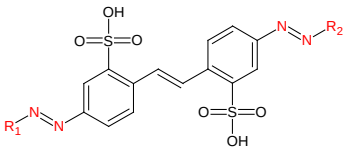
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

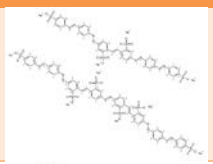
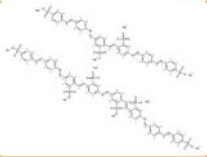
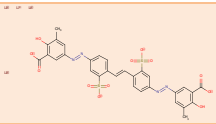
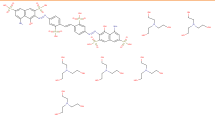
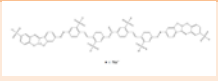
Group Name: Stilbenesulfonic acid diazo dyes

General structure: 

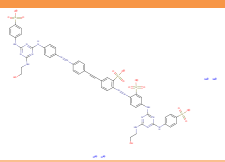
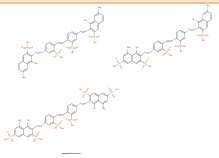
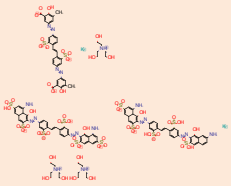
Revision history

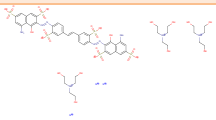
Version	*Date*	*Description*
1.0	26 June 2024	

Table 1. Substances within this group:

Sub-grouping	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]
Na salts	215-397-8*	1325-54-8	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, disodium salt, reaction products with 4-[(4-aminophenyl)azo]benzenesulfonic acid, sodium salts		Full, 100-1000
Na salts	680-250-0*	1325-54-8	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, disodium salt, reaction products with 4-[(4-aminophenyl)azo]benzenesulfonic acid, sodium salts		C&L notification
Na salts	215-403-9	1325-65-1	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, disodium salt, reaction products with 4-[(4-amino-1-naphthalenyl)azo]benzenesulfonic acid monosodium salt		Full, not (publicly) available
Na salts	256-783-6	50814-31-8	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, disodium salt, reaction products with 4-[(4-aminophenyl)azo]benzenesulfonic acid monosodium salt		Full, not (publicly) available
Li salts	258-605-2	53523-90-3	Tetralithium 5,5'-[vinylenebis[(3-sulphonato-4,1-phenylene)azo]]bis[3-methylsalicylate]		Full, 10-100
Triethanolamine salts	278-294-7	75701-36-9	3,3'-[ethylenebis[(3-sulpho-p-phenylene)azo]]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonic] acid, compound with 2,2',2''-nitrilotriethanol (1:6)		C&L notification
Na salts	290-714-0	90218-39-6	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, reaction products with 4-[(4-aminophenyl)azo]benzenesulfonic acid, reduced, oxidized, potassium sodium salts		Full, not (publicly) available
Na salts	290-715-6	90218-40-9	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, reaction products with 4-[(4-aminophenyl)azo]benzenesulfonic acid, reduced, oxidized, sodium salts		Not registered
Cu complex	400-020-3	82027-60-9	Hexasodium [4,4''-azoxybis(2,2'-disulfonatostilbene-4,4'-diylazo)]-bis[5'-sulfonatobenzene-2,2'-diolato-O(2),O(2),N(1)]-copper(II)		NONS

