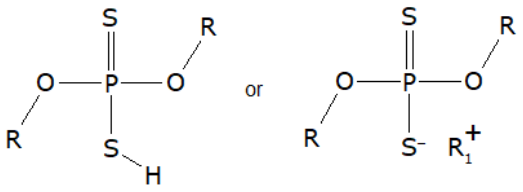
Assessment of regulatory needs

Authority: ECHA

Date: 29/10/2021

Group Name: Dialkyl (and diaryl) dithiophosphates (DDP)

General structure[1]:

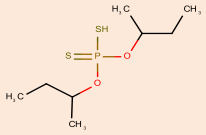
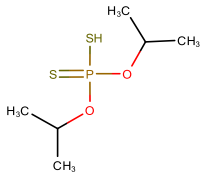
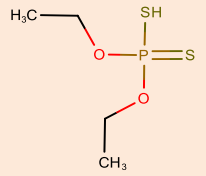
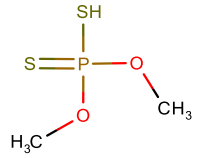
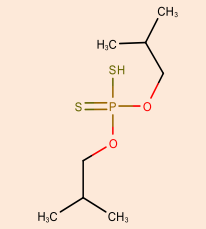
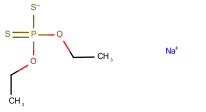


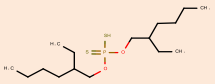
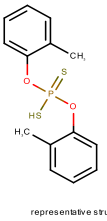
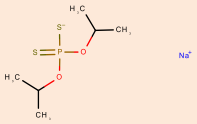
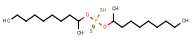
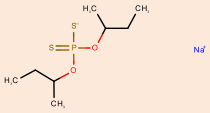
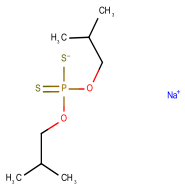
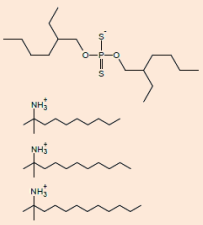
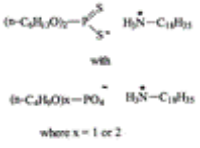
Revision history

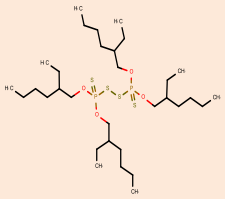
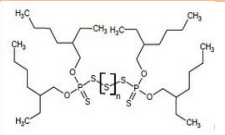
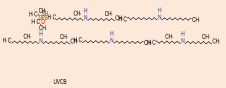
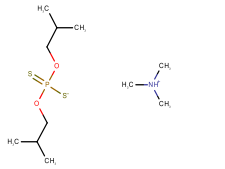
Version	*Date*	*Description*
1	29/10/2021	

[1] To be provided only when feasible

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures [and/ or] Substance name acronyms (*)	Registration type (full/OSI/TII/ NONS), highest tonnage band among all the registrations (t/y)
203-501-4	107-55-1	O,O-di-sec-butyl hydrogen dithiophosphate		Intermediate (OSII or TII)
203-503-5	107-56-2	O,O-diisopropyl hydrogen dithiophosphate		Intermediate (OSII or TII)
206-055-9	298-06-6	O,O-diethyl hydrogen phosphorodithioate		Intermediate (OSII or TII)
212-053-9	756-80-9	O,O-dimethyl hydrogen dithiophosphate		TII >1000
218-849-2	2253-52-3	O,O-diisobutyl hydrogen dithiophosphate		Intermediate (OSII or TII)
222-079-2	3338-24-7	sodium O,O-diethyl dithiophosphate		Full, 100-1000

227-376-0	5810-88-8	O,O-bis(2-ethylhexyl) hydrogen dithiophosphate		Intermediate (OSII or TII)
248-273-7	27157-94-4	O,O-bis(methylphenyl) hydrogen dithiophosphate	 representative structure	Full, 10-100
248-322-2	27205-99-8	sodium O,O-diisopropyl dithiophosphate		Full, 10-100
249-111-8	28631-44-9	O,O-diisodecyl hydrogen dithiophosphate		Intermediate (OSII or TII)
251-598-7	33619-92-0	sodium O,O-di-sec-butyl dithiophosphate		Full, 100-1000
258-508-5	53378-51-1	sodium O,O-diisobutyl dithiophosphate		Full, 100-1000
276-159-7	71888-91-0	Amines, C12-14-tert-alkyl, reaction products with O,O-di-C1-14-alkyl hydrogen phosphorodithioate		Full, 10-100
434-280-4		Reaction mass of Octadec-9-en-1-yl ammonium di-n-hexyl phosphorodithioate and Octadec-9-en-1-yl ammonium	 with where x = 1 or 2	Full, 10-100

