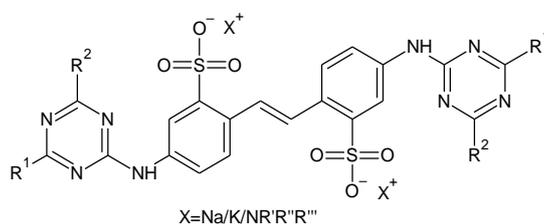


Assessment of regulatory needs

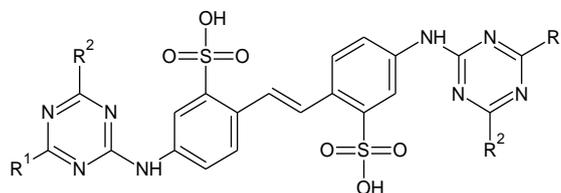
Authority: European Chemicals Agency (ECHA)

Group Name: Stilbenesulfonic acid ditriazine dyes

General structure:



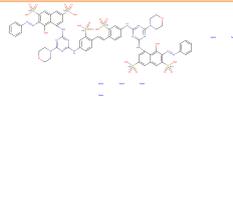
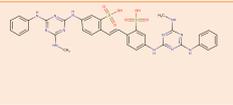
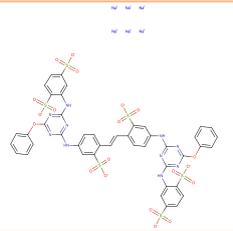
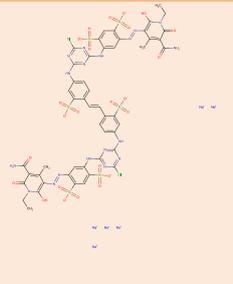
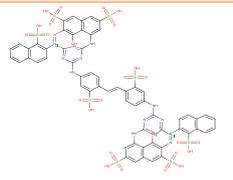
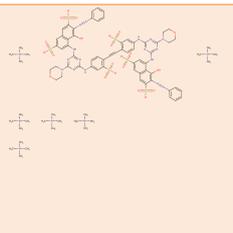
and



Revision history

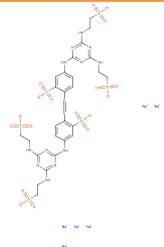
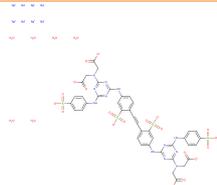
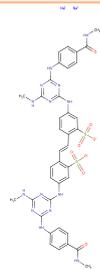
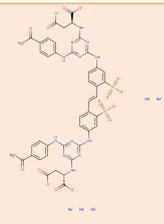
Version	Date	Description
1.0	12 February 2024	

Table 1. Substances within this group

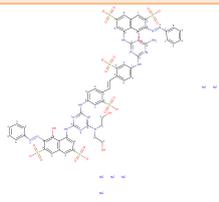
EC/List number	CAS number	Substance name and substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
222-326-4	3426-43-5	Disodium 4,4'-bis[(4-anilino-6-methoxy-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate		Full, 10-100
241-769-4	17791-81-0	Hexasodium 4,4'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diyl]imino]]bis[5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate]		Full, not (publicly) available
252-649-6	35632-99-6	4,4'-bis[[6-anilino-4-(methylamino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonic acid		Not registered
255-284-0	41267-43-0	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino(6-phenoxy-1,3,5-triazine-4,2-diyl)imino]]bis(benzene-1,4-disulphonate)		Not registered
273-662-3	68991-98-0	1,3-Benzenedisulfonic acid, 4,4'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino(6-chloro-1,3,5-triazine-4,2-diyl)imino]]bis[6-[[5-(aminocarbonyl)-1-ethyl-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pyridinyl]azo]-, hexasodium salt		Full, not (publicly) available
301-568-5	94022-69-2	4,4'-[vinylenebis[(3-sulpho-4,1-phenylene)imino(6-chloro-1,3,5-triazine-4,2-diyl)imino]]bis[5-hydroxy-6-[(1-sulpho-2-naphthyl)azo]naphthalene-2,7-disulphonic] acid		Full, not (publicly) available
405-160-9	124537-30-0	Hexakis(tetramethylammonium) 4,4'-vinylenebis((3-sulfonato-4,1-phenylene)imino(6-morpholin-4-yl-1,3,5-triazine-4,2-diyl)imino)bis(5-hydroxy-6-phenylazonaphthalene-2,7-disulfonate)		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>

