944-204-6		Reaction mass of (1Z)-prop-1-en-1-ylphosphonic acid and prop-2-en-1-ylphosphonic acid		TII or OSII, not (publicly) available
944-574-9		Reaction Products of Dimethyl hydrogen phosphite and Alcohols C14-18, Even, Linear		Full, not (publicly) available

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.

Contents

DISCLAIMER

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[2].

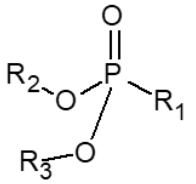
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

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 hydrogenphosphonates and alkylphosphonates, their salts and esters based on the presence of the phosphonate moiety shown in the picture below.



R1: H, alkyl (<C8)
R2, R3: alkyl (<C8), phenyl

The 47 substances have been divided in three sub-groups based on structural features, hazard profile and foreseen final regulatory action:

- Subgroup 1: Alkyl (<C8) diesters of hydrogenphosphonates and alkyl (<C8) phosphonates. The 13 substances in this subgroup contain only one phosphonate moiety and they are alkyl diesters of hydrogenphosphonates and alkylphosphonates in which the carbon numbers of all alkyl chains are lower than C8.

- Subgroup 2: Alkyl esters of alkyl (≥C8) phosphonates. The 5 substances in this subgroup contain only one phosphonate moiety and they are alkyl esters of alkylphosphonates in which the carbon number of the alkyl chain attached to the phosphorus is equal or higher than C8.

- Subgroup 3: Other phosphonates. This subgroup contains hydrogenphosphonates and alkyl phosphonates, their salts and esters other than the ones specified in subgroups 1 and 2. Substances with more than one phosphonate moiety are also included in this subgroup.

Overall, 43 out of 47 substances in this group have active registrations and 28 have at least one full registration under REACH.

Based on information reported in the REACH registration dossiers, subgroup 1 substances are mainly used as intermediates in the manufacture of other substances and/or incorporated covalently in polymeric matrices that are later used in the production of articles. Thus, potential for exposure/release is mainly coming from the manufacturing of the polymers and from the assumed presence of unreacted substances in articles. Professional and consumer uses in lubricants and greases is however also reported for one substance. Article service life is reported besides in polymer preparations also in textile dyes and impregnating products.

All substances of the subgroup 1 may be used as flame retardants. Although explicit evidence of use of these substances as flame retardants is only available for a few substances (EC 225-202-8, EC 231-388-1 and EC 242-555-3), there is evidence in

literature that the rest of the substances in this subgroup are/may be used with that function.[3]

Subgroup 2 substances are mainly used in lubricants and functional fluids with high potential for exposure to professional workers and consumers and high potential for release to the environment. Use as flame retardants is not reported for these substances.

The main use of subgroup 3 substances depends on the size of the alkyl chains present in the substances. Substances with alkyl chains ≥C8 are mainly used as lubricants and functional fluids. Substances with alkyl chains <C8 are mainly used as flame retardants, stabilising agents, intermediates and/or are incorporated covalently in polymeric matrices.

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 EU regulatory risk management –Restriction for potential mutagenicity, reproductive toxicity, STOT RE (including neurotoxicity), P/vP and mobility properties due to the potential for release/ exposure of all subgroup 1 members.

[3] Weil, E.D. and Levchik, S.V. (2017). Phosphorus Flame Retardants. In Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, Inc (Ed.).
Calamari, T.A., Jr., Harper, R.J., Jr. and by Staff, U. (2014). Flame Retardants for Textiles. In Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, Inc (Ed.).
Svara, J., Weferling, N. and Hofmann, T. (2006). Phosphorus Compounds, Organic. In Ullmann's Encyclopedia of Industrial Chemistry, (Ed.).

Based on the data available in the registration dossiers, reproductive toxicity, mutagenicity and neurotoxicity hazards can be expected for all the substances in the subgroup 1.

In general, substances in this subgroup are unlikely to meet the PBT criteria as most substances do not screen for bioaccumulation (log Kow 0.15-3.2). However, all of the substances in the group are potentially (very) persistent and (very) mobile. Compliance check (CCH) can clarify some of these properties however substance evaluation (SEv) could be considered after CCH if needed for potential future regulatory action. Data generation via CCH is suggested to clarify the hazards for EC 217-316-1 (already on-going), EC 225-202-8, EC 231-388-1 and EC 242-555-3 (for aquatic toxicity).