		mono- and di-butylphosphate		
444-160-3		bis[O,O-di(2-ethylhexyl)thiophosphonyl]disulfide		NONS (unclaimed)
605-708-9	174125-93-0	bis(O,O-2-ethylhexyl-thiophosphoryl)polysulfide		Full, 10-100
700-768-3		Amines, bis(C11-14-branched and linear alkyl), O,O-di-iso-Pr phosphorodithioates		Full, 1-10
700-910-4	1354201-99-2	Phosphorodithioic acid, O,O-bis(2-methylpropyl) ester with N, N-dimethylmethanamine (1:1)		Full, 1-10

Contents

DISCLAIMER

Foreword

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

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

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

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

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

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

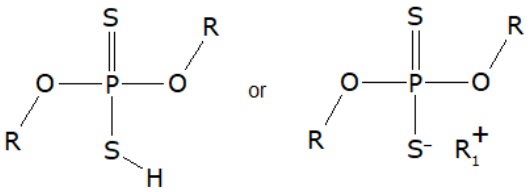
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
PMT	Persistent, mobile in water and toxic
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the **dithiophosphate** moiety shown in the figure below.



The group consists of 18 substances: 10 have a full registration, 7 are only registered as transported or on-site isolated intermediates and 1 is an unclaimed NONS. Out of the 18 group members, 12 are identified as mono-constituent, 1 as multi-constituent and 5 as UVCB.

Eight substances are closely related: 5[3] that are linked via read-across in a category proposed by the registrants and 3[4] that are acids of salts included in the category. The majority of the remaining group members, however, have a significant degree of structural variability; therefore, it is generally not feasible to extrapolate data on (eco)toxicological properties for many group members nor is it possible to assume potential substitution.

This group of substances is structurally related to the groups zinc dialkyl (and diaryl) dithiophosphates (ZDDP), and the thio alkyl esters and acids dialkyldithiophosphates. An assessment of regulatory needs is planned for these groups in the future.

Regarding hazards, the focus of ECHA's assessment is on CMR, sensitiser, ED, PBT/vPvB or equivalent (e.g. PMT), 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 ECHA may consider other hazards where the need for regulatory risk management action at EU level (e.g. neurotoxicity, STOT RE) is identified. Harmonised classification and self-classifications reported by registrants are presented in Annex 1.

Based on information reported in the REACH registration dossiers, most of the substances in the group are used mainly either as lubricants or in mining operations, particularly for ore extraction.

- The lubricant uses occur in the industrial setting but are also used by professionals and consumers; article service life may be relevant as the lubricants are applied into/onto articles such as vehicles and machinery. *There is high potential for release to the environment and exposure of consumers, industrial and professional workers.*

- The use in mining operations occurs only in the industrial setting. U*se in an industrial setting may generally be considered relatively well controlled,*

[3] 206-055-9, 222-079-2, 248-322-2, 251-598-7, 258-508-5

[4] 203-503-5, 203-503-5, 218-849-2

however potential for release and exposure cannot be excluded even though the registrants claim that there is no/minimal release to the environment.

- One substance (EC 605-708-9) is only used industrially as a reactive process regulator in the production of rubber goods. Although the registrant claims that the substance is not included in the produced rubber articles, the associated technical function and environmental release category raise uncertainties and may suggest otherwise. *Therefore there may be a potential for exposure for human health and the environment as a result of article service life; there may also be potential for exposure for industrial workers due to application of air dispersive techniques.*

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

Based on information reported in the REACH registration dossiers, most of the substances in the group have only local effects observed for human health and many are self-classified for aquatic toxicity. In addition, four substances (EC/List 276-159-7, 605-708-9, 700-768-3 and 700-910-4) are known skin sensitisers and are self-classified accordingly. One substance (EC 434-280-4) is self-classified for STOT RE and is a potential reprotoxicant. Another substance (EC 212-053-9) is also a suspected reprotoxicant and is self-classified as such. Four members of the group (EC/List 276-159-7, 434-280-4, 605-708-9 and 700-768-3) have likely PBT/vPvB properties.