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name and substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
416-010-7	-	hexasodium 2,2'-ethene-1,2-diylbis[5-(4,6-bis[(2-sulfonatoethyl)amino]-1,3,5-triazin-2-yl)amino]benzenesulfonate]		Full, not (publicly) available
416-270-1	-	YELLOW ULK 1438		NONS
416-640-2	174305-36-3	Stilbene derivative		NONS
425-580-6	-	LB5BT		NONS
427-310-2	180850-95-7	disodium (E)-1,2-bis-(4-(4-methylamino-6-(4-methylcarbamoylphenylamino)-1,3,5-triazin-2-ylamino)phenyl-2-sulfonato)ethene		NONS
428-760-2	-	9812E		NONS
429-770-1	-	MGE 563		NONS
430-240-5	212501-14-9	L-Aspartic acid, N,N'-[(1E)-1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[(4-acetylphenyl)amino]-1,3,5-triazine-4,2-diyl]]]bis-, sodium salt (1:6)		C&L notification
432-690-8	-	9917E		Full, not (publicly) available
441-080-0	-	FPC-199		NONS
443-850-1	-	MGE 914		Inactive
464-900-9	-	[No public or meaningful name is available]		NONS
470-070-9	-	[No public or meaningful name is available]		NONS
473-880-0	142050-95-1	1,4-Benzenedisulphonic acid, 2,2-[1,2-ethenediylbis[(3-sulpho-4,1-phenylene)imino(6-chloro-1,3,5-triazine-4,2-diyl)imino]]bis-, hexasodium salt		NONS
479-490-7	-	[No public or meaningful name is available]		NONS

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name and substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
- "Substance A"	-	4,4'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bisarenoate sodium salt		Full, not (publicly) available
- "Substance B"	-	[No public or meaningful name is available]		Full, not (publicly) available
- "Substance C"	-	Reaction mass of 4,4'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bisarenoate sodium salt and 2-[[4-[bis(2-hydroxyethyl)amino]-6-[[4-[2-[4-[[4-[bis(2-hydroxyethyl)amino]-6-[arenylamino]-1,3,5-triazin-2-yl]amino]-2-sulfophenyl]ethenyl]-3-sulfophenyl]amino]-1,3,5-triazin-2-yl]amino]arenoate sodium salt and 2,2'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bisarenoate sodium salt		Full, not (publicly) available
946-752-1	-	sodium 5-(4-amino-6-(4-((E)-4-(4-(bis(2-hydroxyethyl)amino)-6-(8-hydroxy-7-((E)-phenyldiazenyl)-3,6-disulfonatophthalen-1-ylamino)-1,3,5-triazin-2-ylamino)-2-sulfonatostyryl)-3-sulfonatophenylamino)-1,3,5-triazin-2-ylamino)-4-hydroxy-3-((E)-phenyldiazenyl)naphthalene-2,7-disulfonate		Full, not (publicly) available

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

Contents

Foreword	7
Glossary	8
1 Overview of the group	9
2 Conclusions and proposed actions	11
3 Justification for the need for regulatory risk management action at EU level (if hazards confirmed)	13
Annex 1: Overview of classifications	16
Annex 2: Overview of uses based on information available in registration dossiers	18
Annex 3: Overview of completed or ongoing regulatory risk management activities	19

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. Assessment of regulatory needs and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

Foreword

The 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 level³. 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 website⁴.