The substances are mainly used as intermediates in the manufacture of other substances and/or incorporated covalently in polymeric matrices that are later used in the production of articles. Thus, a potential for exposure/release is expected mainly from the manufacturing of the polymers and from the unreacted substances or the break-down products from polymer degradation in the polymeric articles.

Although explicit evidence of use of these substances as flame retardants is only available for a few substances (EC 225-202-8, EC 231-388-1 and EC 242-555-3) there is evidence in literature that the other subgroup 1 members can also be used with that function.[3]

Several substances are currently registered as isolated intermediates used under strictly controlled conditions, but it is unclear whether they are solely used in the production of other substances or they are incorporated covalently in polymeric matrices in which case, the conditions in Art. 17/18 of the REACH Regulation might not be fulfilled.

The substance EC 217-316-1 has professional and consumer uses reported in lubricants and greases. Article service life is reported besides in polymer preparations for EC 225-202-8, EC 201-111-9 and EC 212-052-3 also in textile dyes and impregnating products for EC 201-111-9.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazards via harmonised classification (CLH) as Muta 1B, Repro 1B and STOT RE. A proposal for harmonised classification (CLH, Ireland) is already on-going for EC 242-555-3 as Muta 1B and Repro 1B.

CLH i) will require company level risk management measures (RMM) for workers, to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of the restriction entry 29 and 30.

If persistency and mobility properties exist after generation of data, these properties will need to be considered as well and may be confirmed via SVHC identification and inclusion in the Candidate list.

Restriction is considered as the most appropriate regulatory risk management option to address the hazards of these substances and the potential for exposure to professional workers as well as consumers via articles. Professional use is often widespread with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation. Even though professional uses are reported for EC 217-316-1 only, this substance is manufactured in and / or imported to the European Economic Area, at ≥ 1 000 to < 10 000 tonnes per year. As other

substances in subgroup 1 may be alternatives to this substance a restriction is suggested for the entire subgroup 1.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by professionals** is suggested after CLH.

Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[4] which aims to extend to professional users under REACH the level of protection granted to consumers.

Moreover, potential exposure from articles needs further investigation. The need for restricting substances in articles used by professionals or consumers (article service life reported for substances EC 201-111-9, EC 225-202-8 and EC 212-052-3) should be considered in the context of the restriction of professional uses.

During a group restriction preparation it is suggested to investigate whether and which industrial uses may need to be restricted or whether authorisation might be appropriate to address possible risks from industrial uses. In this respect it is noted that the main use as intermediate (monomer) is exempt from authorisation and that on-site isolated intermediates are not be subject to restriction under REACH.

Based on currently available information, there is a need for (further) EU regulatory risk management –Restriction for potential PBT/vPvB hazards and potential for release/ exposure of all subgroup 2 members.

Based on ECHA's assessment of currently available hazard information, all subgroup 2 members fulfil the PBT/vPvB screening criteria[5]. These substances are potentially persistent or very persistent as they are not readily biodegradable. Furthermore, they are also potentially bioaccumulative or very bioaccumulative as they have high Log Kows (Log Kow 7.7-9.48). List. No. 939-595-5 has a low Log Kow (2.23) but is a surface active substance. CCH is proposed for EC 246-904-0, EC 417-170-0 and List. No. 939-595-5 to clarify the potential PBT properties. The need for SEv for substance EC 246-905-6 should be re-visited once the data on PBT properties has been generated for the other substances.

The substances in subgroup 2 are mainly used as lubricating agents in lubricants, greases and functional fluids. These uses are widespread with professional workers and consumers exposed to mixtures containing these substances and high potential release into the environment. In the case of functional fluids it is likely that exposure will be limited by closed systems in which case it should be reflected on possible derogations from the restriction for such uses. The substances are not reported to be used as flame retardants.

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

[5] As defined in REACH Annex XIII and R11 Guidance on PBT assessment (https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/a8cce23f-a65a-46d2-ac68-92fee1f9e54f

Considering the potential identified hazards (*i.e*. PBT properties) and the reported uses, restriction seems to be the most appropriate regulatory risk management tool to address the concern.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via SVHC identification and inclusion on the Candidate List as PBT/vPvB.