[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

Sub-grouping	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]
Na salts	429-230-3	371921-41-4	Tetrasodium 4,4'-bis{4-[4-(2-hydroxyethylamino)-6-(4-sulfonatoanilino)-1,3,5-triazin-2-ylamino]phenylazo}stilbene-2,2'-disulfonate		NONS
Triethanolamine salts	916-899-6	-	Reaction products of tetrazotized 5-amino-2-[(E)-2-(4-amino-2-sulfophenyl)ethenyl]benzenesulfonic acid with 6-amino-4-hydroxynaphthalene-2-sulfonic acid and 4-amino-5-hydroxynaphthalene-2,7-disulfonic acid in 2-[bis(2-hydroxyethyl)amino]ethanol		Full, not (publicly) available
Li salts	916-916-7	-	Reaction mass of lithium sodium 5-amino-3-{[4-(2-{4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)diazenyl]-2-sulfophenyl}vinyl)-3-sulfophenyl]diazenyl}-4-hydroxynaphthalene-2,7-disulfonate 2,2'-(methylimino)diethanol (1:1) and 3,3'-[vinylenebis[(3-sulpho-p-phenylene)azo]]bis[6-amino-4-hydroxynaphthalene-2-sulphonic] acid, lithium sodium salt, compound with 2,2'-(methylimino)diethanol and 3,3'-[vinylenebis[(3-sulpho-p-phenylene)azo]]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonic] acid, lithium sodium salt, compound with 2,2'-(methylimino)diethanol		Full, not (publicly) available
Li salts	939-992-3	1195028-55-7	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-nitro-, sodium salt (1:2), reaction products with 4-[2-(4-aminophenyl)diazenyl]benzenesulfonic acid, lithium sodium salts		Full, not (publicly) available
Cu complexes	943-210-6	-	Reaction product of disodium 4,4'-dinitrostilbene-2,2'-disulphonate, p-[(4-amino-2,5-xylyl)azo]benzenesulphonic acid, 3-[(4-amino-2-methoxyphenyl)azo]-4-hydroxybenzenesulphonic acid, copper (II) sulfate		Full, not (publicly) available
Triethanolamine salts	943-311-5	-	Reaction mass of 5,5'-[vinylenebis[(3-sulpho-p-phenylene)azo]]bis[3-methylsalicylic] acid, potassium salt, compound with 2,2',2''-nitrilotriethanol and potassium 5-amino-3-{[4-(2-{4-[(7-amino-1-hydroxy-3-sulfo-2-naphthyl)diazenyl]-2-sulfophenyl}vinyl)-3-sulfophenyl]diazenyl}-4-hydroxy-7-sulfonaphthalene-2-sulfonate - 2,2',2''-nitrilotriethanol (1:1) and 3,3'-[vinylenebis[(3-sulpho-p-phenylene)azo]]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonic] acid, potassium salt, compound with		Full, not (publicly) available

Sub-grouping	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]
			2,2',2''-nitrilotriethanol and 3,3'-[vinylenebis[(3-sulpho-p-phenylene)azo]]bis[6-amino-4-hydroxynaphthalene-2-sulphonic] acid, potassium salt, compound with 2,2',2''-nitrilotriethanol		
Triethanolamine salts	943-325-1	-	3,3'-[ethylenebis[(3-sulpho-p-phenylene)azo]]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonic acid] hexasodium salt AND 3,3'-[ethylenebis[(3-sulpho-p-phenylene)azo]]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonic] acid, compound with 2,2',2''-nitrilotriethanol (1:6)		Full, 10-100
Cu complexes	944-111-0	-	Reaction products of diazotized 4-aminobenzenesulfonic acid coupled with aniline, subsequently coupled with diazotized 2-aminobenzoic coupled with 7-amino-4-hydroxynaphthalene-2-sulfonic then reacted with (E)-6,6'(ethene-1,2-diyl)bis(3-nitrobenzenesulfonic acid), chelated with copper, sodium salt		Full, not (publicly) available
Na salts	944-247-0	-	Reaction products of condensation between disodium 4,4'-dinitrostilbene-2,2'-disulfonate and 4'-aminoazobenzene-4-sulphonic acid, sodium salts		Full, 1-10
Cu complexes	944-517-8	-	Reaction products of 3-amino-4-hydroxybenzenesulfonic acid with 2,5-Dimethoxyaniline , condensed with 4, 4'-dinitrostilbene-2,2'-disulfonic acid, chelated with copper, sodium salt		Full, 1-10
Cu complexes	950-102-2	-	Reaction products of 3-amino-4-hydroxybenzenesulfonic acid with 2,5-Dimethoxyaniline , the intermediate is than condensed with 4, 4'-dinitrostilbene-2,2'-disulfonic acid, chelated with copper, potassium salt		Full, not (publicly) available
Na salts	950-134-7	-	Reaction products of diazotized 3-amino-4-hydroxybenzenesulphonic acid with 2,5-dimethoxyaniline, subsequently condensed with 4,4'-dinitrostilbene-2,2'-disulphonic acid, sodium salts		OSII or TII

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

(*) When a dossier is submitted without EC/List no, REACH-IT automatically assigns a List no to the dossier. Sometimes, due to IT technical limitations, duplicate List no's are created. In this group the following are considered duplicate entries: EC no 215-397-8 and List no 680-250-0. In general, EC no's take precedence over List no's.

