

## Assessment of regulatory needs

**Authority: ECHA**

**Group Name: sulfoxyethyl-/vinyl-sulfonylphenyldiazenylnaphthalene-functionalised reactive azo dyes**

### Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
<b>1.0</b>	3 April 2024	

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Substances within this group:

EC/List no	CAS no	Substance name and Substance name acronyms (*)	Registration type (full, OSII or TII, NONS, cease manufacture), highest tonnage band among all the registrations (t/y) <sup>1</sup>
241-164-5	17095-24-8	tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate (Reactive Black)	Full, (not) publicly available
243-653-9	20262-58-2	Disodium 6-acetamido-4-hydroxy-3-[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2-sulphonate	C&L notified
269-197-0	68189-39-9	7-acetamido-4-hydroxy-3-[[4-[[2-(sulphooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2-sulphonic acid	Cease manufacture
282-468-8	84229-70-9	tetrasodium 4-amino-6-[[2,5-dimethoxy-4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]-5-hydroxy-3-[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate	Full, (not) publicly available
287-574-8	85536-87-4	7-acetamido-4-hydroxy-3-[[4-[[2-(sulphooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2-sulphonic acid, sodium salt	Full, 10-100
300-644-5	93951-21-4	tetrasodium 4-amino-5-hydroxy-6-[[2-methoxy-5-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]-3-[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate	Full, 10-100
401-010-1	-	dilithium 7-acetamido-1-hydroxy-2-(4-((2-sulfonatooxy)ethylsulfonyl)phenylazo)naphthalene-3-sulfonate	Cease manufacture
423-730-5	250688-43-8	disodium 8-amino-5-{4-[2-(sulfonatoethoxy)sulfonyl]phenylazo}naphthalene-2-sulfonate	Full, (not) publicly available
427-680-5	188907-52-0	4-amino-3-[[4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-1-naphthalene sulfonic acid	Full, (not) publicly available
429-070-4	214362-06-8	7-amino-3,8-bis-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]-4-hydroxynaphthalene-2-sulfonic acid, Na/K salt; 7-amino-3-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4-hydroxy-8-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]naphthalene-2-sulfonic acid, Na/K salt; 7-amino-8-[4-(2-sulfoxyethylsulfonyl)-phenylazo]-4-hydroxy-3-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]naphthalene-2-sulfonic acid, Na/K salt; reaction mass of: 7-amino-3,8-bis-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4-hydroxynaphthalene-2-sulfonic acid, Na/K salt	Full, 100-1000
432-080-1	-	Alkali salt of substituted amino alkyl sulfonyl aryl diazo naphthalene sulfonate	Full, (not) publicly available