SVHC identification is highly recommended for further regulatory processes under REACH (Restriction). In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

Confirmation of the hazard properties via SVHC identification is not considered sufficient to minimise potential releases of the substances in the environment. A restriction is seen as the most appropriate option as potential for exposure is expected from the consumer and professional uses of the substances as lubricating agents.

Releases to the environment from consumer uses cannot be avoided. Widespread professional uses are typically non-contained and non-automated leading to releases to the environment.

Therefore, a restriction of the substances as such or in mixtures (concentration limit in mixtures) used by consumers and professional workers is suggested after SVHC identification, with the aim to minimise exposures and emissions to humans and the environment. It is also suggested to consider industrial uses as part of the restriction work to identify the most appropriate way to ensure also minimisation of releases from the industrial uses.

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 consumer/professional uses as potential exposure from articles needs further investigation first.

Based on the information available in the registration dossiers, clinical signs that may be attributed to neurotoxicity were identified in an OECD 422 test for List. No. 939-595-5. These effects will be further investigated under CCH to clarify whether the findings relate to general toxicity of the substances or have a neurotoxicological origin. There are no other health hazard concerns for the substances in subgroup 2.

Based on currently available information, there is no need for (further) EU regulatory risk management for any of the substances in subgroup 3.

Based on ECHA's assessment of currently available hazard information, no potential human health hazards were identified besides skin sensitisation. EC 443-520-7 is self-classified as Skin Sens. 1A, EC 275-063-2 and List No. 944-574-9 are self-classified as Skin Sens. 1B.

For substances self-classified and/or with potential skin sentising properties there is no need for EU RRM as for industrial and professional uses, sufficient and consistent self-classification by registrants should trigger adequate risk management measures according to workplace legislation. Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing substances List no. 944-

574-9 and EC 275-063-2. However, there is a concern related to skin sensitisers and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern. Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

Based on information available in the registration dossiers, the substances in this subgroup are unlikely to fulfil the PBT/vPvB screening criteria, because they are either readily biodegradable, simulation studies indicate that the substances are not persistent, and/or they do not screen as potentially bioaccumulative (Log Kow <1 to 2.2). CCH is however proposed for EC 246-608-1, EC 275-063-2, EC 300-326-6, List. Nos. 701-298-1 and 944-574-9 to confirm no PBT properties.

Some substances have potential P/vP combined with mobility and some have also been identified as likely aquatic toxicants.

Data generation is proposed for the substances EC 213-607-2, EC 225-218-5 and List. No. 915-680-2 to confirm no aquatic toxicity properties, for EC 217-315-6 to confirm aquatic toxicity and for EC 225-218-5, EC 422-210-5, and List.No. 915-680-2 to request phys-chem data for the assessment of potential mobility in the environment.

The remaining substances are intermediates and further data cannot be obtained at this time.

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[6] 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/ List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1 Alkyl(<C8)diesters of hydrogenphosphonates and alkyl(<C8)phosphonates 201-111-9 212-052-3 212-091-6 212-783-8 215-896-0	Known or potential hazard for mutagenicity, reproductive toxicity, STOT RE	Known or potential hazard for P/vP and aquatic toxicity	Mainly incorporated covalently in polymeric materials as flame retardants that are later used in the production of articles. Potential for exposure for workers and release during manufacturing of the polymers and for consumers from the unreacted substances in the polymeric	**Need for EU RRM: Restriction** <u>Justification:</u> The harmonised classification as MR 1 will require company level risk management measures for workers to be in place and would trigger the restriction entry 29, 30 and by that ensure that the	**First step:** CCH for 217-316-1 225-202-8, 231-388-1 242-555-3 **Next steps (if hazard confirmed):** CLH Restriction

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

Subgroup name, EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
217-316-1 225-076-4 225-202-8 231-388-1 235-996-8 242-555-3 619-646-5 909-044-3			preparations during article service life. 217-316-1 is used in lubricants and greases. Potential for exposure for workers and consumers and release to the environment.	substances are not included in consumer mixtures above the limits specified in that entry. The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.	

