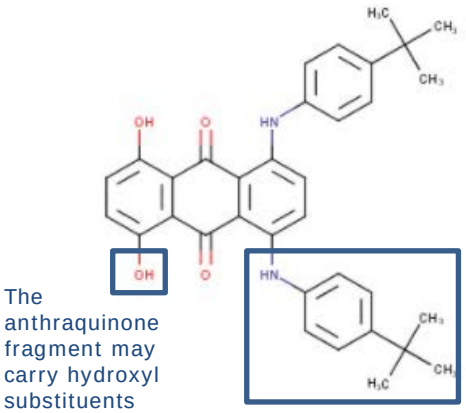
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Group Name: Aminoaryl Anthraquinones

General structure:



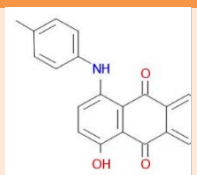
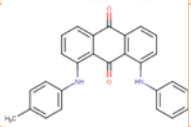
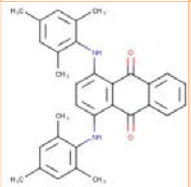
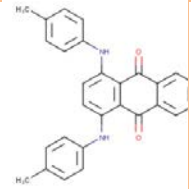
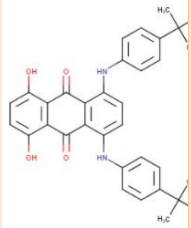
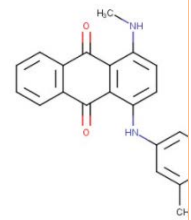
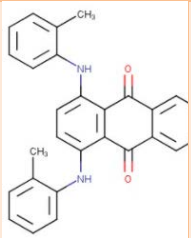
The anthraquinone fragment may carry hydroxyl substituents

One or more aniline like substituents on the anthraquinone

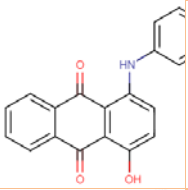
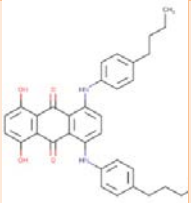
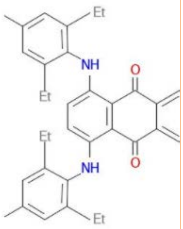
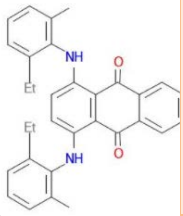
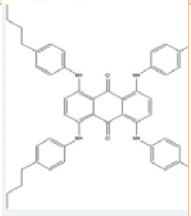
Revision history

Version	*Date*	*Description*
1.0	15 February 2023	

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full/OSI/TII/NONS), highest tonnage band among all the registrations (t/y) [1]
201-353-5	81-48-1	1-hydroxy-4-(p-toluidino)anthraquinone		**Full, 10-100 t/y**
201-398-0	82-16-6	1,8-bis[(4-methylphenyl)amino]anthraquinone		**Full, Not (publicly) available**
204-155-7	116-75-6	1,4-bis(mesitylamino)anthraquinone		**Full, 10-100 t/y**
204-909-5	128-80-3	1,4-bis(p-tolylamino)anthraquinone		**Full, 10-100 t/y**
225-443-9	4851-50-7	1,4-bis[[4-(1,1-dimethylethyl)phenyl]amino]-5,8-dihydroxyanthraquinone		**Full, Not (publicly) available**
229-059-2	6408-50-0	1-(methylamino)-4-[(3-methylphenyl)amino]anthraquinone		**Full, Not (publicly) available**
229-792-8	6737-68-4	1,4-bis[(2-methylphenyl)amino]anthraquinone		**Full, Not (publicly) available**

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

242-939-0	19286-75-0	1-anilino-4-hydroxyanthraquinone		**C&L notification**
248-895-9	28198-05-2	1,4-bis[(4-butylphenyl)amino]-5,8-dihydroxyanthraquinone		**Full, Not (publicly) available**
251-178-3	32724-62-2	1,4-bis[(2,6-diethyl-4-methylphenyl)amino] anthraquinone		**Full, 100-1000 t/y**
255-460-7	41611-76-1	1,4-bis[(2-ethyl-6-methylphenyl)amino] anthraquinone		**Full, Not (publicly) available**
445-710-5	108313-21-9	9,10-Anthracenedione, 1,4,5,8-tetrakis[(4-butylphenyl)amino]-		**Full, Not (publicly) available**