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.

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].

[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).

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

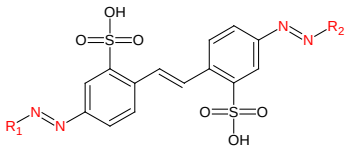
Glossary

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
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

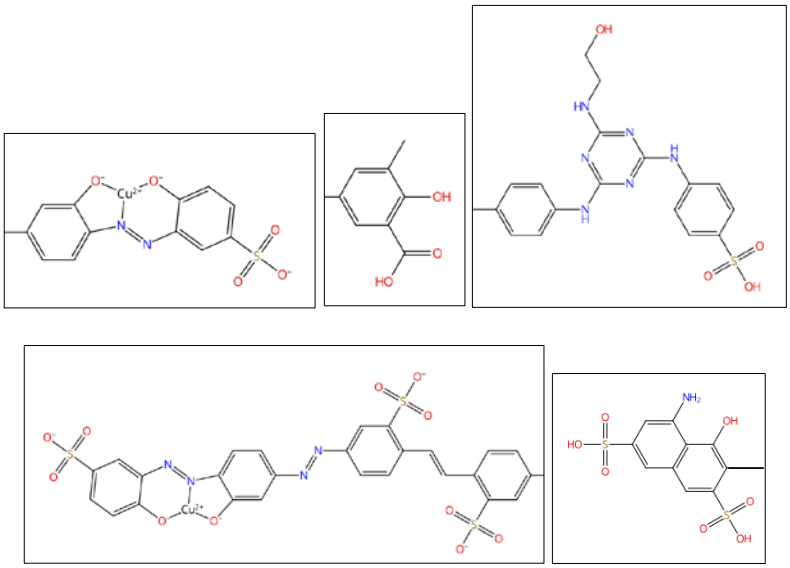
Explanations on the scope of this assessment is available in the foreword to this document. Please read it carefully before going through the report.

ECHA has grouped together structurally similar substances based on the presence of the stilbenedisulfonic acid moiety (sulfonic acid groups in ortho position) with an azo group in para positions, as shown in the figure below. The substances belonging to the group are called stilbene dyes and are "direct dyes"[5].



The R_1 and R_2 substituents on the azo bond are aromatic groups variously substituted, including additional azo bonds in para position, further linked to aromatic moieties and additional stilbenedisulfonic acid groups. R_1 and R_2 may therefore be very bulky grups. R_1 and R_2 can be the same, or different.

Below are a few examples of different R groups:



The substances are salts: sodium, lithium and triethanolamine salts (also as a combination). Some of the substances are copper chelated. The introduction of copper often increases considerably the light- and wetfastness of the dyes, since complexing blocks the hydrophilic groups, and improve the absorption into the substrate [6].

[5] Dyes that can be applied without the use of a mordant.

[6] Light Fastness: the standard measures the resistance to fading of dyed or printed textile colours when exposed to daylight. The higher the number the longer the printed or dyed colours in the fabric will stay true to the original.

The group members were subgrouped as indicated in Table 1:

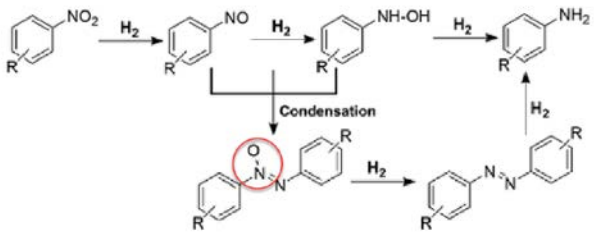
Subgroup 1: sodium salts

Subgroup 2: copper complexes

Subgroup 3: lithium salts

Subgroup 4: triethanolamine salts.