² [Working with Groups - ECHA \(europa.eu\)](https://echa.europa.eu/working-with-groups)

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 "2,2'-(ethene-1,2-diyl)bis{5-[(1,3,5-triazin-2-yl)amino]benzene-1-sulfonic acid}" (stilbene) backbone, with the triazine groups carrying at least one amino substituent at R¹ and R² as shown in Figure 1. This specific group includes the substances that were left out from the group "Ditriazine stilbenedisulfonic acid dyes" which included the substances belonging to the optical brighteners category named "Stilbene Fluorescent Whitening Agents (SFWA)", and substances very similarly related in terms of R¹ and R² moieties. Therefore, the substances of this group present a higher diversification at the R¹ and R² substituents. In fact, a variety of substituents on the aniline ring, and also more complex moieties like naphthalenedisulfonic acid- diazo derivatives can be found as R¹ and R². Additionally, some of the substances are monosubstituted triazines, preserving the Cl moiety.

There are 26 substances in the group of which 10 with active registrations, two not registered, one with a C&L notification, one inactive and 12 unclaimed NONs.

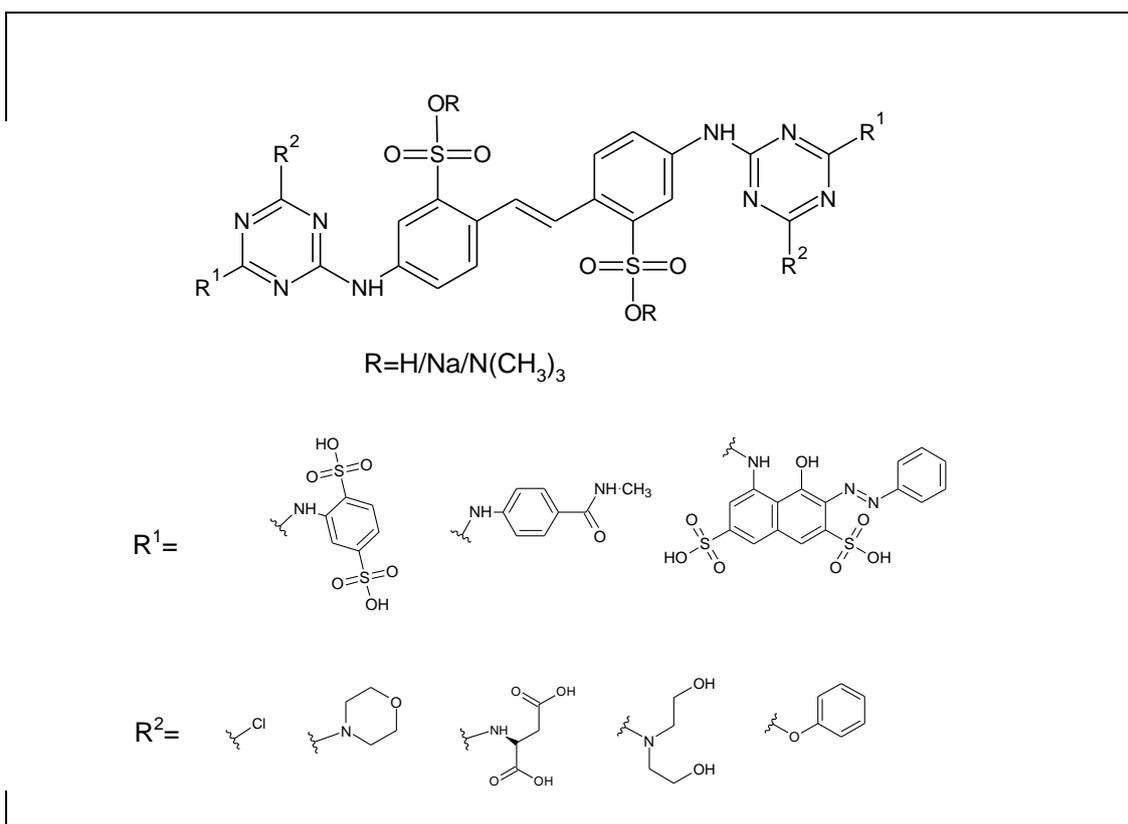


Fig. 1. Examples of ditriazine stilbenedisulfonic acid dyes belonging to this group. There is a high variability in terms of R¹ and R². R¹ can be also an azo-derivative, R² can be a Cl (i.e. only one aminogroup has been introduced on the structure)

Optical brighteners are fluorescent dyes that absorb invisible ultraviolet light in the 300-400 nm range and re-emit in the visible spectrum violet-to-blue, fluorescent light. The blue light emitted by the brightener "masks" the yellow or brown tones

of the substrate and makes it look cleaner and brighter than it would otherwise appear to the naked eye.