This table contains also group members that are not registered (yet) but have a C&L notification under the CLP Regulation. However, the list is currently non-exhaustive. Once further regulatory risk management action on one or more registered substances is being considered, ECHA will make an additional search for related C&L notified substances to be included in the group and develop a regulatory strategy for them.

Contents

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

Foreword

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

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

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the 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].

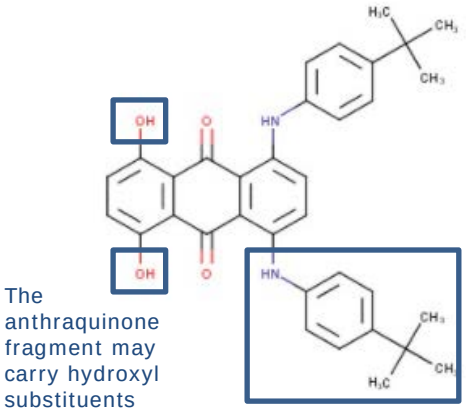
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

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
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the anthraquinone moiety shown in the figure below. The substances in this group are all arylamino anthraquinones. The anthraquinone core fragment has one or more secondary amino bridged phenyl rings that may have 0-3 saturated C1-C4 alkyl substituents. In addition, a few of the substances have hydroxyl substituents on the phenyl ring, and one of the substances (EC 229-059-2) has a methylamino-substituent on the phenyl ring.



Via the EU Observatory for nanomaterials we note that some group members are listed in the FR and/or BE Nano inventories (EC 201-353-5, EC 204-155-7 and EC 204-909-5). This information is not reflected in the registration dossiers of these substances[3]. Consequently, there is uncertainty whether those substances are manufactured or imported in the European Union as nanoforms. The REACH Regulation (as amended by Regulation Commission Regulation (EU) 2018/1881) sets out explicit information requirements for nanoforms of substances. Manufacturers and importers of nanoforms should meet these specific information requirements as of 1 January 2020. However, as the registration dossiers currently submitted on the substances do not cover any nanoforms, the present assessment relates only to non-nanoforms.

Based on information reported in the REACH registration dossiers, the substances in the group are mainly used as pigment, dye or as a fuel additive (as a marker for tax purposes). Pigments or dyes are used in polymer preparations, coatings and paints, inks and toners, photo-chemicals, finger paint, paper/board treatment, textile dyes, leather treatment, and laboratory chemicals. There is potential for exposure and release for nearly all substances as professional, consumer and article uses are reported in registration dossiers. There is doubt over the uses indicated by one registrant for several of the substances. This sole registrant indicates mainly industrial uses as intermediate, biocide or process regulator (polymerisation), which is not in line with other registrations (often part of a joint submission), and not in line with what we would expect for this type of substance. Industry should update their registration dossiers and clarify whether, or not, the uses reported for these substances are supported. In the next iteration to this assessment of

[3] By 14 October 2021

regulatory needs, if no update of the registration dossiers has been submitted, those uses will be considered to be of relevance, and if the potential hazard properties confirmed, then further regulatory risk management will be considered.

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 further EU regulatory risk management (restriction and authorisation) as the main hazards identified are potential carcinogenicity and/or potential PBT/vPvB for all substances in the group, and two of the substances (EC 201-353-5 & EC 229-059-2) are likely skin sensitisers.

Based on ECHA's assessment of currently available information, all the substances in the group are flagged as having potential carcinogenicity based on the presence of the Anthraquinone moiety (Anthraquinone, EC no. 201-549-0, CLH: Carc. 1B). At this stage, there is no information indicating the interlink of some of the substances with the anthraquinone regarding carcinogenicity. Despite the lack of data and the uncertainty on the metabolic pathway of the group, the substances are considered potentially carcinogenic (as a worst-case assumption). Depending on the outcome of the data generation under CCH, further data generation on carcinogenicity might need to be considered.