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

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<b>432-100-9</b>	-	reaction mass of: pentasodium 4-amino-5-hydroxy-3- {(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenylazo}-6- {(E)-2-sulfonato-4-[2- (sulfonatooxy)ethylsulfonyl]phenylazo}naphthalene- 2,7-disulfonate;tetrasodium 4-amino-5-hydroxy-3- {(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenylazo}-6- [(E)-2-sulfonato-4- (vinylsulfonyl)phenylazo]naphthalene-2,7- disulfonate;tetrasodium 4-amino-5-hydroxy-6- {(E)-2-sulfonato-4-[2- (sulfonatooxy)ethylsulfonyl]phenylazo}-3-[(E)-4- (vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate	Not registered
<b>445-040-3</b>	577954-20- 2	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-8-[2- [2-sulfo-4-[[2- (sulfooxy)ethyl]sulfonyl]phenyl]diazanyl]-, potassium sodium salt (1:?:?), coupled with diazotized 2-[(4- amino-5-methoxy-2-methylphenyl)sulfonyl]ethyl hydrogen sulfate	Full, 10-100
<b>445-280-9</b>	<b>371921- 40-3</b>	reaction mass of: pentasodium 4-amino-5-hydroxy-3- {(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenylazo}-6- {(E)-2-sulfonato-4-[2- (sulfonatooxy)ethylsulfonyl]phenylazo}naphthalene- 2,7-disulfonate; tetrasodium 4-amino-5-hydroxy-3- {(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenylazo}-6- [(E)-2-sulfonato-4- (vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; tetrasodium 4-amino-5-hydroxy-6-[(E)-2-sulfonato-4- [2-(sulfonatooxy)ethylsulfonyl]phenylazo]-3-[(E)-4- (vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; trisodium 4-amino-5-hydroxy-3-[(2- hydroxyethylsulfonyl)-phenylazo]-6-[(E)-2-sulfonato- 4-(vinylsulfonyl)phenylazo]naphthalene-2,7- disulfonate; trisodium 4-amino-5-hydroxy-3-[(E)-4- (vinylsulfonyl)phenylazo]-6-[(E)-2-sulfonato-4- (vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; trisodium 4-amino-5-hydroxy-3-[(E)-4- (vinylsulfonyl)phenylazo]-6-[-2-sulfonato-4-(2- hydroxyethylsulfonyl)phenylazo]naphthalene-2,7- disulfonate	Full, (not) publicly available
<b>445-810-9</b>	536737-09- 4	tetrasodium 4-amino-3,6-bis[(2,5-dimethoxy-4- {2- (sulfonatooxy)ethyl]sulfonyl}phenyl)diazanyl]-5- hydroxynaphthalene-2,7-disulfonate (Reactive Navy 00-0286)	Full, (not) publicly available
<b>610-522-6</b>	503155-49- 5	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3-[[2- methoxy-5-methyl-4-[[2-(sulfooxy)ethyl]sulfonyl] phenyl]azo]-8-[[2-sulfo-4-[[2- (sulfooxy)ethyl]sulfonyl]phenyl]azo]-, tetrasodium salt	Full, (not) publicly available
<b>612-023-9</b>	607724-37- 8	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3-[2- [4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazanyl]-8-[2- [2-sulfo-4-[[2- (sulfooxy)ethyl]sulfonyl]phenyl]diazanyl]-, sodium salt (1:4)	Full, (not) publicly available
<b>612-028-6</b>	607724-47- 0	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3,8- bis[[4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-, trisodium salt	Full, (not) publicly available
<b>695-988-9</b>	100556-82- 9	Disodium 4-amino-5-hydroxy-3,6-bis{(E)-[4- (vinylsulfonyl)phenyl]diazanyl}naphthalene-2,7- disulfonate (Reactive Black 5 bis-vinyl)	C&L notified
<b>701-348-2</b>	-	Reaction mass of disodium 6-acetamido-4-hydroxy-3- [(4- {2- (sulfonatooxy)ethyl]sulfonyl}phenyl)diazanyl]naphthal- ene-2-sulfonate and sodium 6-acetamido-4-hydroxy- 3- {[4(vinylsulfonyl)phenyl]diazanyl}naphthalene-2- sulfonate	Full, (not) publicly available
<b>701-365-5</b>	-	Reaction products of 4-amino-5-hydroxynaphthalene- 2,7-disulfonic acid, coupled twice with diazotized 2- [(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts	Full, 100-1000
-	-	[No public or meaningful name is available]	Full, (not) publicly available

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<b>815-135-8</b>	1386899-40-6	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[3-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazenyl]-6-[2-[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazenyl]-, sodium salt (1:5)	Full, (not) publicly available
-	-	Reaction mass of sodium amino-bis{[4-(ethenylsubstituted)phenyl]diazenyl}-hydroxynaphthalenesulfonate and polysodium amino-{[4-(ethenylsubstituted)phenyl]diazenyl}-{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazenyl}-hydroxynaphthalenesulfonate and polysodium amino-bis{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazenyl}-hydroxynaphthalenesulfonate	Full, (not) publicly available
<b>944-110-5</b>	-	Reaction products of diazotised 2-amino-5-{[2-(sulfooxy)ethyl]sulfonyl}benzenesulfonic acid coupled with 7-amino-4-hydroxynaphthalene-2-sulfonic acid, subsequently coupled with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts	Full, 1-10
<b>946-353-2</b>	-	Reaction products of diazotized 2-amino-5-{[2-(sulfooxy)ethyl]sulfonyl}benzenesulfonic acid coupled with 7-amino-4-hydroxynaphthalene-2-sulphonic acid, subsequently coupled with diazotized 2-[(3-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium and potassium salts	Full, 1-10
<b>946-849-9</b>	-	Reaction products of diazotised 2-amino-5-{[2-(sulfooxy)ethyl]sulfonyl}benzenesulfonic acid coupled with 6-amino-4-hydroxynaphthalene-2-sulfonic acid, subsequently coupled with diazotized 2-[(3-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium and potassium salts	Full, 1-10
-	-	Reaction products of diazotized amino-{[2-(sulfooxy)ethyl]sulfonyl}arylsulfonic acid coupled with sodium amino-hydroxy-[(sulfo-{[2-(sulfooxy)ethyl]sulfonyl}aryl]diazenyl]arylsulfonate, sodium salts	Full, 1-10

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

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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)<sup>2</sup>. 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<sup>3</sup>. 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.