Subgroup name, EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				Specific restriction for use in articles is proposed as potential exposure from articles is likely.	
Subgroup 2 Alkyl esters of alkyl(≥C8)phosphonates 246-904-0 246-905-6 268-740-9 417-170-0 939-595-5	Inconclusive hazard for STOT RE for 939-595-5 No hazard or unlikely hazard for the other substances in the group.	Known or potential hazard for PBT/vPvB	Mainly used in lubricants and greases and in functional fluids. Potential for exposure for workers and consumers and release to the environment.	**Need for EU RRM: Restriction** <u>Justification:</u> 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. Restriction of professional uses is preferred over authorisation as it is considered to be	**First step:** CCH for 246-904-0, 417-170-0, 939-595-5 potentially followed by SEv for 246-905 -6 **Next steps (if hazard confirmed):** SVHC identification Restriction

Subgroup name, EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
				more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses.	
Subgroup 3, other phosphonates 213-607-2 216-388-1 216-765-0 217-123-2 217-315-6 222-904-6 224-902-0 225-121-8 225-218-5 225-897-8 237-027-4 243-869-3 246-608-1 246-928-1 254-320-2 275-063-2 300-326-6 422-210-5 435-710-3 443-520-7 444-960-2	Known or potential hazard for skin sensitisation for 275-063-2, 443-520-7 and 944-574-9 No hazard or unlikely hazard for the other substances in the group.	Known or potential hazard for P/vP for 213-607-2, 216-388-1, 216-765-0, 217-123-2, 224-902-0, 243-869-3, 435-710-3, 443-520-7 Known or potential hazard for aquatic toxicity for 216-388-1, 216-765-0, 217-123-2 217-315-6 222-904-6 696-577-7	Substances with alkyl chains are ≥C8 are mainly used in lubricants and functional fluids. Potential for exposure for workers and consumers and release to the environment. Substances with alkyl chains are <C8 are mainly used as intermediates and/or incorporated covalently in polymeric matrices. Potential for exposure/release is mainly coming from the manufacturing of the polymers and	**Currently no need for EU RRM** <u>Justification:</u> Harmonised/self-classification followed by implementation of necessary RRMs should be sufficient to ensure safe use at the workplace. The concern related to the presence of skin sensitisers in consumer mixtures is under investigation.	CCH for 246-608-1, 275-063-2, 300-326-6, 701-298-1, 944-574-9, 213-607-2, 225-218-5, 915-680-2, 217-315-6, 225-218-5 422-210-5, 915-680-2

Subgroup name, EC / List number	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
618-709-4 696-577-7 701-298-1 915-680-2 919-645-2 921-798-5 944-204-6, 944-574-9			from the unreacted substances in the polymeric preparations during article service life.		

Annex 1: Overview of classifications

Data extracted on 7 april 2021.

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
201-111-9	diethyl ethylphosphonate		Acute Tox. 4 H302 Eye Damage 1 H318 Aquatic Chronic 2 H411	Eye Irrit. 2 H319 Skin Irrit. 2 H315 STOT Single Exp. 3 H335
212-052-3	dimethyl methylphosphonate		Eye Irrit. 2A H318 Muta. 1B H340 Repr. 2 H361, Fertility	Repr. 2 H361, specific effect:fertility Eye Irrit. 2 H319 Acute Tox. 4 H302 Flam. Liquid 3 H226 Aquatic Chronic 3 H412 Repr. 2 H361 Acute Tox. 4 H332
212-091-6	diethyl phosphonate		Eye Damage 1 H318 Skin Sens. 1B H317	STOT Single Exp. 3 H335 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335
212-783-8	dimethyl phosphonate		Skin Sens. 1 H317 Carc. 2 H351 Aquatic Chronic 3 H412 Muta. 2 H341	Eye Irrit. 2 H319 Skin Sens. 1B H317 Skin Irrit. 2 H315 Acute Tox. 3 H311 Flam. Liquid 3 H226
215-896-0	bis(1-methylethyl) methylphosphonate		Not registered	Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335
217-316-1	dibutyl phosphonate		Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Chronic 3 H412	Carc. 2 H351 Eye Damage 1 H318 STOT Single Exp. 3 H335, affected organs: lungs Acute Tox. 4 H312 STOT Single Exp. 3 H335
225-076-4	dimethyl vinylphosphonate		Acute Tox. 4 H302	Skin Corr. 1B H314
225-202-8	diphenyl phosphonate		Muta. 2 H341 Acute Tox. 4 H302 Skin Irrit. 2 H315 Eye Damage 1 H318 Eye Irrit. 2 H319 Skin Sens. 1 H317	STOT Single Exp. 1 H370 Eye Irrit. 2A H319 Skin Corr. 1A H314 STOT Single Exp. 3 H335