Compliance check is envisaged for all the substances subject to registration under Article 10 to REACH, due to uncertainties on these hazards arising from unreliable data, incorrect adaptations and uncertainties due to solubility issues. Substance evaluation (SEv) may be considered later on as a possibility to follow the carcinogenicity concern but this will be investigated after the compliance check.

Furthermore, all members in the group fulfil the screening PBT/vPvB criteria[4]. All group members are not readily biodegradable and therefore screen as potentially P/vP. There are uncertainties on their bioaccumulation potential based on their log Kow (screening criteria for B/vB) and QSAR estimation. The estimations of either Kow and BCF have a low reliability in the absence of data generated on pigments in the family of Anthraquinone. Furthermore the QSAR used, have been applied outside of their applicability domain for the family of Anthraquinone. Despite the high uncertainty and coefficient of variations of the QSAR tools, the estimations provided would nevertheless support a potential for bioaccumulation. All substances are therefore considered as potential PBT/vPvB substances. Compliance check is envisaged for all group members subject to registration under Article 10 to REACH to clarify these properties.

If the potential carcinogenicity and PBT/vPvB properties are confirmed then restriction is proposed to address consumer and professional uses which are widespread in coatings, paints, inks and toners, and industrial uses and article service life.

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazards via harmonised classification (CLH) as carcinogen 1 and SVHC identification for the PBT/vPvB properties.

CLH i) will trigger company level risk management measures (RMM) under OSH legislation for workers, 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 28.

Use in textiles, leather and fur may be restricted for CMR category 1 classified substances via entry 72 (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

When developing the harmonised classification proposals for carcinogenicity, it is suggested to consider adding skin sensitisation for one substance (EC 201-353-5) used in textile dyes and leather treatment. Even if this substance is concluded as not carcinogenic after clarification of the hazard, the classification as skin sensitiser would ensure the substance to be subject to the proposed[5] restriction on the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances.

SVHC identification will trigger (i) supply chain communication and (ii) substances in articles requirements.

Releases to the environment from consumer uses cannot be avoided. Professional use is typically widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with typically 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.

Furthermore, widespread professional uses are typically non-contained and non-automated leading to releases to the environment. In addition, potential for exposure and releases to the environment from articles cannot be excluded.

Therefore, a **restriction of the substances as such or in mixtures (concentration limit in mixtures)** used by consumers, professional workers and industrial workers, is suggested after CLH and SVHC identification, with the aim to

[4] As defined in REACH Annex XIII and R11 Guidance on PBT assessment (https://echa.europa.eu/documents/10162/17224/information_requirements_r11_en.pdf/)

[5] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e182446136

protect consumers and workers and minimise as much as possible the releases to the environment. Moreover, restricting substances used in articles is also proposed.

In addition, the use of the most harmful substances by consumers and professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability[6] which aims to extend to some new hazard classes and to professional users under REACH the level of protection granted to certain hazard classes (CMRs) and consumers.

It is suggested to cover possibly also industrial uses as part of the restriction. However, the need for authorisation might be considered for industrial uses excluded from the scope of the restriction as it may not be proportionate to restrict all uses.

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.

Please note that a CEFIC-ECHA project[7] is ongoing in parallel, under which companies are undertaking dossier improvement actions with the aim to generate data to address compliance issues. In this context, registrants of these substances (EC 201-398-0, 204-909-5, 255-460-7, 251-178-3, 204-155-7, 225-443-9) informed of a testing strategy and have submitted testing proposals. The information generated, if present in the registrations, will be taken into account on deciding on the needs for compliance checks in the future.

