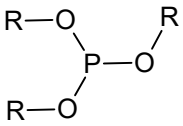
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Alkyl phosphites

General structure:

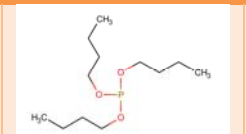
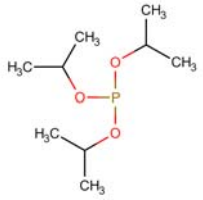
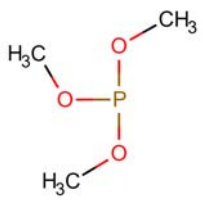
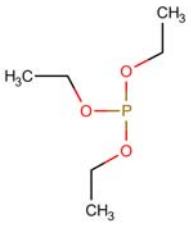
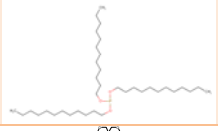


R = alkyl

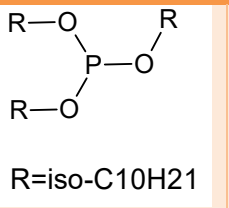
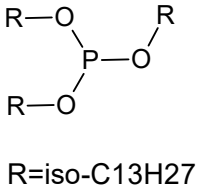
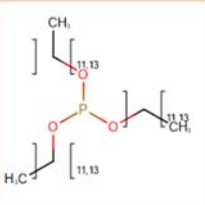
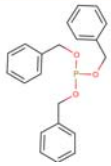
Revision history

Version	*Date*	*Description*
1.0	2 April 2024	

Substances within this group:

EC/List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
203-061-3	102-85-2	Tributyl phosphite		OSII or TII
204-130-0	116-17-6	Triisopropyl phosphite		OSII or TII
204-471-5	121-45-9	Trimethyl phosphite		OSII or TII
204-552-5	122-52-1	Triethyl phosphite		OSII or TII
221-356-5	3076-63-9	Tridodecyl phosphite		C&L notification
223-276-6	3806-34-6	O,O'-dioctadecylpentaerythritol bis(phosphite)		Full, 100-1000

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

EC / List no	CAS no	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) [1]
246-998-3	25448-25-3	Triisodecyl phosphite		Full, 100-1000
278-758-9	77745-66-5	Triisotridecyl phosphite		Full, 100-1000
297-701-9	93686-48-7	Phosphorous acid, tri-C12-14-alkyl esters		Full, not (publicly) available
604-823-1	15205-57-9	Tribenzyl phosphite		Cease manufacture
Not (publicly) available	Not (publicly) available	Substance 1 (name not (publicly) available)	Not (publicly) available	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.

Contents

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Foreword

The assessment of regulatory needs of a group of substances is an iterative, informal process to help authorities consider the most appropriate way to address an identified concern for a group of substances or a single substance and decide whether further regulatory risk management activities are necessary.

The grouping is mainly based on structural similarity and associations made by the registrants between substances through read-across and category approaches as well as category associations from external sources (e.g. OECD categories)[2]. These methods are different from grouping as defined in Section 1.5 of Annex XI to REACH because the scope and intended use of ECHA's grouping is different. Thus, in this context, grouping does not aim to validate read-across and category approaches according to the Annex XI requirements but rather to support a faster and more consistent approach for regulating chemicals and avoid regrettable substitution.

The focus of the assessment is largely based on information available in the registration dossiers and on properties requiring regulatory risk management action at EU level[3]. The information reported on uses is from the registration dossiers (IUCLID) and is used as a proxy for assessing how widespread uses are and whether potential for exposure to humans and releases to the environment can be expected. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

The outcome of these assessments are proposals for immediate (the first action) and subsequent regulatory action(s), including the foreseen ultimate regulatory action (last foreseen regulatory action) to address the identified concern(s) in case the potential hazards are confirmed. For example, further data generation through compliance check is suggested as a first action, to confirm the identified hazard.

Where hazards are confirmed, regulatory risk management actions could be considered for the whole group, for a subgroup or for individual substances within the group. The robustness of the group depends on the stage of assessment and the level of certainty this stage requires. For example, the needs for grouping under restriction may differ from the needs for grouping for the purpose of harmonised classification. Group membership is reconsidered accordingly throughout the iterative assessment of regulatory needs, for example, after further information is generated and the hazard has been clarified or when new insights on uses and risks are available.

The assessment of regulatory needs in itself does not represent a regulatory action, but rather a preparatory step to consider further possible regulatory actions at the level of individual substances or groups/subgroups of substances.