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<sup>2</sup> [Working with Groups - ECHA \(europa.eu\)](https://eucha.europa.eu)

<sup>3</sup> 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).

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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<sup>4</sup>.

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<sup>4</sup> <https://echa.europa.eu/understanding-assessment-regulatory-needs>

## Glossary

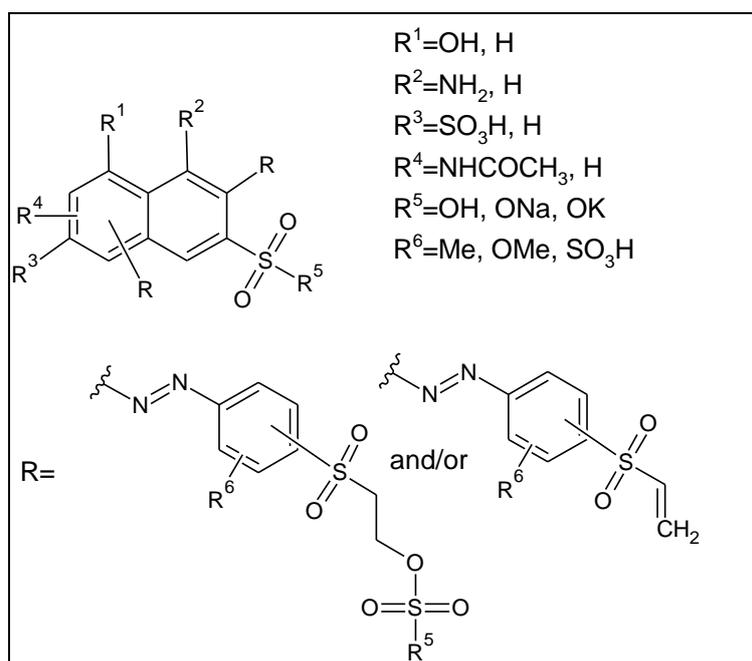
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
DEv	Dossier evaluation
ED	Endocrine disruptor
NONS	Notified new substances
OEL	Occupational exposure limit
OSII or TII	On-site isolated intermediate 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 which have the following structural features:

- a naphthalene (mono or di) sulfonic acid/sodium (or potassium) sulfonate, -OH, -NH<sub>2</sub>, or NHCOCH<sub>3</sub> substituted;
- one or two (4-{[2-(sodium (or potassium) sulfonatoxy or sulfoxy)ethyl]sulfonyl}phenyl)diazenyl or [4-(vinylsulfonyl)phenyl]diazenyl group (monoazo or diazo dyes)
- Specific substituents on the aromatic and naphthalene rings (see Fig. 1)



**Figure 1: Representation of the chemical structures of the substances in the group**

Dyes with similar backbones, but containing heteroaromatic moieties (e.g. triazine) were excluded from this group<sup>5</sup>.

There are 28 substances in the group. Out of these 28 substances, four do not have active REACH registrations (i.e. they are inactive, revoked, or only C&L notified). Majority of the substances have only low tonnage registrations.

These types of azodyes are among the so-called "reactive dyes" because they form covalent bonds with the substrate they colour. Based on information reported in the REACH registration dossiers all registered substances of the group have this as their only use. The main application is in textiles, where the substances are used by industrial workers, professionals and consumers, resulting in high potential for exposure to humans and environment. Other applications are in paper, leather and fur dyeing, plus for some substances additionally in wood, rubber, plastic and other products. Article service life is reported, however, due to the reactive nature of

<sup>5</sup> This is the first group of sulfoxyethyl/vinylsulfonylphenyldiazenylnaphthalene dyes. The substances in the second group contain additional (hetero) moieties/functional groups.

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these dyes, exposure from those articles seems to be limited, though some uncertainty still remains. The only exception is one substance (EC 269-197-0) that was only used as food additive, however for this substance there are currently no active registrations.

## 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**

EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<b>241-164-5</b> <b>282-468-8</b> <b>287-574-8</b> <b>300-644-5</b> <b>429-070-4</b> <b>432-080-1</b> <b>695-988-9</b> <b>701-348-2</b>	Known or potential hazard for skin sensitisation and respiratory sensitisation	Known or potential hazard for aquatic toxicity for EC 427-680-5 and 432-100-9	High potential for exposure from use as reactive dye by industrial, professional and consumer users. Low exposure potential expected from articles, but some uncertainties.	<b>First step:</b> CCH 241-164-5, 282-468-8, 287-574-8, 300-644-5, 429-070-4, 432-080-1, 695-988-9, 701-348-2, 807-339-0, 701-365-5
<b>a substance with confidential identifiers</b> <b>701-365-5</b>	No hazard or unlikely hazard for mutagenicity  Note: EC 427-680-5, 401-010-1 and 445-280-9 already have harmonised classification as skin sens. 1	All others no hazard or unlikely hazard	The overall volume varies according to registrations.	<b>Potential next steps (if hazard confirmed after data generation):</b> <b>CLH for skin sensitisation</b>  <u>Justification:</u> Harmonised classification as skin sensitizer would be needed for the future restriction on the use of
<b>432-100-9</b> <b>445-810-9</b> <b>815-135-8</b> <b>269-197-0</b> <b>427-680-5</b> <b>445-040-3</b> <b>610-522-6</b> <b>612-023-9</b>				

