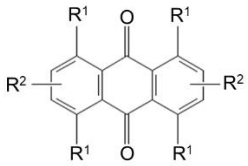
Assessment of regulatory needs

Authority: Swedish Chemicals Agency

Group Name: Primary amine and hydroxy anthraquinones

General structure:

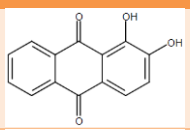
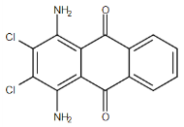
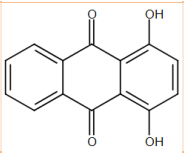
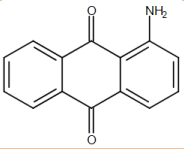
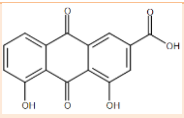
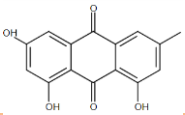
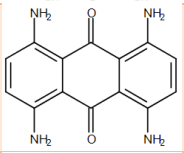
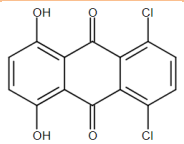
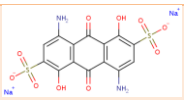


R^1 = -H, -OH or NH2, at least one -OH or -NH2
R^2 = various

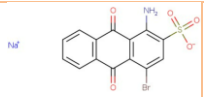
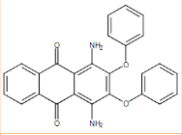
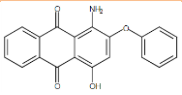
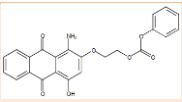
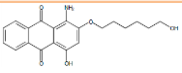
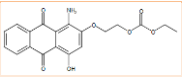
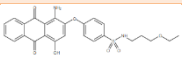
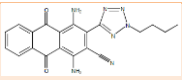
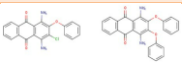
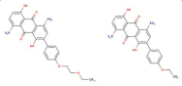
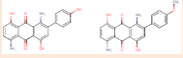
Revision history

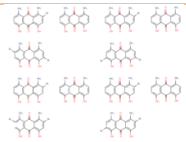
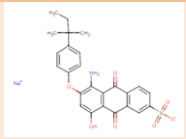
Version	*Date*	*Description*
1.0	3 May 2024	

Substances within this group:

EC/List number	CAS number	Substance name	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y)[1]
200-782-5	72-48-0	1,2-dihydroxyanthraquinone (Mordant red 11)		Ceased manuf.
201-348-8	81-42-5	1,4-diamino-2,3-dichloroanthraquinone (Disperse violet 28)		Ceased manuf.
201-368-7	81-64-1	1,4-dihydroxyanthraquinone (Solvent orange 86)		Full, 10-100 T
201-423-5	82-45-1	1-aminoanthraquinone		TII or OSII
207-521-4	478-43-3	9,10-dihydro-4,5-dihydroxy-9,10-dioxoanthracene-2-carboxylic acid		TII or OSII
208-258-8	518-82-1	1,3,8-trihydroxy-6-methylanthraquinone		C&L
219-603-7	2475-45-8	1,4,5,8-tetraaminoanthraquinone (Disperse blue 1)		C&L
220-599-4	2832-30-6	1,4-dichloro-5,8-dihydroxyanthraquinone		TII or OSII
220-678-3	2861-02-1	Disodium 4,8-diamino-1,5-dihydroxy-9,10-dioxoanthracene-2,6-disulphonate (Acid blue 45)		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