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
			STOT Rep. Exp. 2 H373, affected organs: nervous system Aquatic Acute 1 H400 Aquatic Chronic 2 H411	STOT Rep. Exp. 1 H372 Skin Corr. 1C H314 Repr. 1B H360 STOT Single Exp. 3 H335 Muta. 1B H340 Skin Sens. 1A H317
231-388-1	diphenyl methylphosphonate		Acute Tox. 3 H301 Acute Tox. 3 H311 Aquatic Chronic 2 H411	-
235-996-8	bis(1,1-dimethylethyl) phosphonate		Not registered	Skin Corr. 1B H314 Skin Sens. 1B H317
242-555-3	dimethyl propylphosphonate	(Proposal) Muta. 1B Repr. 1B	Repr. 1B H360, specific effect:fertility: positive at 500 mg/kg/day (liter size, pup survival until PND4) Eye Irrit. 2 H319	Repr. 1B H360
619-646-5	Phosphonic acid, P-2-propen-1-yl-, diethyl ester		Acute Tox. 4 H302 Eye Irrit. 2 H319	Skin Irrit. 2 H315 Eye Irrit. 2A H319 STOT Single Exp. 3 H335
909-044-3	Reaction mass of dimethyl phosphonate and methyl hydrogenphosphonate and phosphonic acid		Skin Sens. 1B H317 Carc. 2 H351 Met. Corr. 1 H290 Acute Tox. 4 H302 Eye Damage 1 H318 Muta. 2 H341 Skin Corr. 1A H314	-
246-904-0	dimethyl octadecylphosphonate		Aquatic Chronic 4 H413	Acute Tox. 4 H332 STOT Single Exp. 3 H335 Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT Single Exp. 3 H335
246-905-6	methyl hydrogen octadecylphosphonate		Aquatic Chronic 4 H413	-
268-740-9	Potassium ethyl octylphosphonate		Not registered	STOT Rep. Exp. 2 H373 Eye Damage 1 H318 Aquatic Chronic 2 H411

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
				Aquatic Chronic 3 H412 Skin Irrit. 2 H315
417-170-0	bis(2-ethylhexyl)octylphosphonate	*Aquatic Acute 1 H400* *Aquatic Chronic 1 H410*	Aquatic Chronic 1 H410	-
939-595-5	Reaction mass of diethyl octylphosphonate and potassium ethyl octylphosphonate		Skin Irrit. 2 H315 Eye Damage 1 H318 STOT Rep. Exp. 2 H373, affected organs: May cause damage to organs (kidney) through prolonged or repeated exposure Aquatic Chronic 2 H411	-
213-607-2	methylphosphonic acid		Acute Tox. 4 H302 Skin Corr. 1B H314 Eye Damage 1 H318	Met. Corr. 1 H290
216-388-1	phenylphosphonic acid		Acute Tox. 4 H302 Skin Irrit. 2 H315 Skin Corr. 1 H314 Eye Damage 1 H318	Skin Corr. 1B H314 STOT Single Exp. 3 H335 Skin Corr. 1C H314
216-765-0	tetraisopropyl methylenebisphosphonate		Aquatic Chronic 3 H412 Acute Tox. 4 H302 Eye Irrit. 2A H319 Acute Tox. 4 H312	Acute Tox. 3 H311 Eye Damage 1 H318 Eye Irrit. 2 H319 Skin Irrit. 2 H315 Aquatic Chronic 2 H411 STOT Single Exp. 3 H335 Acute Tox. 3 H331 Acute Tox. 3 H301
217-123-2	vinylphosphonic acid		Met. Corr. 1 H290 Skin Corr. 1C H314 Eye Damage 1 H318	Skin Corr. 1B H314
217-315-6	dioctyl phosphonate		Eye Irrit. 2 H319 Aquatic Chronic 3 H412	STOT Single Exp. 3 H335
222-904-6	bis(2-ethylhexyl) phosphonate		Skin Irrit. 2 H315 Eye Irrit. 2 H319 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	STOT Single Exp. 3 H335 Eye Damage 1 H318 STOT Single Exp. 3 H335 STOT Single Exp. 3 H335
224-902-0	tetraethyl [1,4-phenylenebis(methylene)]bisphosphonate		Acute Tox. 4 H302	Skin Irrit. 2 H315 STOT Single Exp. 3