[2] Working with Groups - ECHA (europa.eu)

[3] Regarding hazard properties the focus is for instance 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 report. This does not mean that the substances do not have other known or potential hazards. In some specific cases, ECHA may consider additional hazards (e.g. neurotoxicity, STOT RE).

Publication of ARNs makes it easier for companies to follow the latest status of their substances of interest, anticipate potential regulatory actions and make strategic choices in their chemicals portfolio.

For more information on assessments of regulatory needs please consult ECHA's website[4].

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

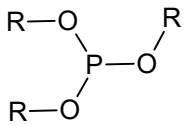
Glossary

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
ENV ED	Endocrine disruptor for the environment
HH ED	Endocrine disruptor for human health
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
PMT/vPvM	Persistent, mobile, and toxic / very persistent and very mobile
RDT	Repeated dose toxicity
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
TPE	Testing proposal evaluation

1 Overview of the group

Explanations on the scope of this assessment are available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of the alkylphosphite moiety shown in the figure below and which were not included in previous groups of aryl and mixed alkyl aryl phosphites ('Mono-, di-phenyl phosphite derivatives' and 'Triphenylphosphite and its derivatives').



R = alkyl

The group contains mainly substances with linear alkyl groups or branched alkyl groups. In addition, the group includes benzyl phosphite. There are mono-constituent and multi-constituent/UVCB substances in the group.

There are 11 substances in the group of which five with full registrations and four intermediates. The group also includes one substance with inactive (intermediate) registration and one not registered substance.

Based on information reported in the REACH registration dossiers, the substances in the group are used in the following ways:

- four of the substances are used as antioxidants and stabilizing agents mainly in polymer preparations, adhesives and sealants, coatings and paints, and ink and toners;
- one substance is used as lubricating agent in lubricants, greases, metal working fluids and hydraulic fluids;
- four substances are used as intermediates.

For two of the substances used as antioxidants and stabilising agents, the registrants indicate professional, consumer and article use in most of the product categories. For the two other substances used as antioxidants (and one also stabilising agent) the registrants indicate article service life in one product category (polymer preparation). For the substance used as lubricating agent the registrants indicate professional use for two product categories. So, there is potential for exposure for humans and the environment for all these substances. For the substances used as intermediates low exposure of humans and the environment is assumed.

2 Conclusions and proposed actions

The conclusions and actions proposed in the table below are based mainly on the REACH and CLP information available at the time of the assessment by ECHA. The conclusions are preliminary suggestions from a screening-level assessment done by ECHA with the aim to propose the next steps for further work (e.g., strengthening of the hazard conclusions, clarification of the uses and/or potential for exposure). 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 may be updated, and conclusions and actions revisited.

Table 1: Conclusions and proposed actions

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
246-998-3 278-758-9 Substance 1	Known or potential hazard for ED and Skin Sensitisation	Known or potential hazard for ED Known or potential hazard for aquatic toxicity for 278-758-9 Inconclusive hazard for PBT/vPvB for PMT/vPvM Inconclusive hazard for aquatic toxicity except for EC 278-758-9	The substances are mainly used in polymer preparation, adhesives and sealants, coatings and paints, ink and toners; one substance is additionally used in lubricants. High potential for exposure – professional and consumer use indicated for two of the substances, for two (about half) of their uses.	**First step:** CCH **Potential next steps (if hazard confirmed after data generation):** Substance evaluation SVHC identification/ CLH **Potential last action:** **Restriction** for industrial, professional and consumer uses Authorisation can be considered for industrial uses. <u>Justification</u>: The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
			Article service life is indicated for the three substances (polymer articles). Releases to environment also foreseen.	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. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.
203-061-3 204-130-0 204-471-5 204-552-5 604-823-1* *Intermediate inactive registration	Inconclusive hazard for ED for EC 204-130-0 Known or potential hazard for ED for EC 204-552-5, hazard related to impurity	Known or potential hazard for aquatic toxicity for EC 203-061-3, and 204-552-5 Inconclusive hazard for PBT/vPvB and PMT/vPvM Inconclusive hazard for ED for EC 204-130-0 Inconclusive hazard for aquatic toxicity for EC 204-130-0 204-471-5 and	According to the registrations these substances are used as intermediates only, under strictly controlled conditions, in industrial settings only, and therefore expected low potential for exposure.	**Currently no need for EU RRM** <u>Justification</u>: According to the reported uses, low potential for exposure to both human health and environment is expected. Actions may be re-considered if there is a change in the registration status and/or reported uses, when the assessment will be revisited.