Based on currently available information, **there is a need for EU regulatory risk management –** namely **restriction** (for EC 276-159-7, 434-280-4, 700-768-3) to address the PBT/vPvB hazard.

Based on ECHA's assessment of currently available hazard information, three members in the group fulfil the screening PBT criteria and therefore are considered as potential PBT/vPvB substances[5]. They are not readily biodegradable and screen for PvP properties; they have a log Kow above 4.5, are ionisable and surface active - indicating a high potential for bioaccumulation; and they show low LC50 values indicating a high likelihood that these substances will be toxic to aquatic life with long-lasting effects. In addition to potential PBT/vPvB properties, two of the members (EC/List 276-159-7 and 700-768-3) are self-classified for skin sensitisation and another member (EC 434-280-4) has been identified as a potential reprotoxicant due to observed effects in provided studies indicating a potential for developmental toxicity and immunotoxicity.

As a first step, the PBT/vPvB hazard potential (and reproductive toxicity, where relevant) will require further data generation to be clarified – a compliance check will be initiated for substances registered at 10-100 t/y (EC 276-159-7 and 434-280-4) to request the relevant studies. However, one member (List 700-768-3) is registered at a lower tonnage band (1-10 t/y) for which data that can be requested under CCH is limited and therefore substance evaluation is proposed to clarify the PBT/vPvB properties.

[5] Guidance on PBT/vPvB assessment

All of the substances for which PBT/vPvB potential has been identified are used as lubricants (or other technical fluids) by professionals and consumers and are applied into/onto articles (e.g. vehicles and machinery) for which release is expected. They are also used in the industrial setting in open systems where release/exposure are likely to occur. Consequently, release/exposure are likely for all life cycle stages relevant to this use. For those substances where the PBT/vPvB properties will be confirmed after evaluation activities are completed, restriction targeting the use as lubricant (or other technical fluid) in all settings (industrial, professional, consumer, use in articles) is proposed as the most appropriate regulatory risk management option. This would ensure that releases and exposure are minimised throughout the whole life cycle of the substance. However, the final scope of the restriction would be clarified during the official restriction process and is dependent on a more detailed assessment of uses. Due to this uncertainty, it is important to note that further/parallel action may be needed (e.g. CLH) to address the reproductive toxicity potential for EC 434-280-4 – depending on the severity of the repro hazard and stringency of the restriction for PBT/vPvB, additional measure may be needed to ensure adequate protection of e.g. industrial workers.

Substances confirmed to have PBT/vPvB properties following data generation activities would be proposed for SVHC identification. Identification as an SVHC and inclusion in the Candidate list would ensure hazard confirmation at EU level and communication on the hazard in the supply chain. It would also emphasise the importance of seeking less harmful alternatives for these substances.

Based on currently available information, **it is not possible to assess the need for regulatory risk management** as information on hazard and exposure is not sufficient to conclude on PBT/vPvB hazard for one member in the group (for List 605-708-9).

Although there is not enough data available to conclude on the hazard properties for this substance, there are preliminary indications for PBT/vPvB. In addition, there are many uncertainties regarding the release and exposure potential. The registrant has reported use only in the industrial setting in the production of rubber articles with no ASL, claiming that the substance is reactive and is not included in the produced rubber articles. However, there are inconsistencies in the provided information (e.g. technical function, environmental release categories) and a lack of clarity raising uncertainties, particularly: i) whether the substance is fully reactive or present in the final article ii) whether the reaction product is present in the final article and has similar hazard properties iii) whether substance itself or reaction product can be released from rubber articles during use iv) whether there are degradation products with similar hazard properties. In light of these uncertainties, exposure for human health and the environment cannot be excluded. As a next step, a compliance check will be opened to request further data, particularly to clarify the PBT/vPvB potential. The strategy will be updated once more data is available however it is worth highlighting that further EU RRM may be needed in case properties are confirmed.

Based on currently available information, **there is no need for (further) EU regulatory risk management** for all other members in the group.