The substances included in this group are mainly in their salt forms (with sodium, potassium, or protonated amines as counterion). Only one substance is the free sulfonic acid. The substances are well-defined, mono- or multi-constituent substances. The most common impurities found in the compositions are, for example, partially reacted constituents, i.e., primary amines, (where one alkyl group has cleaved), OH- or Cl- substituents on the triazine moieties, and salts.

Based on information reported in the REACH registration dossiers, these substances are used as optical brighteners/ whitening agents primarily in the production of articles, namely, paper products and textiles. There is thus considerable article service life by inclusion into paper matrices, as well as by incorporation in textiles and leather.

A few of the substances are also used in leather treatment and in washing and cleaning products (detergents).

Six of the substances have been indicated for widespread uses (professional and consumer) and therefore are considered to have high potential for exposure/release (EC/List 222-326-4, 946-752-1, Substance A, Substance B, Substance C, 241-769-4).

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, 'disulfonated anilines' 432-690-8 Substance B 428-760-2 473-880-0 255-284-0	Known or potential hazard for reproductive toxicity	No hazard or unlikely hazard for aquatic toxicity. No hazard or unlikely hazard for PBT/vPvB and mobility to be confirmed	Substance B Used in the production of textile and paper articles	First step: CCH for EC 432-690-8 and 'Substance B' Potential next steps (if hazard confirmed after data generation): CLH Potential last action: Restriction <u>Justification:</u> If Repr is confirmed, uses by professionals and uses in certain types of articles best managed by restriction.
Subgroup 2 241-769-4 946-752-1 273-662-3 301-568-5	No hazard or unlikely hazard except Known or potential hazard	No hazard or unlikely hazard for aquatic toxicity. No hazard or unlikely hazard for PBT/vPvB or mobility.	Used in the production of textile and paper articles, with high potential for exposure of humans and the environment from textiles	First step: CCH for EC 222-326-4, 241-769-4, List 946-752-1, Substances A and C Potential last action:

ASSESSMENT OF REGULATORY NEEDS

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Suggested regulatory actions
416-270-1 Substance A Substance C 222-326-4 429-770-1 416-640-2 427-310-2 430-240-5 441-080-0 443-850-1 464-900-9 479-490-7 425-580-6 470-070-9 252-649-6	for STOT RE for EC 241-769-4			Currently no need for EU RRM <u>Justification:</u> Overall, either no or unlikely hazard that would lead to concern for the reported uses or trigger RRM, or self-classification will require company level risk management measures (RMM) for workers to be in place.
Outlier substances in subgroup 2 405-160-9 416-010-7	Known or potential hazard for skin sensitisation	Known or potential hazard for aquatic toxicity for EC 405-160-9 No hazard or unlikely hazard for PBT/vPvB or mobility.	No use information available for 405-160-9; 416-010-7 used in paper products and photochemicals.	No action <u>Justification:</u> Currently, no need for action, however, if professional uses or presence in articles intended for skin contact are identified in the future, a restriction can be considered

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

The group is divided into two subgroups:

Subgroup 1: Group members containing disulfonated aniline groups in their structure: EC 255-284-0, 428-760-2, 432-690-8, 473-880-0, 'Substance B'.

Subgroup 2: all remaining group members, quite diverse in terms of substituents. Substituents include, for example, monosulfonated aniline, morpholine, hydroxyethyl amino moieties, aminobenzoic acid, aminomethyl benzamide, phenoxy groups and azo dyes.