Subgroup name, EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
		604-823-1		
223-276-6 297-701-9	Known or potential hazard for skin sensitisation for EC 297-701-9	Known or potential hazard for aquatic toxicity for EC 223-276-6 Inconclusive hazard for PBT/vPvB Inconclusive hazard for PMT/vPvM for EC 297-701-9 Inconclusive hazard for aquatic toxicity for EC 297-701-9	For EC 223-276-6 industrial use in polymer preparation and article service life are indicated in the dossier. For EC 297-701-9 industrial and professional uses in lubricants, metal working fluids and hydraulic fluids are indicated. The use in lubricants has a high potential for exposure of workers and professionals.	**First step:** CCH **Potential last action:** **Currently not possible to assess the regulatory needs** <u>Justification</u>: It is not possible to assess the needs for regulatory risk management for EC 223-276-6 and 297-701-9 as information on hazard is not sufficient to conclude on PBT/vPvB and on PMT/vPvM. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH). Concerning the aquatic toxicity and skin sensitisation hazards there is currently no need for EU-wide regulatory risk management: self-classification as skin sensitiser and aquatic toxic requires company level risk management measures (RMM) for workers and for environment, respectively, be in place.

3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)

Suggested regulatory risk management action for substances EC 246-998-3 and 278-758-9 and for Substance 1 if Endocrine Disruptor hazards for human health and the environment are confirmed.

Based on currently available information, there is a potential hazard for ED hazards for human health and the environment.

For substance EC 278-758-9 and Substance 1 the available information show adverse effects on thyroid suggesting an ED hazard via a thyroid (T) modality. The adverse thyroid effects for Substance 1 are demonstrated by follicular cell hypertrophy and thyroid stimulating hormone (TSH), T3 and T4 changes in a screening study in rat. For EC 278-758-9, thyroid and parathyroid weight changes were reported in a sub-chronic toxicity study in rat, and thyroid weight and T3 changes were reported in a prenatal developmental toxicity study in rat.

Based on common structural features (all three substances are branched alkyl phosphites), the ED hazard from substance EC 278-758-9 and Substance 1 is tentatively extrapolated to substance EC 246-998-3.

However, because some REACH standard information requirements relevant to and supporting the CLP ED criteria comparison for EC 246-998-3 are not available, data generation is needed to clarify the ED hazard for human health for EC 246-998-3. For Substance 1, ED classification may be warranted based on the current REACH data set.

The adverse outcome pathway (AOP) for ED hazard via the T modality[5] may produce adverse neurodevelopmental effects related to learning and memory.

Based on currently available environmental information it is not possible to conclude on the need for data generation before HH ED is first clarified. The suggested HH ED modality for the three substances (EC 246-998-3, 278-758-9 and Substance 1) indicates potential relevance for ENV ED as well. However, the currently available information does not allow to conclude on ENV ED relevance at a population level yet. Therefore, it is proposed that first the HH ED pathway and adversity are clarified under CCH, and based on this information, data generation for ENV ED may be considered for example under substance evaluation for the substances EC 246-998-3 and 278-758-9 and Substance 1.

For all the above substances there is a potential hazard for skin sensitisation. Registrants have self-classified the substances as Skin sensitiser (category 1).

Based on ECHA's screening of currently available hazard information, it is not possible to conclude on PBT/vPvB properties or PMT/vPvM properties for EC 246-

[5] OECD Adverse Outcome Pathway on Inhibition of Thyroperoxidase and Subsequent Adverse Neurodevelopmental Outcomes in Mammals:

https://www.oecd-ilibrary.org/environment/adverse-outcome-pathway-on-inhibition-of-thyroperoxidase-and-subsequent-adverse-neurodevelopmental-outcomes-in-mammals_ea5aa069-en#:~:text=Adverse%20Outcome%20Pathway%20on%20inhibition%20of%20Thyroperoxidase%20and,the%20inhibition%20of%20thyroperoxidase%20%28TPO%29%20during%20mammalian%20development .

998-3, 278-758-9, and Substance 1 (see below where the PBT/vPvB and PMT/vPvM properties of all substances are summarised).

Further data generation is proposed to clarify human health and/or environmental hazards of three substances (EC 246-998-3, 278-758-9 and Substance 1).

For substances EC 246-998-3 and 278-758-9 the registrants have reported industrial, professional and consumer uses in polymer preparation, adhesives, sealants, coatings and paints and ink and toners. For substance EC 278-758-9 also industrial and consumer uses in lubricants are reported. Article service life is also reported for the substances EC 246-998-3 and 278-758-9 and Substance 1 (for polymer articles). In terms of exposure, there is potential for workers, consumers and environment exposure.