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EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>612-028-6</b>  <b>Reaction mass of sodium amino-bis{[4-(ethenylsubstituted)phenyl]diazenyl}-hydroxynaphthalenesulfonate and polysodium amino-{[4-(ethenylsubstituted)phenyl]diazenyl}-{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazenyl}-hydroxynaphthalenesulfonate and polysodium amino-bis{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazenyl}-hydroxynaphthalenesulfonate</b>  <b>944-110-5</b>  <b>946-353-2</b>  <b>946-849-9</b>  <b>Reaction products of diazotized amino-{[2-(sulfoxy)ethyl]sulfonyl}aryl sulfonic acid coupled with sodium amino-hydroxy-[(sulfo-{[2-(sulfoxy)ethyl]sulfonyl}aryl</b></p>				<p>skin sensitiser substances in textile, leather, fur and hide articles.</p>

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EC/List no, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
<p><b>)diazenyl]arylsulfonate, sodium salts</b></p> <p><b>445-280-9</b>  <b>401-010-1</b>  <b>423-730-5</b></p>				

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

#### **Suggested regulatory risk management action for all substances if hazard for skin and respiratory sensitisation is confirmed.**

Based on currently available information, there is a potential hazard for skin and respiratory sensitisation.

**Hazard for skin sensitisation** has been identified for several group members. For the substances List 815-135-8, List 612-028-6, EC 445-040-3 and Reaction mass of sodium amino-bis{[4-(ethenylsubstituted)phenyl]diazanyl}-hydroxynaphthalenesulfonate and polysodium amino-{[4-(ethenylsubstituted)phenyl]diazanyl}-{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazanyl}-hydroxynaphthalenesulfonate and polysodium amino-bis{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazanyl}-hydroxynaphthalenesulfonate there are positive Local Lymph Node Assay (LLNA) studies available. Furthermore, three other substances included in this group have an existing harmonised classification as Skin Sens. 1 (ECs 401-010-1, 427-680-5 and 445-280-9), while 11 further substances are self-classified for skin sens. 1B (see Annex 1).

It is assumed that all substances in the group potentially have the same skin sensitising hazard, due to the similarity in structural features and reactive chemical groups. Compliance check is proposed, when possible, as a first step to clarify the hazard further. The data generation is expected to confirm the skin sensitisation potential assumed to be triggered by the reaction product vinyl sulfone released from all substances in the group. Therefore, the overall aim is to have consistent regulatory measures across the whole group irrespective of the tonnage band or use profile.

The main exposure potential arises from the use of these substances as dyes in textiles (highest volumes and direct contact with skin). Reactive dyes, like the ones in this group, are assumed to be consumed by irreversible covalent bonding to the fabric and presumably cannot be released. Nevertheless, the current information leaves some uncertainties for example in relation to hazard potential of breakdown products. Remaining uncertainties on potential releases from articles will be considered when updating this regulatory strategy following data generation.

Following the data generation, the first step of the regulatory risk management should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as *skin sensitiser for all substances*. When preparing the proposals, it may be considered what would be the best way to develop them, for instance whether to make a proposal for the group of substances, to submit them individually or jointly. There could also be an entry based on the common active moiety (likely vinyl sulfone). Such approach would ensure that any additional substances with the same active moiety and properties could be covered by the CLH entry in future.

For substances used in textiles, leather, fur and hide articles, there is an ongoing restriction proposal from FR/SE on skin sensitisers (and skin irritants and corrosive substances). Under the current proposal for restriction, harmonised classification would be needed for the restriction to apply.

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For industrial and professional uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers, however it would not address the remaining uncertainties for exposure from articles and to consumers. The substances of this group seem also not to be covered by the entry 43 into Annex XVII of REACH, restricting azodyes in textiles and leather which by reductive cleavage may release aromatic amines listed in Appendix 8 of REACH, or azodyes listed in Appendix 9. The dyes of this group do not contain substances listed in Appendix 9 or release aromatic amines listed in Appendix 8 to REACH.