228-391-5	6258-06-6	Sodium 1-amino-4-bromo-9,10-dioxoanthracene-2-sulphonate		TII or OSII
229-066-0	6408-72-6	1,4-diamino-2,3-diphenoxyanthraquinone (Solvent Violet 59)		Full, 10-100 T
241-442-6	17418-58-5	1-amino-4-hydroxy-2-phenoxyanthraquinone (Disperse red 60)		Full, 10-100 T
248-882-8	28173-59-3	2-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthryl)oxy]ethyl phenyl carbonate (Disperse red 302:1)		Full, not (publicly) available
251-889-9	34231-26-0	1-amino-4-hydroxy-2-[(6-hydroxyhexyl)oxy]anthraquinone (Disperse red 91)		Full, not (publicly) available
254-959-7	40530-60-7	2-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthryl)oxy]ethyl ethyl carbonate (Disperse red 302)		Full, not (publicly) available
276-602-4	72363-26-9	4-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthryl)oxy]-N-(3-ethoxypropyl)benzenesulphonamide (Disperse red 92)		Full, 10-100 T
401-470-3	93686-63-6	1,4-diamino-2-(2-butyltetrazol-5-yl)-3-cyanoanthraquinone (Disperse Blue 361)		NONS
423-220-2	12223-77-7	A mixture of: 1,4-diamino-2-chloro-3-phenoxyanthraquinone; 1,4-diamino-2,3-bis-phenoxyanthraquinone (Disperse violet 38)		NONS
483-400-1		[No public or meaningful name is available]	[No structure available]	NONS
600-569-0	104491-84-1	Reaction mass of 4,8-diamino-2-[4-(2-ethoxyethoxy)phenyl]-1,5-dihydroxy-9,10-anthraquinone and 4,8-diamino-2-(4-ethoxyphenyl)-1,5-dihydroxy-9,10-anthraquinone (Disperse blue 214)		Full, not (publicly) available
943-670-8		Reaction mass of 1,5-diamino-4,8-dihydroxy(4-hydroxyphenyl)anthraquinone and 1,5-diamino-4,8-dihydroxy-2-(4-methoxyphenyl)anthraquinone		Full, 1-10 T

944-699-9		Reaction products of 1,5-diaminoanthracene-9,10-dione and 1,8-diaminoanthracene-9,10-dione with bromine (Disperse blue 56, 1,5-diaminobromo-4,8-dihydroxy-9,10-anthracenedione, 31810-89-6)		Full, 10-100 T
944-856-1		sodium 5-amino-8-hydroxy-9,10-dioxo-6-(4-(tert-pentyl)phenoxy)-9,10-dihydroanthracene-2-sulfonate		Full, 1-10 T

This table contains also group members that are only notified under the CLP Regulation, however, the list is not necessarily exhaustive.

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. Assessments 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 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
ED	Endocrine disruptor
NONS	Notified new substances
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
(Q)SAR	Quantitative/qualitative structure activity relationships
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

The substances in the group "primary amine and hydroxy anthraquinone" are anthraquinones and have the following structural features:

- Anthraquinones with -NH_2 and/or -OH in positions 1,4,5 or 8
- Other substituents in positions 2,3,6 and 7
- Non-substituted Ar-NH_2 (i.e. primary amines in the group only)

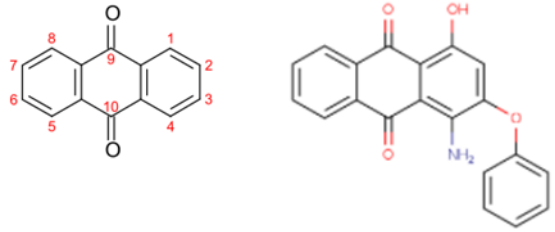


Figure 1. Anthraquinone (left) and EC 241-442-6 - disperse red 60 (right) as representative of the subgroup of "primary amine and hydroxy anthraquinone".

21 substances have REACH registrations, 14 of which are full registrations, 4 intermediate registrations and 3 non-updated NONS. Two of the substances have only inactive registrations (ceased manufacture) and two have only C&L notifications. Most of the substances are well-defined mono-constituents. The chemical identity of the substances is clear and consistent with the identifiers.