Suggested regulatory risk management action for subgroup 1 'disulfonated anilines' if reproductive toxicity hazard is confirmed

Based on currently available information, there is a potential hazard for reproductive toxicity hazards.

The related substances in the optical brighteners category named "Stilbene Fluorescent Whitening Agents (SFWA)" have undergone comprehensive compliance checks and further data generation. Some data generation is however still ongoing, so that final conclusions for all endpoints are also not available for the substances in this present group. However, existing studies for the SFWA category may justify the classification of the disulfonated aniline-containing substances as Repr. 1B or 2. Effects observed include testes atrophy, decreased number of implantations and corpora lutea, decreased fertility index, also leading to a lower number of dams with live born pups, affecting mean number of pups/litter. For the time being, a worst-case classification as Repr. 1B is assumed for the strategy. Based on the structural similarity to the SFWA category, i.e. the presence of amino disulfonated aniline substituents, the assumption of potential reproductive and developmental toxicity hazard can also be extended to the disulfonated substances (subgroup 1) in this group. An endocrine mode of action can be postulated for the reproductive toxicity observed; however, at this stage ED potential is not yet flagged until further assessment under CCH is performed.

Compliance check is suggested for the disulfonated EC 432-690-8 and for 'Substance B', to clarify and confirm their potential reproductive and developmental toxicity hazard and to confirm low toxicity for other endpoints: no hazard for mutagenicity, target organ toxicity, carcinogenicity or skin sensitisation, PBT/vPvB, PMT or aquatic toxicity has been identified for all subgroup 1 substances so far based on the available data. The hazard potential will be re-evaluated after data generation.

The first step of the regulatory risk management action, should the hazard be confirmed as Repr. 1B, would be the harmonised classification (CLH).

A CLH as Repr. 1B i) would require company level risk management measures (RMM) under the 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, by means of the restriction in REACH Annex XVII, entry 30 (reproductive toxicity). A CLH would also support regulatory action under other regulations.

CLH is also a prerequisite for restricting 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)).

The substance 'Substance B' is used in the production of paper articles, and as textile dye, also leading to article service life indication. The uses have only been reported as industrial and formulation. Hence, at 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 in category 1B is confirmed, a restriction be considered on the use of these substances in articles. In relation to such a restriction, it should be noted that the substances may be tightly bound in certain matrices and thus exposure in such a situation is likely to be low. As an example, FWAs applied onto paper penetrate the cellulose fibres in a monomolecular form and aggregate. Hence, FWAs cannot easily leave the interior of the fibre nor can they be separated in flotation froth or washed through a sieve⁵. The number of sulfonic acid groups affects the affinity of the FWA for cellulose and thus the migration potential⁶. Therefore, in the restriction proposal process, the applications from which releases actually occur should be identified. For example, migration of FWA into solvents/food from paper used in food contact materials (FCM) has been tested and found negligible – in fact, the testing of migration is always required where FWA are added to paper or board used for FCM⁷. Further, Regulation (EU) No 10/2011 allows the use of some stilbene-based FWA as additives in plastic FCM. In contrast, wash-out of FWA from textiles can be relevant and the gradual release of FWA from textiles is well known. The use of optical brighteners in detergents is intended to enhance whiteness, replacing the wash-out FWA that were used in the production of the textile.

Currently no need to suggest (further) regulatory risk management actions for substances of subgroup 2

Based on currently available information, for carcinogenicity, mutagenicity, reproductive and developmental toxicity, target organ toxicity (except EC 241-769-4), skin sensitisation (except EC 405-160-9 and 416-010-7), PBT/vPvB, PMT/vPvM or aquatic toxicity hazards are considered unlikely, not warranting classification, for subgroup 2 (which are non-/mono-sulfonated substances), based on the available data. EC 405-160-9 also has a harmonised classification as Aquatic Chronic 3.