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
				H335 Eye Irrit. 2 H319
225-121-8	propylphosphonic acid		Met. Corr. 1 H290 Skin Corr. 1B H314 Eye Damage 1 H318	-
225-218-5	octylphosphonic acid		Eye Damage 1 H318 Acute Tox. 4 H302 STOT Rep. Exp. 2 H373, affected organs: Kidneys Skin Corr. 1B H314	STOT Rep. Exp. 2 H373 Skin Corr. 1C H314 Met. Corr. 1 H290 STOT Rep. Exp. 2 H373
225-897-8	dodecylphosphonic acid		STOT Rep. Exp. 2 H373, affected organs: kidney Skin Corr. 1B H314 Eye Damage 1 H318	Met. Corr. 1 H290 Skin Corr. 1C H314
237-027-4	#N/A		Not registered	-
243-869-3	3,9-dibenzyl-2,4,8,10-tetraoxa-3,9-diphosphaspiro[5.5]undecane 3,9-dioxide		-	-
246-608-1	(Z,Z)-di-9-octadecenyl phosphonate		Muta. 2 H341	-
246-928-1	cis-propenylphosphonic acid		Skin Corr. 1A H314	-
254-320-2	Aluminium triethyl triphosphonate	*Eye Dam. 1 H318*	Not registered	-
275-063-2	diisotridecyl phosphonate		Skin Sens. 1B H317 Aquatic Chronic 4 H413	-
300-326-6	Phosphonic acid, mixed C12-20-alkyl and C14-18-unsatd. alkyl derivs.		-	-
422-210-5	2,4,6-tri-n-propyl-2,4,6-trioxo-1,3,5,2,4,6-trioxatriphosphorinane	*Skin Corr. 1B H314*	Skin Corr. 1B H314	Met. Corr. 1 H290
435-710-3	Phosphonic acid, P,P'-1,12-dodecanediylbis-		Not registered	-

EC / List No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
443-520-7	Tetrasodium ethylene 1,1-diphosphonate		Eye Irrit. 2A H319 Skin Sens. 1A H317 Acute Tox. 4 H302	-
444-960-2	Sodium ethyl phosphonate		-	-
618-709-4	Phosphonic acid, [2-(hydroxyphosphinyl)ethylidene]bis-, pentasodium salt		Eye Damage 1 H318 Skin Corr. 1A H314	-
696-577-7	Phosphonic acid, P-phenyl-, zinc salt (1:1)		Aquatic Acute 1 H400 Aquatic Chronic 1 H410	-
701-298-1	Dialkyl C18 and C18-unsaturated phosphonates		-	-
915-680-2	915-680-2		-	-
919-645-2	Phosphine oxide, 1,1'-(1,12-dodecanediyl)bis[1,1-bis(1-methylethyl)-		Skin Irrit. 2 H315 Acute Tox. 4 H312 Acute Tox. 4 H302 Eye Damage 1 H318	-
921-798-5	2,5-dihydroxy-3,6-dimethyl-3,6-bis(dihydroxyphosphinyl)-1,4,2,5-dioxadiphosphorane-2,5-dioxide		Acute Tox. 4 H302 Eye Damage 1 H318 Skin Corr. 1A H314 Met. Corr. 1 H290	-
944-204-6	Reaction mass of (1Z)-prop-1-en-1-ylphosphonic acid and prop-2-en-1-ylphosphonic acid		Skin Corr. 1A H314 STOT Single Exp. 3 H335, affected organs: Respiratory system	-
944-574-9	Reaction Products of Dimethyl hydrogen phosphite and Alcohols C14-18, Even, Linear		Skin Sens. 1B H317	Skin Sens. 1B H317, specific concentration: >=31.6

(*) 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 7 April 2021.