The first step of the regulatory risk management action proposed, should the hazard exist, is to confirm via SVHC identification under REACH or CLH under CLP[6] the potential ED properties for human health and the environment, for EC 246-998-3, 278-758-9 and Substance 1. When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly.

SVHC identification or CLH is required as a step prior to authorisation and highly recommended as a step prior to 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.

The reported professional uses (in adhesives, sealants, coatings and paints) are expected to be widespread (at many sites and by many users). 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.

Consumers may be co-exposed to the substances used by professionals e.g. house painters.

Therefore, a **restriction of the substance as such or in mixtures (concentration limit in mixtures) used by consumers and industrial and professional workers** is suggested after SVHC/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**Error! Bookmark not defined.** 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 *(*reported for substances EC 246-998-3 and 278-758-9 and for Substance 1*)* should be considered in the context of the restriction of professional uses.

[6] The hazard classes PBT/vPvB, PMT/vPvM, ED have been introduced in CLP: CLP Delegated Act (europa.eu). Therefore, instead of SVHC identification under REACH, these hazards may be confirmed via CLH. It is not clear when to use which legal route (SVHC under REACH or CLH under CLP) during the period that both legal options are available.

Currently no need to suggest (further) regulatory risk management actions for substances EC/List 203-061-3, 204-130-0, 204-471-5, 204-552-5 and 604-823-1.

ED hazard for EC 204-130-0 is currently inconclusive and will be clarified via extrapolation after further data for the above other branched alkyl phosphites becomes available. For substances EC 203-061-3 and 204-552-5 it is not possible to conclude on their PBT/vPvB (or PMT/vPvM) properties (see below).

For EC 204-552-5 there is potential ED hazard as it contains an impurity that has potential ED hazard, acting via (T) modality.

The substances listed above are registered as on-site isolated intermediate or transported isolated intermediate (EC 203-061-3, 204-130-0, 204-471-5, 204-552-5) or their manufacture is reported to have ceased (List 604-823-1). Based on the chemical structure and reported uses is not possible to conclude on the potential for these substances to substitute those for which regulatory risk measures are being proposed (i.e. EC 246-998-3 and 278-758-9 and Substance 1).

Therefore, no EU regulatory risk management action is currently proposed for any of the aforementioned substances due to low exposure potential. It is worth noting however that the strategy may need to be revisited and need for further regulatory action reconsidered if there is a change in the registration status or reported uses for any of these substances.

Currently not possible to suggest regulatory risk management actions for for substances EC 223-276-6 and 297-701-9.

Based on ECHA's screening of human health hazards, for substance EC 297-701-9 there is a potential hazard for skin sensitisation. Registrants have self-classified the substance as Skin Sensitiser (category 1). Substance EC 223-276-6 is currently not self-classified for skin sensitisation but based on ECHA's assessment the currently available information is unreliable and conclusion requires further data generation under compliance check.

Based on ECHA's assessment of currently available information substance EC 297-701-9 is unlikely to fulfil the criteria for ED hazard for human health. This is based on no observed indication of hazard in available experimental thyroid and related hormone measurements. The unlikely ED hazard is preliminarily extrapolated to the other linear alkyl substance EC 223-276-6. This will be clarified through compliance check for EC 297-701-9 and 223-276-6.

Based on ECHA's screening of currently available environmental hazard information of all the substances in the group, it is not possible to conclude on PBT/vPvB properties of any substance in the group or PMT/vPvM properties for EC 297-701-9 (as well as the 3 other substances addressed above, EC 246-998-3, 278-758-9 and Substance 1):

- these substances are potentially persistent or very persistent (P/vP) as they are not readily biodegradable based on:
    - screening tests (*i.e.,* <60/70% degradation in an OECD 301 B or D (EC 223-276-6, 246-998-3, 278-758-9 and 297-701-9) or
    - extrapolation (high uncertainty) from other structurally similar group members (Substance 1).
- these substances do not have any experimental information (e.g no experimental BCF or log Kow) and it is not possible to conclude on their potency for being bioaccumulative or very bioaccumulative (B/vB). However, based on unverified QSAR models, the predicted log Kow values indicate very high lipophilicity and potential for bioaccumulation;
- the specified four substances (EC 246-998-3, 278-758-9, 297-701-9 and

Substance 1) do not have any experimental information on their potency to partition in organic material (e.g. log Koc) and it is not possible to conclude on their potency for being mobile (M) or very mobile (vM) in the environment;

- these substances have low water solubility and do not have any information on long-term toxicity to fish and *Daphnia*, and therefore, it is not possible to conclude on their potency to meet the T criteria (NOEC or EC10 < 0.01 mg/L) for the environment. However, available data on human health shows that two substances (EC 278-758-9 and Substance 1) could be considered as potential ED. In addition, available data on the ED property of EC 246-998-3 is limited and it is not possible to conclude on its potency to meet the T criteria for human health.