One substance (List 700-910-4) is self-classified for skin sensitisation and used industrially in mining operations, particularly for ore extraction. It is expected that the correct self-classification should trigger adequate company level risk management measures and ensure safe use at the workplace. Several substances are self-classified for aquatic toxicity, one of which is also self-classified as Repr. 2. These substances are registered under Article 17/18 where it is expected that

the intermediate uses occur under strictly controlled conditions. Therefore, due to the low exposure potential, no further action is currently proposed. For all remaining members, no further regulatory risk management action is currently proposed either due to a) unlikely hazard potential for both human health and environment b) or due to low release/exposure. Data generation under compliance check will be initiated for selected substances to confirm the low hazard potential.

It is worth noting that cresol (EC 215-293-2) is reported as a constituent for one member in the group (EC 248-273-7). Cresol was previously assessed for regulatory needs as part of group "methylated/ethylated phenols" where it was found to be a likely developmental neurotoxicant, based on read-across from m-cresol. However, an overall conclusion on cresol is pending action on an impurity/constituent of concern for which data generation has been initiated. Therefore, the conclusion for the member of this group (EC 248-273-7) is based on data provided on the substance itself but may need to be revised once hazards for the constituents are clarified.

3 Conclusions and actions

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

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
276-159-7 **700-768-3**	Known or potential hazard for skin sensitisation	Known or potential hazard for PBT/vPvB	Industrial, professional and consumer use as lubricant. Article service life may be considered relevant. Likely environmental release and high exposure potential for consumers and workers (industrial and professional).	**Need for EU RRM: Restriction** <u>Justification:</u> SVHC identification would ensure confirmation of PBT/vPvB hazard at EU level. Restriction for use in lubricants (and other technical fluids) for all life cycle stages (including industrial where there is high exposure potential due to open systems) would minimise release and exposure.	**First step:** CCH for 276-159-7, 434-280-4 SEV for 700-768-3 **Next steps (if hazard confirmed):** • SVHC identification • Restriction
434-280-4	Known or potential hazard for STOT RE and reproductive toxicity				

				Restriction is considered as the most appropriate regulatory risk management option to address the widespread consumer and professional uses as well as use in articles, noting that articles are not in the sope of authorisation.	
605-708-9	Known or potential hazard for skin sensitisation	Inconclusive hazard for PBT/vPvB	Industrial use in the production of rubber goods where article service life may be relevant. Release and exposure cannot be excluded.	**No hypothesis yet** Justification: Not enough data available to conclude on hazard properties in addition to uncertainties on exposure and release potential.	**First step:** CCH
222-079-2 **248-273-7** **248-322-2** **251-598-7** **258-508-5** **444-160-3**	No hazard or unlikely hazard	No hazard or unlikely hazard	Industrial use in mining operations, particularly for ore extraction. Limited release and exposure. 444-160-3 is an unclaimed NONS	**Currently no need for EU RRM** Justification: Low hazard potential (for most) and no widespread use reported; correct self-classification (local effects, skin sens)	No action *CCH to confirm low hazard for 248-322-2 and 251-598-7*

700-910-4	Known or potential hazard for skin sensitisation			should trigger sufficient RMM in the industrial setting.	
203-501-4 **206-055-9** **249-111-8**	No hazard or unlikely hazard	No hazard or unlikely hazard	Unlikely release and exposure potential - registered under Article 17/18 (intermediate use under strictly controlled conditions)	**Currently no need for EU RRM** <u>Justification:</u> Exposure is unlikely – the substances are used under strictly controlled conditions.	
203-503-5 **218-849-2** **227-376-0**		Known or potential hazard for aquatic toxicity			
212-053-9	Known or potential hazard for reproductive toxicity				

Annex 1: Harmonised classifications and self-classifications reported by registrants (reporting performed on 19/05/2021)