Based on information reported mainly in the REACH registration dossiers, the anthraquinones are colorants where the main uses are for dyeing of textiles, leather and paper. Article service life is relevant for these uses and for textile and leather dyeing often also professional and/or consumer uses are reported. These uses are reported for a majority of the (non-intermediate) substances and imply high potential for exposure to humans and release to the environment, especially from consumer and professional uses but also potentially from article service life. Some additional uses include uses in inks and toners, as well as in polymers.

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

Read-across is extensively applied by registrants both within the group but also from substances outside the current group definition. Although the substances within the group share similarities in terms of structure, no clear trends were observed for human health nor environmental endpoints. Therefore, it was generally not feasible to extrapolate amongst group members and the following conclusions are primarily based on data provided for individual substances. It was also not considered relevant to include an assessment of the potential for substitution as the substances are colorants where variations in substitution patterns affects colour and/or uses.

During screening we observed potential for PBT/vPvB or skin sensitisation; about half of the substances in the group have potential PBT/vPvB properties. For some of the substances a potential for reproductive toxicity and ED for human health or mutagenicity was also identified. The potential for carcinogenicity was investigated for the substances in the group based on the presence of the anthraquinone moiety,

however, our assessment did not indicate a general concern for carcinogenicity for the group. Additional hazard endpoints were screened in the assessment and discussed below or indicated in the table in section 3 when relevant.

Based on available information, there is a need for EU regulatory risk management (restriction) for PBT/vPvB (EC 229-066-0, List 600-569-0, List 944-699-9) or PMT/vPvM (EC 220-678-3) substances with potential for release/exposure. Reported uses include professional or consumer uses and article service life for most substances, mainly in textiles or leather. For EC 220-678-3, EC 229-066-0 and List 944-699-9 additional or other uses are reported such as paper- and board treatment products. In this assessment, EC 220-678-3 with potential PMT/vPvM properties is treated similarly from a regulatory risk management perspective as substances with potential PBT/vPvB properties. Note, however, that for EC 220-678-3 only industrial and article service life in metal surface treatment products is reported and it could be that the substance may be tightly bound in certain matrices which needs consideration in a restriction proposal process.

EC 229-066-0, List 600-569-0 and List 944-699-9 all have screening information which indicate potential PBT/vPvB hazards, based on ready biodegradation test or inherent biodegradation test results and log K_{OW}-values > 4.5. However, there is no higher tier degradation simulation or bioaccumulation information to conclude on the hazards and these substances are therefore considered as potential PBT/vPvB substances. EC 220-678-3 has screening information which indicate potential PMT/vPvM hazard, based on ready biodegradation test and K_{OC} < 2 (predicted). Further data generation is required to confirm the hazards. Due to uncertainties on PBT/vPvB and PMT/vPVM properties, compliance check is proposed for the substances.

The first step of the regulatory risk management action proposed for EC 220-678-3, EC 229-066-0, List 600-569-0 and List 944-699-9, should the hazard exist, is the confirmation of PBT/vPvB or PMT/vPvM hazards via CLH under CLP (or SVHC identification under Reach). CLH or SVHC identification are 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.

When the PBT/vPvB or PMT/vPvM properties are confirmed, the restriction is proposed to address all uses with the aim to minimise releases to the environment. Professional uses are reported for all but one substance, in ink and toners or textiles, and expected to be widespread (many sites and by many users). Widespread professional uses are typically non-contained and non-automated leading to releases to the environment. Also, consumer uses are reported for EC 229-066-0 and potential exposure from articles needs further investigation. It is suggested to cover 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.

Based on hazard information available in the registration dossiers, complemented by (Q)SAR predictions, there is known or potential hazard for aquatic toxicity for 17 substances (EC 200-782-5, EC 201-348-8, EC 208-258-8, EC 219-603-7, EC 220-599-4, EC 220-678-3, EC 229-066-0, EC 241-442-6, EC 248-882-8, EC 251-889-9, EC 254-959-7, EC 276-602-4, EC 401-470-3, EC 423-220-2, EC 483-400-1, List 600-569-0, and List 944-856-1).