Adequate product labelling should in principle provide consumers with sufficient information to manage risks arising from the use of mixtures containing these substances. However, there is a concern related to skin sensitisers (potentially) present in consumer mixtures and the need to further investigate whether further regulatory actions are needed and what would be the best options to address this concern.

Such concern has already been identified in other groups of substances and was brought for further discussion to Member States. Work is ongoing on this generic issue by both Member States and ECHA which may affect the regulatory actions on substances in this group.

Regarding the substance EC 269-197-0 that was previously registered for use as a food additive (colouring agent) only, harmonised classification for skin sensitisation would also appear sufficient. Eventhough skin sensitisation is a hazard that usually is not looked at for food additives, still a harmonised classification would allow EFSA to establish additional measures if such would be needed. The CLH would also ensure that this substance is not used as a reactive dye substitute for similar substances in the group.

With respect to respiratory sensitisation, it has to be highlighted that several registrations advise against uses including spraying and dust applications, in particular for professional and consumer uses. This indicates that there is a potential concern for respiratory sensitisation. Though data generation cannot be requested for respiratory sensitisation, further occupational data might be provided during compliance check if available to the registrants when clarifying the reason for self-classification. A harmonised classification for respiratory sensitisation could be considered alongside CLH for skin sensitisation.

Due to some substance having inactive registrations, it is not possible to clarify the potential hazards of these substances. However, also these substances are proposed to follow the same regulatory route as the other substances in the group. If the registration status changes, and if still needed, data generation and potentially follow up actions can be re-considered when the assessment will be revisited.

Based on currently available information, there is a known hazard for aquatic toxicity for EC 427-680-5 and 432-100-9 that have harmonised classification as Aquatic chronic 3. Harmonised classification for aquatic toxicity requires company level risk management measures (RMM) for environment to be in place. Therefore, it is proposed that there is currently no need for (further) EU-wide regulatory risk management for this environmental hazard.

Based on currently available information, mutagenicity hazards are considered unlikely for all substances. For 15 substances, there is at least an Ames test with the registered substance however six of those substances miss the HPRT/MLA to address *in vitro* gene mutation in mammalian cells. For about half of the

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registrations the required Prival modification with reduction of the azo bond was used in the Ames test OECD TG 471. Four Ames test are positive, and three chromosome aberration (CA) studies are positive with one being ambiguous. In a few cases, there is no study to follow the positive *in vitro* result, these can be follow up in the CCH proposed. There are nine negative *in vivo* mutagenicity studies, mainly CA and Micronucleus assay.

For the moment, the available data on mutagenicity does not allow a final conclusion to be made, however it is expected that the data generation proposed will confirm the low hazard potential and there is no need to propose further EU regulatory risk management on this aspect.

Furthermore, based on currently available information, carcinogenicity hazards are considered unlikely for all substances in the group based on the available data. There are four old (1967) non-guideline carcinogenicity studies made with Reactive Black EC 241-164-5 (Annex IX). Even if the studies do not follow the current principles of regulatory testing, it is considered that no hazard has been identified in these studies. Furthermore, the *in vivo* genotoxicity studies are negative. The Annex X 8.9.1. criteria are not considered met, therefore carcinogenicity studies could not be requested under CCH. The remaining uncertainty is partly due to inconclusive data on mutagenicity. After data generation on mutagenicity, proposed for some substances, also the assessment of carcinogenicity can be revisited if needed.

In addition, based on currently available information also reproductive toxicity, repeated dose toxicity (RDT) and PBT/vPvB and PMT/vPvM hazards are considered unlikely for all substances in the group based on the available data. For reproductive toxicity, for two substances screening study TG 421 and for one substance pre-natal developmental toxicity study TG 414 have been submitted. No effect on fertility or development was seen in these studies. Based on similar functional groups in the substances, the findings from the available reproductive toxicity studies are likely to apply to all substances with read-across adaptations and any remaining uncertainty. For RDT no specific systemic adverse effects have been observed in the seven studies available. Based on similar functional groups in the substances, the findings from the available RDT studies are likely to apply to all substances with remaining uncertainty.

Based on ECHA's screening assessment of currently available hazard information, all members in this group are unlikely to have PBT/vPvB and PMT/vPvM properties. The substances are not readily biodegradable and the low values of Kow are not pertinent for predicting (low) bioaccumulation potential for these ionised substances. However, simulation and bioaccumulation studies on EC 241-164-5 resulting in not (v)P (DT50 2 days) and not (v)B (BCF < 11) indicates low concern for the other group members as well. The substances are not T based on ecotox, nor HH toxicity, data.