Some of the substances present an azoxy moiety, which is formed during the formation of the diazo bond.



There are 20 substances in the group of which 15 with full registrations, 1 intermediate, 2 NONS and other 2 not registered substances. A third not registered substance is a duplicate.

Based on information reported in the REACH registration dossiers, the substances in this group are used as dyes, covering a wide range of applications. The most common applications are in inks and toners, leather treatment products, paper and board treatment products, textile dyes and impregnating products, and in polymer preparations. All but one of the substances are used in professional products, and nine of the substances are also used in consumer products. Most have also article service life indicated. The use pattern is the same, regardless of which cation the salt/complex contains. These uses can lead to exposure of humans, and releases to the environment are likely. One substance (List 950-134-7, a Na-salt) is only indicated for use as intermediate.

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 number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
Subgroup 1, 'sodium salts' 215-397-8 + 215-403-9 256-783-6 290-714-0 290-715-6 429-230-3* 680-250-0+* 944-247-0 950-134-7* + duplicates	No hazard or unlikely hazard	Inconclusive hazard for PBT/vPvB and PMT/vPvM	Dyes used for textiles, paper, leather and inks High potential for exposure from consumer use of dyes and dyed articles * no consumer or professional uses or use not known	**First step:** Pending Action CCH for EC 215-397-8 **Potential last action:** **Currently not possible to assess the regulatory needs** Justification: It is not possible to assess the needs for regulatory risk management for Subgroup 1 substances as information on hazard is not sufficient to conclude on PBT/vPvB and PMT/vPvM. The needs for regulatory risk management actions will be assessed once generation of data for subgroup members is completed.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
Subgroup 2, 'copper complexes' 400-020-3* 943-210-6 944-111-0 944-517-8 950-102-2	Known or potential hazard for reproductive toxicity for 943-210-6	Known or potential hazard for aquatic toxicity for 943-210-6. Inconclusive hazard for PBT/vPvB and PMT/vPvM	Dyes used for textiles, paper, leather and inks High potential for exposure from consumer use of dyes and dyed articles * no consumer or professional uses or use not known	**First step:** CCH for EC 943-210-6 **Potential next step (if hazard confirmed after data generation):** CLH for EC 943-210-6 **Potential last action:** Restriction for EC 943-210-6 Justification: The reported professional uses are widespread (at many sites and many users) with relatively low levels of operational controls and risk management measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be more efficient and effective to introduce controls at the level of placing on the market rather than at the level of uses. Potential exposure from articles needs further investigation, restriction for use in articles to be considered together with the restriction of professional uses.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the 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)). Due to low hazard, no need for further regulatory risk management is indicated for any of the other substances in this subgroup.
Subgroup 3, 'lithium salts' 258-605-2 916-916-7 939-992-3	Known or potential hazard for reproductive toxicity	Inconclusive hazard for PBT/vPvB and PMT/vPvM except List 916-916-7	Dyes used for textiles, paper, leather and inks; coatings and paints High potential for exposure from consumer use of dyes and dyed articles	**First steps:** CCH for EC 939-992-3 CLH **Potential last action:** Restriction <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 measures but with often frequent exposures with a long duration. Restriction of professional uses is preferred over authorisation as it is considered to be

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				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. CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the 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)).
Subgroup 4, 'triethanolamine salts' 278-294-7* 916-899-6 943-311-5* 943-325-1	Known or potential hazard for skin sensitisation for List 943-325-1, 916-899-6	Known or potential hazard for aquatic toxicity for 916-899-6. Inconclusive hazard for PBT/vPvB and PMT/vPvM	Dyes used for textiles, paper, leather and inks; coatings and paints High potential for exposure from consumer use of dyes and dyed articles * no consumer or professional uses or use not known	**First steps:** CCH for List 916-899-6 CLH for List 943-325-1, 916-899-6 **Potential last action:** Restriction for List 943-325-1, 916-899-6 <u>Justification</u>: Harmonised classification as skin sensitiser would be needed for the future restriction on the use of skin sensitiser substances in textile, leather, fur and hide articles.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
				Consider restriction for professional uses and for other articles than textiles and leather articles. Due to low hazard, no need for further regulatory risk management is indicated for any of the other substances in this subgroup.