EC 401-470-3 and EC 423-220-2 are the only substances having harmonised classification (Aquatic Chronic 4). One substance is self-classified by the registrant

as Aquatic Acute 1 and Aquatic Chronic 1 (EC 201-368-7), one as Aquatic Chronic 1 (EC 200-782-5), one as Aquatic Chronic 3 (EC 220-678-3) and one as Aquatic Chronic 4 (List 944-856-1). CCH is proposed for some of the substances with known or potential hazard for aquatic toxicity but also for substances which are inconclusive as regards aquatic toxicity. It is expected that following data generation for aquatic toxicity registrants would adequately self-classify the substances. The self-classification will require company level risk management measures (RMM) for environment to be in place. It is therefore proposed that there is currently no need for EU-wide regulatory risk management based on aquatic toxicity.

Based on currently available information, there is also a need for EU regulatory risk management (restriction) for mutagenicity (EC 201-368-7, EC 248-882-8, EC 251-889-9 and EC 254-959-7) or reproductive toxicity and ED for human health (EC 201-368-7) for substances with potential for release/exposure. Reported uses include professional or consumer uses and article service life, mainly in textiles.

For mutagenicity, the substances have positive *in vitro* studies without follow-up tests. Hence, additional data is needed on the substances to conclude on mutagenicity hazard by CCH or the finalization of ongoing studies.

The potential for carcinogenicity was investigated for the substances in the group based on the presence of the anthraquinone moiety. Anthraquinone (EC 201-549-0, not in the scope of the current group) has a harmonised classification as Carc. 1B, H350, but was concluded by RAC as not warranting classification as mutagenic. Our assessment of the group did not indicate a concern for carcinogenicity except for EC 219-603-7 which also has a harmonised classification as Carc. 1B and seems to cause tumours of similar type and location as those observed for anthraquinone[5]. The substance has no harmonised classification for mutagenicity, is not registered and no experimental data on mutagenicity were available for screening. The type and degree of substitution on the anthracene substructure is a major determining factor with regards to mutagenic and carcinogenic potential and site of action, and hence simple read-across from these compounds warrants caution (RAC opinion on anthraquinone, 2015)[6]. There are data from long-term NTP studies of EC 208-258-8 in rats and mice available[7], however, the data were considered as equivocal evidence in male mice by NTP based on a low incidence of uncommon renal tubule neoplasms and would not meet the CLP criteria for classification for carcinogenicity on its own. Moreover, the findings were not similar with regards to type and location compared to anthraquinone. EC 208-258-8 is not registered and no data for mutagenicity were available for screening. Note that the conclusion on carcinogenicity in the current ARN contrasts the conclusion in the ARN on Aminoaryl anthraquinones[8]. In the latter, a worst-case assumption in the absence of experimental data on carcinogenicity was made and the potential for carcinogenicity was extrapolated on the basis of the presence of the anthraquinone moiety; for the current ARN analysis of the experimental data available for EC 208-258-8 does not explicitly support such extrapolation to all group members among the primary amine and hydroxy anthraquinones. It can however not be excluded that individual substances in the group may have carcinogenic potential. With regards to EC 219-603-7, an RMOA by NL MSCA finalized in 2011, concluded on no need for further RRM for the substance. Since the substance is still only notified to

[5] 15th Report on Carcinogens (nih.gov)

[6] RAC opinion on anthraquinone

[7] TR-493 (nih.gov)

[8] Assessment of regulatory needs (ARN), (GMT_282_arylamine_anthraquinones_Report_public.pdf)

the C&L Inventory, the current harmonized classification is considered a sufficient RRM and thus, no further regulatory action is proposed.