## Annex 1: Overview of classifications

Data extracted on 19 Oct 2020.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
<b>241-164-5</b>	17095 -24-8	tetrasodium 4-amino-5-hydroxy-3,6-bis[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate (Reactive Black)	Not included in Annex VI, but on RoI (Germany)	Resp. Sens. 1, H334 Skin Sens. 1, H317
<b>269-197-0</b>	68189 -39-9	7-acetamido-4-hydroxy-3-[[4-[[2-(sulphooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2-sulphonic acid	-	-
<b>282-468-8</b>	84229 -70-9	tetrasodium 4-amino-6-[[2,5-dimethoxy-4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]-5-hydroxy-3-[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate	-	Resp. Sens. 1B, H334 Skin Sens. 1B, H317
<b>287-574-8</b>	85536 -87-4	7-acetamido-4-hydroxy-3-[[4-[[2-(sulphooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2-sulphonic acid, sodium salt	-	-
<b>300-644-5</b>	93951 -21-4	tetrasodium 4-amino-5-hydroxy-6-[[2-methoxy-5-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]-3-[[4-[[2-(sulphonatooxy)ethyl]sulphonyl]phenyl]azo]naphthalene-2,7-disulphonate	-	Resp. Sens. 1, H334 Skin Sens. 1, H317
<b>401-010-1</b>	-	dilithium 7-acetamido-1-hydroxy-2-(4-((2-sulfonatooxy)ethylsulfonyl)phenylazo)naphthalene-3-sulfonate	Annex VI index number 016-043-00-3 Skin sens. 1	Skin sens. 1, H317
<b>423-730-5</b>	25068 8-43-8	disodium 8-amino-5-{4-[2-(sulfonatoethoxy)sulfonyl]phenylazo}naphthalene-2-sulfonate	Annex VI index number 607-637-00-9 Eye Dam. 1	Eye Dam. 1, H318
<b>427-680-5</b>	18890 7-52-0	4-amino-3-[[4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-1-naphthalene sulfonic acid	Annex VI index number 607-583-00-6 Eye Dam. 1 Skin Sens. 1	Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 3

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			Aquatic Chronic 3	
<b>429-070-4</b>	21436 2-06-8	7-amino-3,8-bis-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]-4-hydroxynaphthalene-2-sulfonic acid, Na/K salt; 7-amino-3-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4-hydroxy-8-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]naphthalene-2-sulfonic acid, Na/K salt; 7-amino-8-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4-hydroxy-3-[4-(2-sulfoxyethylsulfonyl)-2-sulfophenylazo]naphthalene-2-sulfonic acid, Na/K salt; reaction mass of: 7-amino-3,8-bis-[4-(2-sulfoxyethylsulfonyl)phenylazo]-4-hydroxynaphthalene-2-sulfonic acid, Na/K salt	Annex VI index number 611-144-00-4  Eye Dam. 1	Eye Dam. 1, H318
<b>432-080-1</b>	-	Alkali salt of substituted amino alkyl sulfonyl aryl diazo naphthalene sulfonate	-	-
<b>432-100-9</b>	-	reaction mass of: pentasodium 4-amino-5-hydroxy-3-[(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]-6-[(E)-2-sulfonato-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]naphthalene-2,7-disulfonate;tetrasodium 4-amino-5-hydroxy-3-[(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]-6-[(E)-2-sulfonato-4-(vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate;tetrasodium 4-amino-5-hydroxy-6-[(E)-2-sulfonato-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]-3-[(E)-4-(vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate	Annex VI index number 611-166-00-4  Eye Dam. 1  Aquatic Chronic 3	R41 (Eye Dam. 1)  R52/53 (Aquatic Chronic 3)
<b>445-040-3</b>	57795 4-20-2	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-8-[2-[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazanyl]-, potassium sodium salt (1:?:?), coupled with diazotized 2-[(4-amino-5-methoxy-2-methylphenyl)sulfonyl]ethyl hydrogen sulfate	Not included in Annex VI, but final lead CA proposal R41 & R43 and not classified for env	Eye Dam. 1, H318  Skin Sens. 1B, H317
<b>445-280-9</b>	37192 1-40-3	reaction mass of: pentasodium 4-amino-5-hydroxy-3-[(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]-6-[(E)-2-sulfonato-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]naphthalene-2,7-disulfonate; tetrasodium 4-amino-5-hydroxy-3-[(E)-4-[2-(sulfonatooxy)ethylsulfonyl]phenyl azo]-6-[(E)-2-sulfonato-4-	Annex VI index number 611-178-00-X  Eye Dam. 1  Skin Sens. 1  Aquatic Chronic 3	Eye Dam. 1, H318  Skin Sens. 1, H317  Aquatic Chronic 3