Due to the limited availability of data, compliance check is suggested for the substances EC 222-326-4, 241-769-4, 'Substance A', 'Substance C' and List 946-

⁵ Jamnicki Hanzer, S.; Lozo, B.; Barušić, L. Producing Direct Food Packaging Using Deinked Office Paper Grades—Deinkability and Food Contact Suitability Evaluation. *Sustainability* **2021**, *13*, 12550.

⁶ Shi, H., Liu, H., Ni, Y., Yuan, Z., Zou, X., and Zhou, Y. (2012). "Review: Use of optical brightening agents (OBAs) in the production of paper containing high-yield pulps," *BioRes.* 7(2), 2582-2591.

⁷ Cefi: FOOD CONTACT GUIDELINES FOR THE COMPLIANCE OF PAPER & BOARD MATERIALS AND ARTICLES https://www.cefi.org/wp-content/uploads/2020/09/Food-Contact-Guidelines_2019.pdf

752-1 to confirm low toxicity for the endpoints above. For these substances, use information is available and they have widespread uses.

For EC 241-769-4, based on the information available (effects on hematological parameters, increased extramedullary hematopoiesis in the spleen), classification for STOT RE 2 appears to be warranted. Such classification is however not reported in the registration dossier. Registrants are invited to consider the information available, self-classify the substance, and update their registration dossiers and Safety Data Sheets accordingly.

Some other group members also show effects related to hematological parameters, increased extramedullary hematopoiesis (EC 429-770-1, 464-900-9) or kidney effects (EC 416-640-2), which would not meet STOT RE classification criteria. This could also apply to more group members. It can however not be confirmed because of the low data availability, and will be re-evaluated after data generation, where possible.

List 946-752-1 is used in the production of paper articles and as textile dyes, also leading to article service life indication. It is also used in the treatment of leather. Only this substance is reported for professional use (as textile dye). The professional uses may indicate relatively low levels of operational controls and risk management measures. Furthermore, environmental releases may be significant from such uses.

For the other three substances, in addition to paper, textile and leather treatment, also use in washing and cleaning products, including for professional and consumer use, is reported. If the lack of hazards of concern is confirmed, no actions need to be taken. If, on the other hand, health or environmental hazards are found, appropriate actions including harmonised classification and restriction need to be initiated.

The substance EC 405-160-9 has a harmonised classification as Skin Sens 1, and EC 416-010-7 is self-classified as skin sensitiser (Skin Sens 1). The uses of the former are not known, but the latter has industrial uses in paper products and photochemicals. For industrial uses, sufficient and consistent self-classification by registrants should require company level risk management measures (RMM) to be in place for workers. In light of the currently known uses, restricting these substances does not appear to be necessary. However, while the risk from paper products in general may be small, should the substances be used in papers intended for sanitary or otherwise skin contact use, the need of a restriction should be further examined.

Annex 1: Overview of classifications

Data extracted on 19 May 2022.

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
222-326-4	3426-43-5	disodium 4,4'-bis[(4-anilino-6-methoxy-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate	-	-
241-769-4	17791-81-0	hexasodium 4,4'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diyl]imino]]bis[5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate]	-	-
273-662-3	68991-98-0	1,3-Benzenedisulfonic acid, 4,4'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino(6-chloro-1,3,5-triazine-4,2-diyl)imino]]bis[6-[[5-(aminocarbonyl)-1-ethyl-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pyridinyl]azo]-, hexasodium salt	-	-
301-568-5	94022-69-2	4,4'-[vinylenebis[(3-sulpho-4,1-phenylene)imino(6-chloro-1,3,5-triazine-4,2-diyl)imino]]bis[5-hydroxy-6-[(1-sulpho-2-naphthyl)azo]naphthalene-2,7-disulphonic] acid	-	-
405-160-9	124537-30-0	hexakis(tetramethylammonium) 4,4'-vinylenebis[(3-sulfonato-4,1-phenylene)imino(6-morpholin-4-yl-1,3,5-triazine-4,2-diyl)imino]bis(5-hydroxy-6-phenylazonaphthalene-2,7-disulfonate)	Acute Tox. 3 Hazard Statement: H301 (Minimum classification) Aquatic Chronic 3 Statement: H412 Skin Sens. 1 Statement: H317	-
416-010-7	3656-31-3	hexasodium 2,2'-ethene-1,2-diylbis[5-({4,6-bis[(2-sulfonatoethyl)amino]-1,3,5-triazin-2-yl}amino)benzenesulfonate]	-	Skin Sens. 1 H317
416-270-1	-	YELLOW ULK 1438	-	-
416-640-2	-	Stilbene derivative	-	-
427-310-2	180850-95-7	disodium (E)-1,2-bis-(4-(4-methylamino-6-(4-methylcarbamoylphenylamino)-1,3,5-triazin-2-ylamino)phenyl-2-sulfonato)ethene	Eye Dam. 1 Statement: H318	-
430-240-5	-	L-Aspartic acid, N,N'-[(1E)-1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[(4-acetylphenyl)amino]-1,3,5-triazine-4,2-diyl]]]bis-, sodium salt (1:6)	-	-
432-690-8	-	9917E	-	-
443-850-1	-	MGE 914	-	-