For EC 201-368-7 there is also a potential for reproductive toxicity hazard and ED for human health. This is due to effects on the oestrus cycle in combination with observed estrogenic activity based on read-across by the registrants from the structurally similar substances EC 208-258-8 (C&L notification) and EC 200-782-5 (ceased manufacture). For EC 208-258-8 there are data from a 14-weeks NTP study in rats showing that the oestrous cycle length was significantly increased in females exposed to 1,250 or 5,000 ppm of the substance via diet. Estrogenic activity is reported for both EC 208-258-8 (receptor binding and transactivation) and EC 200-782-5 (receptor binding). There are also data from developmental toxicity studies of EC 208-258-8 in rats and mice reporting significant reduction in the average fetal body weight per litter in mice at high dose (6000 ppm or 1005 mg/kg/day). For EC 229-066-0 and EC 248-882-8 there are negative Reproduction/Developmental Toxicity Screening Tests/ Combined Repeated dose toxicity study (OECD TG 421 and OECD TG 422), respectively, available. For the other substances in the group with potential for release/exposure there are no experimental reproductive toxicity data available or read-across (of unconfirmed acceptability) to negative studies of substances outside the group is applied. Extrapolation of reproductive toxicity and ED for human health for the substances in the whole group was therefore not done due to uncertainties in predicted properties attributable to differences in type and degree of substitution on the antracene moiety. The potential hazards identified for EC 201-368-7 should be clarified through CCH (evaluation of the read-across adaptation), possibly followed by SEv.

Should the potential mutagenicity or reproductive toxicity and ED (human health) hazards be confirmed for EC 201-368-7, EC 248-882-8, EC 251-889-9 and EC 254-959-7, CLH is proposed as a first step towards restriction. CLH i) will require company level risk management measures (RMM) under the occupational safety and health (OSH) legislation 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 (reported for EC 251-889-9), by means of restriction entry 30.

Furthermore, CLH is also a prerequisite to restrict the presence of the substances in clothing and other textiles, and footwear articles, by means of restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)); EC 201-368-7, EC 248-882-8, EC 251-889-9, EC 254-959-7 is reported to be used in textiles. Subsequently a **restriction of the substances as such or in mixtures (concentration limit in mixtures)** used by professional workers and industrial workers, is suggested. Moreover, restricting substances used in articles other than textiles (relevant for EC 201-368-7) could be considered.

For EC 241-442-6 and List 943-670-8 with skin sensitisation hazard only, **harmonised classification** is proposed (ongoing for EC 241-442-6). The proposal for harmonised classification of EC 241-442-6 as Skins Sens. 1A was based on data from a GPMT (OECD TG 406) demonstrating a positive response in 100% of the animals following the use of a 1% intradermal induction dose of the substance. For List 943-670-8 read-across from EC 241-442-6 for skin sensitization was used in the registration. For consumers, there is a need to investigate whether further regulatory actions are needed and what would be the best options to address a concern. Work is currently ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on the substance. For article service life, harmonized classification as a skin sensitizer would ensure that the substances are within the suggested scope of the upcoming restriction from FR/SE

on skin sensitisers in textile, leather, hide and fur. For other article service life (i.e. paper and paper board) it should be identified whether releases from such materials lead to exposure and whether there is a need for restriction of such uses.

No hypothesis can be built for EC 276-602-4, NONS 401-470-3 and NONS 483-400-1 as there is not sufficient information to conclude on the absence or presence of hazard and/or exposure. Compliance check is proposed for EC 276-602-4 due to uncertainties in skin sensitization properties arising from unreliable data or uncertainties in read-across adaptations. If the hazard is confirmed by data generation or read-across adaptations, classification may be in need of harmonisation on the basis of reported uses in textile and/or leather and will subsequently be covered by the restriction on skin sensitisers in clothing and other textiles (upcoming restriction). NONS 401-470-3 and NONS 483-400-1 are proposed for substance evaluation as they are potential PBT/vPvB substances with no information on uses but with screening information which indicate potential PBT/vPvB hazards, based on experimental biodegradation test results and log K_{OW}-values > 4.5. However, there is no higher tier degradation simulation or bioaccumulation information to conclude on the hazards and these substances are therefore considered as potential PBT/vPvB substances.