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications
203-501-4	107-55-1	O,O-di-sec-butyl hydrogen dithiophosphate		Skin Corr. 1B H314 Met. Corr. 1 H290	
203-503-5	107-56-2	O,O-diisopropyl hydrogen dithiophosphate		Aquatic Chronic 3 H413 Skin Corr. 1B H314 Acute Tox. 4 H302 Met. Corr. 1 H290	Eye Dam 1 (H318)
206-055-9	298-06-6	O,O-diethyl hydrogen phosphorodithioate		Skin Corr. 1B H314 Acute Tox. 4 H332 Acute Tox. 4 H302	
212-053-9	756-80-9	O,O-dimethyl hydrogen dithiophosphate		Skin Corr. 1B H314 Met. Corr. 1 H290 Acute Tox. 4 H302 Acute Tox. 4 H332 Repr. 2 H361 Aquatic Chronic 3 H412 Flam. Liquid 3 H226	
218-849-2	2253-52-3	O,O-diisobutyl hydrogen dithiophosphate		Aquatic Chronic 3 H412 Met. Corr. 1 H290 Skin Corr. 1B H314	
222-079-2	3338-24-7	Sodium O,O-diethyl dithiophosphate		Acute Tox. 4 H302 Acute Tox. 4 H332 Skin Corr. 1C H314 Eye Damage 1 H318	
227-376-0	5810-88-8	O,O-bis(2-ethylhexyl) hydrogen dithiophosphate		Aquatic Chronic 3 H412 Eye Damage 1 H318 Skin Corr. 1B H314	

248-273-7	27157-94-4	O,O-bis(methylphenyl) hydrogen dithiophosphate		Acute Tox. 3 H301 Acute Tox. 3 H311 Skin Corr. 1B H314	
248-322-2	27205-99-8	Sodium O,O-diisopropyl dithiophosphate		Skin Corr. 1C H314	Skin Corr. 1B (H314) Eye Dam. 1 (H318)
249-111-8	28631-44-9	O,O-diisodecyl hydrogen dithiophosphate		*Not classified*	
251-598-7	33619-92-0	Sodium O,O-di-sec-butyl dithiophosphate		Skin Corr. 1C H314	
258-508-5	53378-51-1	Sodium O,O-diisobutyl dithiophosphate		Skin Corr. 1C H314	Skin Corr 1B H314 Eye Dam 1 H318
276-159-7	71888-91-0	Amines, C12-14-tert-alkyl, reaction products with O,O-di-C1-14-alkyl hydrogen phosphorodithioate		Flam. Liquid 3 H226 Skin Sens. 1B H317 Aquatic Chronic 2 H411	Aquatic Chronic 4 H413
434-280-4	-	Reaction mass of Octadec-9-en-1-yl ammonium di-n-hexyl phosphorodithioate and Octadec-9-en-1-yl ammonium mono- and di-butylphosphate		Skin Irrit. 2 H315 Eye Irrit. 2A H319 STOT Rep. Exp. 2 H373 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	
444-160-3	71426-89-6	Bis[O,O-di(2-ethylhexyl)thiophosphonyl]disulfide		*Not classified*	
605-708-9	174125-93-0	bis(O,O-2-ethylhexyl-thiophosphoryl)polysulfide		Skin Sens. 1B H317 Aquatic Chronic 4 H413	
700-768-3	1285610-71-0	Amines, bis(C11-14-branched and linear alkyl), O,O-di-iso-Pr phosphorodithioates		Skin Irrit. 2 H315 Skin Sens. 1B H317 Aquatic Chronic 2 H411	
700-910-4	1354201-99-2	Phosphorodithioic acid, O,O-bis(2-methylpropyl) ester with N, N-dimethylmethanamine (1:1)		Acute Tox. 4 H302 Eye Damage 1 H318 Skin Sens. 1 H317	

Annex 2: Overview of uses based on information available in registration dossiers (19/05/2021)

The table below is an overview of the main types of applications reported for the substances within the group in the registration dossiers.

Main types of applications structured by product or article types	EC/ List 222-079-2	EC/ List 248-273-7	EC/ List 248-322-2	EC/ List 251-598-7	EC/ List 258-508-5	EC/ List 276-159-7	EC/ List 434-280-4	EC/ List 605-708-9	EC/ List 700-768-3	EC/ List 700-910-4
PC 24: Lubricants, greases, release products						F,I,**P,C, (A)**	F,I,**P,C, (A)**		F,I,**P,C, A**	
PC 25: Metal working fluids						F,I,**P**				
PC 16: Heat transfer fluids						I,**P**				
PC 17: Hydraulic fluids						F,I,**P**			I	
PC 32: Polymer preparations and compounds								F,I		
PC 19: Intermediate	I				I					
Mining operations ***E.g. PC 40: Extraction agents; PC 20: Products such as ph-regulators, flocculants, precipitants, neutralisation agents***	F,I	F,I	F,I	F,I	F,I					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 (14/06/2021)

No relevant completed or ongoing regulatory risk management activities for any of the group members.