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

Suggested regulatory risk management action for subgroups 2 (copper complex, List 943-210-6) (if the reproductive toxicity hazard is confirmed), 3 (lithium salts, all substances), and 4 (triethanolamine salts, List 916-899-6 and 943-325-1).

The substances in the Li-salt subgroup have (potentially) the hazard of reproductive toxicity, due to the presence of the lithium ion. In ECHA's Risk Assessment Committee (RAC) opinion adopted 16 September 2021, based on experimental and human data, the RAC concluded for three inorganic lithium substances, lithium carbonate ($LiCO_3$, EC 209-062-5), lithium chloride (EC 231-212-3), and lithium hydroxide (LiOH, EC 215-183-4), that classifications as **Repr. 1A; H360FD, and Lact. H362** are warranted under the CLP regulation. The systemic toxicity including reproductive toxicity is determined by the lithium cation. The lithium cation remains unchanged in the body, and due to similarities with sodium and potassium cations it uses the sodium ion channels to reach target organs. For the subgroup members, the mass percentage of lithium, calculated in a worst case scenario and taking into account the water content of the substances, is above the threshold level of 0.3% for classification of mixtures according to CLP.

Furthermore, the substance List 943-210-6 in the Cu-complexes subgroup has potentially the hazard of reproductive toxicity.

Two substances in the triethanolamine salts subgroup are skin sensitisers; two out of the three available local lymph node assay (LLNA) studies for the subgroup members are positive. For the other member of the triethanolamine salts subgroup there is a negative LLNA study.

As indicated below, it was not possible to conclude on the PBT/vPvP and PMT/vPvM hazards of the substances in the group as there is not sufficient information to have a holistic view based on the available information for the substances, with the exception of List 916-916-7 which meets the criterion for ready biodegradability. The hazard potential will be re-evaluated after data generation suggested for the group members List 916-899-6, 939-992-3 and 943-210-6.

Subgroup 2:

The available information indicates potential for reproductive toxicity for the substance List 943-210-6 in subgroup 2, 'copper complexes'. The potential hazard should be verified by compliance check (also including verification of environmental fate and toxicity potential).

The first step of the regulatory risk management action, should the hazard be confirmed, would be the harmonised classification (CLH) as toxic to reproduction.

If harmonised classification as Repr. in Category 1 is confirmed, the use of the substance in consumer mixtures will be restricted under entry 30 of Annex XVII to REACH. Further, professional use is often widespread with relatively low levels of operational controls and risk management measures but often with frequent exposures with long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation. Therefore, a restriction of the substances as such and in mixtures (concentration limit in mixtures) used by professionals is suggested after CLH.

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

market rather than at the level of uses.

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability 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 should be considered in the context of the restriction of professional uses. It is known that EC 943-210-6 is used as dye in textile, paper and leather articles, thus leading to article service life indication. The uses are indicated as both industrial and professional. At industrial production stage, high levels of operational controls and risk management measures should be in place. Furthermore, environmental releases would be regulated and monitored based on the relevant environmental legislation.

It is proposed that, if reproductive toxicity is confirmed, a restriction be considered on the use of the substance for professional use especially as textile dye and use in textile articles. In relation to such a restriction for other types of articles, it should be noted that the substances may be tightly bound in certain matrices and thus exposure in such a situation may be low. Therefore, in the restriction proposal process, it should be clarified whether exposure to the articles can actually lead to releases and thus exposure to the substances. For textiles, the already existing restriction entry 72 could possibly be made use of.

Subgroup 3:

Currently available information indicates potential for reproductive toxicity due to the presence of the lithium ion in the substances of subgroup 3, 'lithium salts'.

Compliance check is suggested for the substance List 939-992-3 to verify the information available for human health and environmental fate and toxicity and request data where necessary.