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

[7] https://echa.europa.eu/es/echa-cefic-collaboration-on-dossier-compliance

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
204-155-7, **204-909-5,** **229-059-2,** **201-353-5** **201-398-0,** **225-443-9,** **251-178-3,** **255-460-7,** **445-710-5** **242-939-0**	Known or potential hazard for carcinogenicity for skin sensitisation (for EC 229-059-2 and 201-353-5)	Known or potential hazard for PBT/vPvB	Use as pigment or dye, with potential exposure from professional and consumer (and article) uses for EC 204-155-7, 204-909-5, 229-059-2. For EC 201-353-5 there is use in textile dyes. Industrial or professional use as pigment/dye or lab chemical (no consumer uses) for EC 201-398-0, 225-443-9, 251-178-3, 255-460-7, 445-710-5. Industrial use of EC 445-710-5 as a marker in fuel (resulting in <0.1% concentration in the fuel for professional/ consumer uses.	**Need for EU RRM: Restriction** <u>Justification:</u> The harmonised classification as carcinogenic 1 would trigger the restriction entry 28 and by that ensure that the substances are not included in consumer mixtures above the limits specified in that entry. Releases to the environment from consumer and widespread professional uses cannot be avoided. Professional use is typically widespread (at many sites and many users) with relatively low	**First step:** CCH For EC 242-939-0 wait for the CCH for the other substances. For EC 201-398-0, 204-909-5, 255-460-7, 251-178-3, 204-155-7, 225-443-9 wait for ongoing actions under the CEFIC-ECHA project. **Next steps:** CLH for carcinogenicity (including Skin Sens for EC 201-353-5) SVHC identification Restriction

			EC 242-939-0 is C&L notified but not registered (no uses).	levels of operational controls and risk management measures but with typically frequent exposures with a long duration. Widespread professional uses are also typically non-contained and non-automated leading to releases to the environment. Potential exposure and releases to the environment from articles cannot be excluded. Industrial uses to be considered as part of the restriction.	
229-792-8 **248-895-9**	Known or potential hazard for carcinogenicity	Known or potential hazard for PBT/vPvB	Substances claimed to have only industrial intermediate uses however this is doubtful based on the nature of the substances (being dyes/pigments). Suspected use as pigment/dye with potential exposure from industrial, professional and consumer (and article) uses.	**Need for EU RRM:** **Restriction** **Authorisation** Justification: Combination of professional/consumer exposure and substances having carcinogenicity potential due to their Anthraquinone structure. Both substances are also likely PBTs.	**First step:** CCH **Next steps:** CLH for carcinogenicity (including Skin Sens for EC 201-353-5) SVHC identification Restriction

Annex 1: Harmonised classifications and self-classifications reported by registrants (reporting performed on 06/09/2021)

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations[8]	Classification in C&L notifications[9]
201-353-5	*81-48-1*	1-hydroxy-4-(p-toluidino)anthraquinone *(Solvent violet 13)*		*Skin Sens. 1B H317* *Aquatic Chronic 4 H413*	*Skin Sens. 1 H317[4 out of 77]*
201-398-0	*82-16-6*	1,8-bis[(4-methylphenyl)amino]anthraquinone (“*Solvent Violet 36*”)			
204-155-7	*116-75-6*	*1,4-bis(mesitylamino)anthraquinone (“Solvent Blue 104”)*			
204-909-5	*128-80-3*	*1,4-bis(p-tolylamino)anthraquinone (“Solvent Green 3”)*			*Skin Sens. 1 H317[1 out of 64]* *STOT Rep. Exp. 2 H373[1 out of 64]* *Skin Irrit. 2 H315[11 out of 64]* *STOT Single Exp. 3 H335, affected organs: [3 out of 64]* *Eye Irrit. 2 H319[11 out of 64]* *STOT Single Exp. 3 H335, affected organs: respiratory system[2 out of 64]* *Carc. 2 H351[1 out of 64]* *Muta. 2 H341[1 out of 64]* *STOT Single Exp. 3 H335, affected organs: Respiratory System[3 out of 64]*
225-443-9	*4851-50-7*	*1,4-bis[[4-(1,1-dimethylethyl)phenyl]amino]-5,8-dihydroxyanthraquinone (“Solvent Green 28”)*			

[8] The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

[9] The column gives the additional classifications not found in registrations but found in active or inactive C&L notifications (without distinguishing them). For each classification this column also provides the number of C&L notifications that contain the classification out of the total number of C&L notifications received for the substance. A single C&L notification file submitted by a group of notifiers is only counted once.