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		(vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; tetrasodium 4-amino-5-hydroxy-6-[(E)-2-sulfonato-4-[2-(sulfonatooxy)ethylsulfonyl]phenylazo}-3-[(E)-4-(vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; trisodium 4-amino-5-hydroxy-3-[(2-hydroxyethylsulfonyl)-phenylazo]-6-[(E)-2-sulfonato-4-(vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; trisodium 4-amino-5-hydroxy-3-[(E)-4-(vinylsulfonyl)phenylazo]-6-[(E)-2-sulfonato-4-(vinylsulfonyl)phenylazo]naphthalene-2,7-disulfonate; trisodium 4-amino-5-hydroxy-3-[(E)-4-(vinylsulfonyl)phenylazo]-6-[-2-sulfonato-4-(2-hydroxyethylsulfonyl)phenylazo]naphthalene-2,7-disulfonate		
<b>445-810-9</b>	53673 7-09-4	tetrasodium 4-amino-3,6-bis[(2,5-dimethoxy-4-{[2-(sulfonatooxy)ethyl]sulfonyl}phenyl)diazanyl]-5-hydroxynaphthalene-2,7-disulfonate (Reactive Navy 00-0286)	-	-
<b>610-522-6</b>	50315 5-49-5	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3-[[2-methoxy-5-methyl-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-8-[[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-, tetrasodium salt	Not included in Annex VI	Skin Irrit. 2, H315  Skin Sens. 1, H317
<b>612-023-9</b>	60772 4-37-8	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3-[2-[4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazanyl]-8-[2-[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazanyl]-, sodium salt (1:4)	-	-
<b>612-028-6</b>	60772 4-47-0	2-Naphthalenesulfonic acid, 7-amino-4-hydroxy-3,8-bis[[4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]azo]-, trisodium salt	-	Skin Sens. 1B, H317
<b>695-988-9</b>	10055 6-82-9	Disodium 4-amino-5-hydroxy-3,6-bis{(E)-[4-(vinylsulfonyl)phenyl]diazanyl}naphthalene-2,7-disulfonate (Reactive Black 5 bis-vinyl)	-	Resp. Sens. 1, H334  Skin Sens. 1, H317
<b>701-348-2</b>	-	Reaction mass of disodium 6-acetamido-4-hydroxy-3-[(4-{[2-(sulfonatooxy)ethyl]sulfonyl}phenyl)diazanyl]naphthalene-2-sulfonate and sodium 6-acetamido-4-hydroxy-3-[[4(vinylsulfonyl)phenyl]diazanyl]naphthalene-2-sulfonate	-	Resp. Sens. 1B, H334  Skin Sens. 1, H317
<b>701-365-5</b>	-	Reaction products of 4-amino-5-hydroxynaphthalene-2,7-disulfonic	-	-

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		acid, coupled twice with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts		
-	-	[No public or meaningful name is available]	-	Skin Sens. 1, H317
<b>815-135-8</b>	13868 99-40-6	2,7-Naphthalenedisulfonic acid, 4-amino-5-hydroxy-3-[2-[3-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazonyl]-6-[2-[2-sulfo-4-[[2-(sulfooxy)ethyl]sulfonyl]phenyl]diazonyl]-, sodium salt (1:5)	-	Skin Sens. 1B, H317 Aquatic Acute 3
-	-	Reaction mass of sodium amino-bis{[4-(ethenylsubstituted)phenyl]diazonyl}-hydroxynaphthalenesulfonate and polysodium amino-{[4-(ethenylsubstituted)phenyl]diazonyl}-{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazonyl}-hydroxynaphthalenesulfonate and polysodium amino-bis{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazonyl}-hydroxynaphthalenesulfonate	-	Skin Sens. 1B, H317
<b>944-110-5</b>	-	Reaction products of diazotised 2-amino-5-[[2-(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid coupled with 7-amino-4-hydroxynaphthalene-2-sulfonic acid, subsequently coupled with diazotized 2-[(4-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium salts	-	Eye Dam. 1, H318
<b>946-353-2</b>	-	Reaction products of diazotized 2-amino-5-[[2-(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid coupled with 7-amino-4-hydroxynaphthalene-2-sulphonic acid, subsequently coupled with diazotized 2-[(3-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium and potassium salts	-	Eye Dam. 1, H318
<b>946-849-9</b>	-	Reaction products of diazotised 2-amino-5-[[2-(sulfooxy)ethyl]sulfonyl]benzenesulfonic acid coupled with 6-amino-4-hydroxynaphthalene-2-sulfonic acid, subsequently coupled with diazotized 2-[(3-aminophenyl)sulfonyl]ethyl hydrogen sulfate, sodium and potassium salts	-	Eye Dam. 1, H318
-	-	Reaction products of diazotized amino-[[2-(sulfooxy)ethyl]sulfonyl]arylsulfonic acid coupled with sodium amino-hydroxy-[(sulfo-[[2-(sulfooxy)ethyl]sulfonyl]aryl]diazonyl]arylsulfonate, sodium salts	-	-