Subgroup 1:	Hydrogenphosphonates					Alkylphosphonates					
EC No.	212-091-6	212-783-8	217-316-1	225-202-8	909-044-3	201-111-9	212-052-3	225-076-4	231-388-1	242-555-3	619-646-5
PC 32: Polymer preparations and compounds				F, I, A		F, I, (A)	A		F, I, (A)	I, P, A	I, (A)
PC 34: Textile dyes, and impregnating products						F, I, A					
PC 9a: Coatings and paints, thinners, paint removes						F, I					
PC 15: Non-metal-surface treatment products						F, I					
PC 24: Lubricants, greases, release products			F, I, P, C								
PC 21: Laboratory chemicals										I, P	
PC 19: Intermediate	I	I	I		I		I	I	F, I	I	I

Subgroup 2:	Alkylphosphonates		
EC No.	**246-905-6**	**246-904-0**	**939-595-5**
PC 34: Textile dyes, and impregnating products			**F, I, A**
PC 24: Lubricants, greases, release products	**F, I, P, C**	**F, I, P, C**	**F, I**
PC 16: Heat transfer fluids	**I, P**	**I, P**	
PC 17: Hydraulic fluids	**F, I, P**	**F, I, P**	
PC 21: Laboratory chemicals	**F**	**F**	

Subgroup 3:	Hydrogenphosphonates								Alkylphosphonates							
EC No.	**217-315-6**	**222-904-6**	**246-608-1**	**275-063-2**	**300-326-6**	**701-298-1**	**944-574-9**	**444-960-2**	**213-607-2**	**216-388-1**	**217-123-2**	**225-121-8**	**246-928-1**	**944-204-6**	**696-577-7**	**225-218-5**
PC 32: Polymer preparations and compounds	F			F, I, **A**						F, I, **A**	I				I, **P, C, (A)**	I, **(A)**
PC 26: Paper and board treatment products																I

Subgroup 3:	Hydrogenphosphonates								Alkylphosphonates							
EC No.	217-315-6	222-904-6	246-608-1	275-063-2	300-326-6	701-298-1	944-574-9	444-960-2	213-607-2	216-388-1	217-123-2	225-121-8	246-928-1	944-204-6	696-577-7	225-218-5
PC 1: Adhesives, sealants																F
PC 33: Semiconductors																
PC 9a: Coatings and paints, thinners, paint removes	I, **P**															F
PC 18: Ink and toners															F	
PC 15: Non-metal-surface treatment products	F, I, **P**															F, I
PC 14: Metal surface treatment products	F, I, **P**															F
PC 24: Lubricants, greases, release products	F, I, **P**	F	F, I, **P, C**		F, I, **P, C**	F, I, **P, C**	F, I, **P, C**									F, I, **P**
PC 25: Metal working fluids	F				I	F, I, **P**										F, I, **P**

Subgroup 3:	Hydrogenphosphonates								Alkylphosphonates							
EC No.	217-315-6	222-904-6	246-608-1	275-063-2	300-326-6	701-298-1	944-574-9	444-960-2	213-607-2	216-388-1	217-123-2	225-121-8	246-928-1	944-204-6	696-577-7	225-218-5
PC 16: Heat transfer fluids	F, I, **P**					I, **P**										
PC 17: Hydraulic fluids						F, I, **P**										F, I, **P**
PC 35: Washing and cleaning products							F, I, **P**									F, **P**
PC 31: Polishes and wax blends																**P**
PC 9b: Fillers, putties, plasters, modelling clay	I, **P**															
PC 27: Plant protection products								F, I, **P, C**								
PC 21: Laboratory chemicals						F	F									I
PC 19: Intermediate									I	I	I	I	I	I		

Subgroup 3: Polyphosphonates						
EC No.	216-765-0	224-902-0	243-869-3	915-680-2	921-798-5	422-210-5
PC 32: Polymer preparations and compounds			F, I, **P**, **C**, **A**	F, I, **(A)**		
PC 26: Paper and board treatment products			F, I, **P**, **C**, **A**	F, I, **A**		
PC 34: Textile dyes, and impregnating products				F, I, **A**		
PC 23: Leather treatment products			F, I, **P**, **C**, **A**	I, **A**		
PC 1: Adhesives, sealants			F, I, **P**, **C**, **A**			
PC 33: Semiconductors			F, **P**, **C**			
PC 9a: Coatings and paints, thinners, paint removes			F, I, **P**, **C**, **A**	F, I		
PC 18: Ink and toners		I	F, **P**, **C**			
PC 15: Non-metal-surface treatment products				F, I		
PC 29: Pharmaceuticals						I
PC 21: Laboratory chemicals				**P**		
PC 19: Intermediate	F, I	I			I	I

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

Data extracted on 13 April 2021.

EC / List number	RMOA	Authorisation		Restriction *	CLH	Actions not under REACH / CLP (*)
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
242-555-3	YES				YES Muta. 1B H340 Repro 1B H360FD	

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

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