There is **no need for EU regulatory risk management** for List 944-856-1 with low hazard based on existing data. CCH is motivated to confirm low hazard. For 241-442-6 EU RRM (harmonised classification) is ongoing. There is also no need for EU regulatory risk management for any of the substances with potential or inconclusive concern for PBT/vPvB and/or skin sensitisation and/or mutagenicity and/or reproductive toxicity with no information on uses, only intermediate registrations or only notified in the C&L inventory (EC 201-423-5, EC 207-521-4, EC 208-258-8, EC 219-603-7, EC 220-599-4, EC 228-391-5, NONS 401-470-3). In addition, no further regulatory risk management is considered needed for substances with inactive registrations (EC 200-782-5 and EC 201-348-8) or for NONS 423-220-2. The strategy may need to be revisited and the need for further regulatory action reconsidered if registration status changes or if uses are reported.

3 Conclusions and proposed 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. 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. Compliance check and/or substance evaluation are proposed for all substances (when relevant) irrespective of tonnage.

Substance(s) (EC/List number, name)	***Human Health Hazard***	***Environmental Hazard***	***Relevant use(s) & exposure potential***	***Last foreseen action***	***Action***
220-678-3 229-066-0 600-569-0 944-699-9	Known or potential hazard for skin sensitisation for 944-699-9 Inconclusive hazard for skin sensitisation for 229-066-0 and 600-569-0 Inconclusive hazard for mutagenicity for 600-569-0	Known or potential hazard for PBT/vPvB for 229-066-0, 600-569-0, 944-699-9 Known or potential hazard for PMT/vPvM for 220-678-3 Known or potential hazard for aquatic toxicity for 220-678-3, 229-066-0, 600-569-0 Inconclusive hazard for aquatic toxicity for 944-699-9	High exposure potential for workers and/or consumers and the environment: industrial, professional and/or consumer uses. Frequently used in textiles or paper articles. For EC 220-678-3 only industrial uses as adsorptive dyeing of metals.	**Need for EU RRM: Restriction** Justification: Releases to the environment from consumer or widespread professional uses cannot be avoided (except for 220-678-3 with only industrial uses and articles). Potential exposure and releases to the environment from articles cannot be excluded. Industrial uses to be considered as	**First step:** CCH **Next steps (if hazard is confirmed):** CLH (or SVHC identification)

				part of the restriction.	
201-368-7 248-882-8 251-889-9 254-959-7	Known or potential hazard for mutagenicity. For 201-368-7 also known or potential hazard for reproductive toxicity and ED Inconclusive hazard for skin sensitisation for 201-368-7	Known or potential hazard for ED for 201-368-7 Inconclusive hazard for PBT/vPvB Known or potential hazard for aquatic toxicity for 248-882-8, 251-889-9, 254-959-7 Inconclusive hazard for aquatic toxicity for 201-368-7	High exposure potential for workers: several industrial and professional uses. Article service life in textile, leather and paper.	**Need for EU RRM: Restriction** Justification: Restriction for professional uses to give a high level of protection in line with the chemical strategy for sustainability, industrial uses and articles (other than textiles covered by entry 72 of REACH) to be considered as part of the restriction.	**First step:** CCH potentially followed by SEv for EC 201-368-7 **Next step (if hazard is confirmed):** CLH
943-670-8	Known or potential hazard for skin sensitisation	Inconclusive hazard for PBT/vPvB Inconclusive hazard for aquatic toxicity	High exposure potential for workers and consumers and the environment: industrial, professional and consumer uses in textile and leather dyeing. Article service life in textile, leather and paper.	**Need for EU RRM: CLH** Justification: Harmonised classification for skin sensitisation will restrict uses in textiles.	**First step:** CCH