Based on currently available aquatic toxicity hazard information it is not possible to conclude on environmental classification of six substances (EC 204-130-0, 204-471-5, 246-998-3, 297-701-9, 604-823-1 and Substance 1). Two substances (EC 203-061-3 and 204-552-5) in the group are self-classified by the registrants for Aquatic Chronic 3. In addition, three substances (EC 223-276-6, 278-758-9 and 223-276-6) are self-classified by the registrants for Aquatic Chronic 4.

Further data generation is proposed for the following substances to clarify their HH and ENV hazards: EC 223-276-6 and 297-701-9. For the latter substance there is ongoing data generation for its bioaccumulation potential.

Registrants indicate industrial and professional uses for substance EC 297-701-9 and industrial and article uses for substance EC 223-276-6.

It is expected that following data generation for aquatic toxicity and for skin sensitization registrants would adequately self-classify the substances.

For industrial and professional uses, sufficient and consistent self-classification for skin sensitisation by registrants should require company level risk management measures (RMM) to be in place for workers. Also, self-classification for aquatic toxicity, requires company level risk management measures (RMM) for environment to be in place.

However, it is not possible to assess the needs for regulatory risk management for the two substances as information on hazard is not sufficient to conclude on PBT/vPvB and on PMT/vPvM. The needs for regulatory risk management actions will be assessed once generation of data is completed (CCH).

Annex 1: Overview of classifications

Data extracted on 04.07.2023

Table 2

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
203-061-3	102-85-2	tributyl phosphite	-	Skin Irrit. 2 H315 [intermediate (active)] Eye Irrit. 2 H319 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)]
204-130-0	116-17-6	triisopropyl phosphite	-	Acute Tox. 3 H301 [intermediate (inactive)] Skin Irrit. 2 H315 [intermediate (inactive)]
204-471-5	121-45-9	trimethyl phosphite	-	Flam. Liquid 3 H226 [intermediate (active)]
204-552-5	122-52-1	triethyl phosphite	-	Flam. Liquid 3 H226 [intermediate (active)] Skin Sens. 1B H317 [intermediate (active)] Acute Tox. 4 H302 [intermediate (active)] Aquatic Chronic 3 H412 [intermediate (active)]
223-276-6	3806-34-6	O,O'-dioctadecylpentaerythritol bis(phosphite)	-	Aquatic Chronic 4 H413
246-998-3	25448-25-3	triisodecyl phosphite	-	Skin Sens. 1 H317, specific concentration: 20
278-758-9	77745-66-5	triisotridecyl phosphite	-	Skin Sens. 1 H317, specific concentration: 92.1 Aquatic Chronic 4 H413
297-701-9	93686-48-7	Phosphorous acid, tri-C12-14-alkyl esters	-	Skin Sens. 1B H317
604-823-1	15205-57-9	604-823-1	-	-
Not (publicly) available	Not (publicly) available	Substance 1 (name not (publicly) available)	-	Skin Sens. 1 H317

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

Data extracted on 04.07.2023

Table 3

Main types of applications structured by product or article types	EC/ List	223-276-6	246-998-3	278-758-9	297-701-9	EC/ List not (publicly) available (Substance 1)
PC 24: Lubricants, greases, release products				F, I, **C**	F, I, **P**	
PC 25: Metal working fluids					F, I	
PC 17: Hydraulic fluids					F, I, **P**	
PC 32: Polymer preparations and compounds		F, I, **A**	F, I, **A**	F, I, **A**		F, I, **A**
PC 1: Adhesives, sealants			F, **P**, **C**	F, **P**, **C**		
PC 9a: Coatings and paints, thinners, paint removes			F, **P**, **C**	F, **P**, **C**		
PC 18: Ink and toners			F	F		

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

Note: The remaining registered substances of the group are used as intermediates (active intermediate registrations: EC 203-061-3, EC 204-130-0, EC 204-471-5, and EC 204-552-5; inactive: List 604-823-1).

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

Data extracted on 20.07.2023

Table 4

EC / List No	RMOA, ARN	Authorisation		Restriction *	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
204-471-5						OEL
204-552-5						Food contact material

*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, 40 and 75).

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