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

Data extracted 19 Oct 2020.

Main types of applications structured by product or article types	Dyeing of paper products	Dyeing of textiles	Dyeing of other products	Food additive	Ink and toners	Leather dyeing	Uses including spraying or dust advised against
241-164-5	I, (A)	F, I, <b>P</b> , <b>C</b> , (A)				I, (A)	<b>I, P, C</b>
269-197-0 (CoM*)				I			
282-468-8		I, P, <b>C</b> , (A)					<b>I, C</b>
287-574-8		F, I, <b>P</b> , <b>C</b> , (A)			F, I		<b>I, C</b>
300-644-5	F, I, <b>P</b> , <b>C</b> , (A)	F, I, <b>P</b> , <b>C</b> , (A)			F, I, <b>P</b> , <b>C</b> , (A)	F, I, <b>P</b> , <b>C</b> , (A)	<b>I, C</b>
401-010-1 (CoM*)		I					
423-730-5		F, I, (A)					
427-680-5		I					
429-070-4		F, I, <b>P</b> , <b>C</b> , (A)					<b>I, C</b>
432-080-1		I, <b>P</b> , <b>C</b> , (A)					<b>I, C</b>
432-100-9 (not registered)		I, (A)					
445-040-3		F, I, <b>P</b> , <b>C</b> , (A)					
445-280-9		F, I, (A)					
445-810-9		I, P, <b>C</b> , (A)					<b>I, C</b>
610-522-6					I		
612-023-9		F, I, <b>P</b> , <b>C</b> , (A)					
612-028-6		F, I, <b>P</b> , <b>C</b> , (A)					
695-988-9		F, I, <b>P</b> , <b>C</b> , (A)					<b>I, C</b>
701-348-2	I, (A)	I, <b>P</b> , <b>C</b> , (A)	(A)			I, (A)	<b>I, C</b>
701-365-5	I, (A)	F, I, <b>P</b> , <b>C</b> , (A)				I, (A)	<b>I, P, C</b>
**		F, I, <b>P</b> , <b>C</b> , (A)					
815-135-8		F, I, (A)					

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***		F, I, <b>P</b> , <b>C</b> , (A)					
944-110-5	F, I, (A)	F, I, <b>P</b> , (A)				F, I, (A)	<b>C</b>
946-353-2	F, I, (A)	F, I, <b>P</b> , (A)	F, I		F, I	F, I, (A)	
946-849-9	F, I, (A)	F, I, <b>P</b> , (A)	F, I		F, I	F, I, (A)	
****	F, I, (A)	F, I, <b>P</b> , <b>C</b> , (A)	F, I		F, I	F, I, (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. (A) is not reported in the registrations but assumed using expert judgement. The uses advised against are highlighted in green.

\*CoM = Cease of manufacture.

\*\*[No public or meaningful name is available]

\*\*\*Reaction mass of sodium amino-bis{[4-(ethenylsubstituted)phenyl]diazonyl}-hydroxynaphthalenesulfonate and polysodium amino- {[4-(ethenylsubstituted)phenyl]diazonyl}-{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazonyl}-hydroxynaphthalenesulfonate and polysodium amino-bis{[4-(ethenylsubstituted)-2-sulfonatophenyl]diazonyl}-hydroxynaphthalenesulfonate.

\*\*\*\*Reaction products of diazotized amino- {[2-(sulfooxy)ethyl]sulfonyl}arylsulfonic acid coupled with sodium amino-hydroxy-[(sulfo- {[2-(sulfooxy)ethyl]sulfonyl}aryl)diazonyl]arylsulfonate, sodium salt

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

Data extracted on 15 Oct 2020.

EC/List No	RMOA	Authorisation		Restriction *		CLH	Actions not under REACH/CLP
		Candidate list	Annex XIV	Annex XVII	Annex (CLP)	VI	
241-164-5						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.