276-602-4 401-470-3 483-400-1	Inconclusive hazard for skin sensitisation for 276-602-4	Known or potential hazard for PBT/vPvB for 401-470-3, 483-400-1 Known or potential hazard for aquatic toxicity for 276-602-4, 401-470-3, 483-400-1	For 276-602-4, high exposure potential for workers and/or consumers: industrial, professional and/or consumer uses in textile and leather dyeing. Article service life in textile, leather and paper. For 401-470-3 and 483-400-1 no information on uses.	**Currently not possible to assess the regulatory needs** Justification: Inconclusive hazard (276-602-4) or no exposure information (401-470-3 and 483-400-1).	**First step:** CCH for 276-602-4 SEv for 401-470-3, 483-400-1
200-782-5 201-348-8 201-423-5 207-521-4 208-258-8 219-603-7 220-599-4 228-391-5 241-442-6 423-220-2 944-856-1	Known or potential hazard for skin sensitisation for 200-782-5, 208-258-8, 219-603-7, 220-599-4, 228-391-5, 241-442-6 Known or potential hazard for reproductive toxicity and ED for 200-782-5, 208-258-8	Known or potential hazard for PBT/vPvB for 200-782-5, 201-348-8, 219-603-7, 220-599-4 Inconclusive hazard for PBT/vPvB for 201-423-5, 208-258-8, 241-442-6, 423-220-2 Inconclusive hazard for PMT/vPvM for 207-521-4	Intermediate registrations or C&L notifications, no other uses and low exposure potential. Ceased manufacture for 200-782-5 and 201-348-8.	**Currently no need for EU RRM** Justification: According to the reported uses, low potential for exposure to both human health and environment is expected. Actions (including data generation) will be re-considered when the	**First step:** CCH to confirm no/unlikely hazard for 944-856-1

	Known or potential hazard for carcinogenicity and for mutagenicity for 219-603-7	Known or potential hazard for ED for 200-782-5 Known or potential hazard for aquatic toxicity for 200-782-5, 201-348-8, 208-258-8, 219-603-7, 220-599-4, 241-442-6, 423-220-2, 944-856-1 Inconclusive hazard for aquatic toxicity for 201-423-5, 228-391-5		assessment will be revisited if the registration status and/or uses change. EU RRM ongoing for 241-442-6.	

Annex 1: Overview of classifications

Data extracted on 10 Jan 2024.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
200-782-5	72-48-0	1,2-dihydroxyanthraquinone	-	Eye Dam. 1 H318 Skin Sens. 1 H317 Aquatic Chronic 1 H410
201-348-8	81-42-5	1,4-diamino-2,3-dichloroanthraquinone	-	Acute Tox. 4 H302 Eye Irrit. 2 H319
201-368-7	81-64-1	1,4-dihydroxyanthraquinone	-	Aquatic Acute 1 H400, M-factor: 10 Aquatic Chronic 1 H410, M-factor: 10
201-423-5	82-45-1	1-aminoanthraquinone	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335 (respiratory tract)
207-521-4	478-43-3	9,10-dihydro-4,5-dihydroxy-9,10-dioxoanthracene-2-carboxylic acid	-	Skin Irrit. 2 H315 Eye Irrit. 2 H319 STOT SE 3 H335
208-258-8	518-82-1	1,3,8-trihydroxy-6-methylanthraquinone	-	-
219-603-7	2475-45-8	1,4,5,8-tetraaminoanthraquinone	Skin Irrit. 2 H315 Eye Dam. 1 H318 Skin Sens. 1 H317 Carc. 1B H350	-
220-599-4	2832-30-6	1,4-dichloro-5,8-dihydroxyanthraquinone	-	-
220-678-3	2861-02-1	Disodium 4,8-diamino-1,5-dihydroxy-9,10-dioxoanthracene-2,6-disulphonate	-	Aquatic Chronic 3 H412
228-391-5	6258-06-6	Sodium 1-amino-4-bromo-9,10-dioxoanthracene-2-sulphonate	-	Skin Sens. 1 H317
229-066-0	6408-72-6	1,4-diamino-2,3-diphenoxyanthraquinone	-	-
241-442-6	17418-58-5	1-amino-4-hydroxy-2-phenoxyanthraquinone	-	Skin Sens. 1A H317
248-882-8	28173-59-3	2-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthryl)oxy]ethyl phenyl carbonate	-	-
251-889-9	34231-26-0	1-amino-4-hydroxy-2-[(6-hydroxyhexyl)oxy]anthraquinone	-	-
254-959-7	40530-60-7	2-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthryl)oxy]ethyl ethyl carbonate	-	-