An opinion from ECHA's Risk Assessment Committee (RAC) recommends the harmonised classification of three simple lithium salts (lithium content ranging from 9% to 29% w/w) [7] for their reproductive toxic properties. The classification is based on the intrinsic properties of the lithium cation. The lithium cation is also present in the substances of this subgroup, with a lithium mass concentration above the threshold for classification (about 0.6 Li mass % for List 916-916-7, 2.9 Li mass% for List 939-992-3, and about 4 Li mass % for EC 258-605-2).

It has been suggested to look at the possibility to classify all lithium salts substances together on the basis of the toxicity of the lithium cation, to ensure that all the relevant known and future substances would be classified as reprotoxic. However, bioavailability of the lithium cation may need to be taken into account in scoping the CLH entry, as more information on this property would be needed to address all lithium-containing substances.

Based on the above, for this group, there may be a need for harmonised classification as Repr. 1B due to the presence of lithium, based on the intrinsic properties of the lithium cation (Li^+) and applying the principle of classification based on the concentration of constituents. As the substances in the group are lithium salts, the release of the lithium cation is relevant for all the substances.

[7] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18270066e

If harmonised classification as Repr. 1B is agreed, the use of these substances in consumer mixtures will be restricted under entry 30 of Annex XVII to REACH. Further, professional use is often widespread with relatively low levels of operational controls and risk management measures but often with frequent exposures with long duration. In addition, professional users may be self-employed and therefore not covered by occupational safety and health (OSH) legislation. Therefore, a restriction of the substances as such and in mixtures (concentration limit in mixtures) used by professionals is suggested after CLH.

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

In addition, the use of the most harmful substances by professional workers has been recognised as an area of concern under the European Commission's Chemicals Strategy for Sustainability 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 should be considered in the context of the restriction of professional uses.

Subgroup 4:

The available information indicates potential for skin sensitisation for the substances Lists 916-899-6 and 943-325-1 in subgroup 4, 'triethanolamine salts'.

The first step of the regulatory risk management action is the harmonised classification (CLH) as skin sensitising.

Lists 916-899-6 and 943-325-1 are used as dyes in articles and in professional and consumer mixtures. The professional uses may indicate relatively low levels of operational controls and risk management measures, and consumer uses are subject to no operational controls. Furthermore, environmental releases may be significant from such uses.

Therefore, based on the skin sensitisation hazard, a restriction covering the professional uses as well as the use of these substances in textile articles is proposed. Textiles and leather containing skin sensitising substances, which come into contact with the skin, are already covered by an existing restriction proposal, on which there is a positive RAC/SEAC opinion from September 2020. Regarding paper articles, while the risk from paper products in general may be small, the use of these skin sensitising substances in papers intended for sanitary or otherwise skin contact use could be considered for a restriction.

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[8] which aims to extend to professional users under REACH the level of protection granted to consumers.

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

Currently not possible to suggest regulatory risk management actions for subgroup 1 'sodium salts' and substances in subgroup 2 'copper complexes' (except List 943-210-6), and EC 278-294-7 and List 943-311-5 of subgroup 4 'triethanolamine salts'.

Based on the data currently available, none of the substances in the group are likely to be mutagenic (negative *in vitro* studies for nine group members) or to have STOT RE hazard warranting classification; as well as carcinogenic or ED hazard (no indications in the available data).

Substances in subgroup 1 'sodium salts', subgroup 2 'copper complexes' (except List 943-210-6) and subgroup 4 'triethanolamine salts' are, based on the data currently available, unlikely to have reproductive toxicity hazard.

The substances in the Na-salt, Cu-complexes and Li-salt subgroups are unlikely to have the hazard of skin sensitisation (negative test results for the five substances with data in the subgroups). For subgroup 'triethanolamine salts' member List 943-311-5 there is also a negative LLNA study.