251-178-3	*32724-62-2*	*1,4-bis[(2,6-diethyl-4-methylphenyl)amino]anthraquinone ("Reinblau BLW")*			*Muta. 2 H341[1 out of 16]* *Skin Sens. 1B H317[1 out of 16]*
255-460-7	*41611-76-1*	*1,4-bis[(2-ethyl-6-methylphenyl)amino]anthraquinone ("Reinblau RLW")*			*Skin Irrit. 2 H315[1 out of 5]* *STOT Single Exp. 3 H335, affected organs: [1 out of 5]* *Eye Irrit. 2 H319[1 out of 5]*
229-059-2	*6408-50-0*	*1-(methylamino)-4-[(3-methylphenyl)amino]anthraquinone*		*Skin Sens. 1A H317* *Aquatic Chronic 4 H413*	*STOT Single Exp. 3 H335, affected organs: lungs[2 out of 7]* *Skin Irrit. 2 H315[2 out of 7]* *Eye Irrit. 2 H319[2 out of 7]*
229-792-8	*6737-68-4*	*1,4-bis[(2-methylphenyl)amino]anthraquinone*			
242-939-0	*19286-75-0*	1-anilino-4-hydroxyanthraquinone			
248-895-9	*28198-05-2*	1,4-bis[(4-butylphenyl)amino]-5,8-dihydroxyanthraquinone			
445-710-5	108313-21-9	9,10-Anthracenedione, 1,4,5,8-tetrakis[(4-butylphenyl)amino]-			

Annex 2: Overview of uses based on information available in registration dossiers 06/09/2021)

Main types of applications structured by product or article types	445-710-5	229-792-8	201-398-0	229-059-2	201-353-5	225-443-9
PC 11: Explosives						
PC 13: Fuels*	F, I, P, C					
PC 32: Polymer preparations and compounds			F, I		F, I, P, C, A	F, I
PC 9c: Finger paint					F, I, P, C	
PC 9a: Coatings and paints, thinners, paint removes					F, I, P, C	
PC 18: Ink and toners				F, I, P, C	F, I, P, C	F
PC 26: Paper and board treatment products					F, I, P, C, A	
PC 34: Textile dyes, and impregnating products					F, I, P, C, A	
PC 23: Leather treatment products					F, I, P, C, A	
PC 21: Laboratory chemicals			I, P		P	P
PC 19: Intermediate		I**	F, I**			
PC 30: Photo-chemicals				P, C		

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

* PC 13: The Substance is formulated into fuel at a level less than 0.1%. It acts as a marker for tax purpose. This use covers the use of the Fuel into which the marker has been formulated.(Professional and consumer uses are considered to be of the mixture, overreported in the registration)
** One registrant has claimed mainly industrial intermediate uses for a number of substances, which is neither consistent with other registrants, nor with the nature of the substances in the group being pigments or dyes.

Main types of applications structured by product or article types	248-895-9	251-178-3	204-155-7	255-460-7	204-909-5
PC 11: Explosives***					F, I, P
PC 13: Fuels		F		F	F
PC 32: Polymer preparations and compounds		F, I, A	F, I, P, C, A	F, I, A	F, I, P, C, A
PC 9c: Finger paint			F, I, P, C		F, I, P, C
PC 9a: Coatings and paints, thinners, paint removes			F, I, P, C		F, I, P, C
PC 18: Ink and toners		F	F, I, P, C	F	F, I, P, C
PC 26: Paper and board treatment products					
PC 34: Textile dyes, and impregnating products					
PC 23: Leather treatment products					
PC 21: Laboratory chemicals		P	F, I, P	P	P
PC 19: Intermediate	I**		F, I**		
PC 30: Photo-chemicals					

*** PC 11 (EC 204-909-5) is used in pyrotechnic smoke generating products

Annex 3: Overview of completed or ongoing regulatory risk management activities (10/08/2021)

No regulatory risk management activities for any of the substances.