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
276-602-4	72363-26-9	4-[(1-amino-9,10-dihydro-4-hydroxy-9,10-dioxo-2-anthryl)oxy]-N-(3-ethoxypropyl)benzenesulphonamide	-	STOT RE. 2 H373(blood)
401-470-3	93686-63-6	1,4-diamino-2-(2-butyltetrazol-5-yl)-3-cyanoanthraquinone	Aquatic Chronic 4 H413	-
423-220-2	12223-77-7	A mixture of: 1,4-diamino-2-chloro-3-phenoxyanthraquinone; 1,4-diamino-2,3-bis-phenoxyanthraquinone	Aquatic Chronic 4 H413	-
483-400-1	-	[No public or meaningful name is available]	-	-
600-569-0	104491-84-1	Reaction mass of 4,8-diamino-2-[4-(2-ethoxyethoxy)phenyl]-1,5-dihydroxy-9,10-anthraquinone and 4,8-diamino-2-(4-ethoxyphenyl)-1,5-dihydroxy-9,10-anthraquinone	-	Skin Sens. 1 H317
943-670-8	-	Reaction mass of 1,5-diamino-4,8-dihydroxy(4-hydroxyphenyl)anthraquinone and 1,5-diamino-4,8-dihydroxy-2-(4-methoxyphenyl)anthraquinone	-	Skin Sens. 1A H317
944-699-9	-	Reaction products of 1,5-diaminoanthracene-9,10-dione and 1,8-diaminoanthracene-9,10-dione with bromine	-	Skin Sens. 1A H317
944-856-1	-	sodium 5-amino-8-hydroxy-9,10-dioxo-6-(4-(tert-pentyl)phenoxy)-9,10-dihydroanthracene-2-sulfonate	-	Aquatic Chronic 4 H413

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

Data for registered substances extracted on 10 Sep 2021, additional information extracted on 9 Jan 2024.

Main types of applications structured by product or article types	201-368-7	220-678-3	229-066-0	241-442-6	248-882-8	251-889-9	254-959-7	276-602-4	600-569-0	943-670-8	944-699-9	944-856-1
PC 34: Textile dyes, and impregnating products	F, I, P, A			F, I, P, C, A	F, I, P, A	F, I, P, C, A	F, I, P, A	F, I, P, C, A	I, P, A	F, I, P, C, A	F, I, P, A	F, I, P, A
PC 23: Leather treatment products	F, I, A			F, I, P, C, A				F, I, A		F, I, P, A	F, I, P, A	F, I, A
PC 26: Paper and board treatment products	F, I, A			F, I, C, A				F, I, A		F, I, A	F, I, A	F, I, A
PC 18: Ink and toners	F, I, P		F, I, P, C, A	F, I, P, C, A				F, I		F, I	F, I	F, I
PC 32: Polymer preparations and compounds	F, I, P		F, I, A	F, I, P, C, A				F, I		F, I	F, I	F, I
PC 24: Lubricants and greases	I, P			F								
PC 9a: Coatings and paints, thinners, paint removers	I, P			F, I, P, C								
PC 14: Metal surface treatment products	P	I, A										
PC 30: Photo-chemicals			P, C	P, C								
PC 21: Laboratory chemicals			P	F, 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

Data extracted on 8 Jan 2024.

EC/List No	RMOA, ARN	Authorisation		Restriction*	CLH	Actions not under REACH/ CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
241-442-6					YES	

*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.