Based on the currently available data, it was not possible to conclude on the PBT/vPvP and PMT/vPvM hazards of the substances in the group, except for List 916-916-7, as there is not sufficient information to have a holistic view based on the available information for the substances. The substances are not readily biodegradable but no experimental biodegradation simulation data are currently available to confirm unlikely/no P/vP hazard. No experimental bioaccumulation data are currently available to confirm no B/vB hazard. Since the substances are ionisable, the reported low logKow's and QSAR estimated BCF values may not be appropriate screening information to indicate the low bioaccumulation potential. Furthermore, the potential mobility of the substances cannot be assessed as experimental adsorption/desorption data are not available. Therefore potential M/vM hazard cannot be ruled out based on currently available information.

It is not possible to assess the needs for regulatory risk management for these group members as information on hazard is not sufficient to conclude on PBT/vPvB and PMT/vPvM. Data generation is planned for EC 215-397-8 and certain other members of the different subgroups to clarify hazard for PBT/vPvB/PMT/vPvM for the substances in the subgroups. The needs for regulatory risk management actions will be assessed once generation of data is completed.

All of the substances are registered for use as dyes in paper, leather and/or textile treatment. In addition, the substances EC 215-397-8 and 256-783-6 are colourants allowed in cosmetic products but restricted to rinse-off products only in column g of Annex IV to the CPR. Both substances are indicated as components of the ingredient CI 40215. However, use in cosmetics has not been registered in any of the REACH registration dossiers.

Annex 1: Overview of classifications

Data extracted on 2/11/2022

EC / List No	CAS No	Substance name	Harmonised classification	Classification in registrations
215-397-8	1325-54-8		-	Skin Sens. 1 H317 (OO)
400-020-3	82027-60-9		Aquatic Chronic 2 H411	-
429-230-3	-		Eye Dam 1 H318	-
916-899-6	-		-	Skin Sens. 1B H317 Aquatic Chronic 3 H412
943-210-6	-		-	Aquatic Chronic 3 H412
943-325-1	-		-	Skin Sens. 1B H317

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

Data extracted on 2/11/2022

Main types of applications structured by product or article types	215-397-8	215-403-9	256-783-6	258-605-2	290-714-0	916-899-6	916-916-7	939-992-3	943-210-6	943-311-5	943-325-1	944-111-0	944-247-0	944-517-8	950-102-2	950-134-7
PC2	I															
PC9a	I			I		I,F,**P,C**	I,F,**P,C**	I			I					
PC16									I							
PC17	I								I		I			I	I	
PC18	I,F	I,F	I,F	I,F,**P,C,A**		I,F,**P,C**	I,F,**P,C**		I,F		I,F	I,F	I,F	I,F	I,F	
PC19																I
PC21				**P**		I,**P**	I,**P**									
PC23	I,F,**P,C,A**	I,F,A	I,F,A					I,F,**C,A**	I,F,**P,A**		I,F,A	I,F,A	I,F,A	I,F,**P,C,A**	I,F,**P,C,A**	
PC26	I,F,**P,C,A**	I,F,A	I,F,A	I,A		F,**P,C,A**	I,F,**P,C**	I,F,**P,A**	I,F, **P,A**	I,F,A	I,F,**P,A**	I,F,A	I,F,A	I,F,**P,C,A**	I,F,**P,C,A**	
PC31	**C**							C								
PC32	I,F	I,F	I,F	A					I,F		I,F	I,F	I,F	I,F	I,F	
PC34	I,F,**P,C,A**	I,F,**P,A**	I,F,**P,A**		**C**			I,F,**P,C,A**	I,F,**P,C,A**		I,F,**P,A**	I,F,**P,A**	I,F,**P,A**	I,F,**P,C,A**	I,F,**P,C,A**	

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

PC 2: Adsorbents
PC 9a: Coatings and paints, thinners, paint removers
PC 16: Heat transfer fluids
PC 17: Hydraulic fluids
PC 18: Ink and toners
PC 19: Intermediate
PC 21: Laboratory chemicals
PC 23: Leather treatment products
PC 26: Paper and board treatment products
PC 31: Polishes and wax blends
PC 32: Polymer preparations and compounds
PC 34: Textile dyes, and impregnating products

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

Data extracted on 16/11/2022

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
215-397-8				YES		
400-020-3						NONs
429-230-3				YES	YES	NONs

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

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