ASSESSMENT OF REGULATORY NEEDS

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations
473-880-0	-	1,4-Benzenedisulphonic acid, 2,2-[1,2-ethenediylbis[(3-sulpho-4,1-phenylene)imino(6-chloro-1,3,5-triazine-4,2-diyl)imino]]bis-, hexasodium salt	-	-
Substance A	-	tetrasodium 4,4'-{ethene-1,2-diylbis[(3-sulfonato-4,1-phenylene)imino{6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl}imino]}dibenzoate	-	-
Substance B	-	[No public or meaningful name is available]	-	-
Substance C	-	Reaction mass of tetrasodium 2-({4-[bis(2-hydroxyethyl)amino]-6-[(4-{2-[4-{4-[bis(2-hydroxyethyl)amino]-6-[(4-carboxylatophenyl)amino]-1,3,5-triazin-2-yl}amino)-2-sulfonatophenyl]ethenyl}-3-sulfonatophenyl)amino]-1,3,5-triazin-2-yl}amino)benzoate and tetrasodium 2,2'-{ethene-1,2-diylbis[(3-sulfonatobenzene-4,1-diyl)imino{6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl}imino]}dibenzoate and tetrasodium 4,4'-{ethene-1,2-diylbis[(3-sulfonatobenzene-4,1-diyl)imino{6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl}imino]}dibenzoate	-	-
946-752-1	-	sodium 5-(4-amino-6-(4-((E)-4-(4-(bis(2-hydroxyethyl)amino)-6-(8-hydroxy-7-((E)-phenyldiazenyl)-3,6-disulfonatophthalen-1-ylamino)-1,3,5-triazin-2-ylamino)-2-sulfonatostyryl)-3-sulfonatophenylamino)-1,3,5-triazin-2-ylamino)-4-hydroxy-3-((E)-phenyldiazenyl)naphthalene-2,7-disulfonate	-	-

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

Data extracted on 8 June 2022.

EC number	273-662-3	443-850-1	432-690-8	430-240-5	416-270-1	416-010-7	301-568-5	222-326-4	Substance C	946-752-1	Substance B	Substance A	241-769-4
PC 35: Washing and cleaning products								I, F, C	P, C, A			P, C, A	I, F
PC 32: Polymer preparations and compounds										I, F			
PC 9a: Coatings and paints, thinners, paint removers	I							I			I		I
PC 18: Ink and toners	I									I, F			
PC 26: Paper and board treatment products						I		I, F, P, C, A	I, F, P, C, A	I, F, A	I, F, A	I, F, P, C, A	I, F, A
PC 34: Textile dyes, and impregnating products								I, F, P, C, A	I, F, P, C, A	I, F, P, A	I, F, A	I, F, P, C, A	I, F, A
PC 23: Leather treatment products								I, F, P, C		I, F, A			
PC 19: Intermediate							I						
PC 30: Photo-chemicals						I							
no product category		(i: 2, p: 2)	()	()	(i: 2)	(i: 1)		(m: 2, a: 2)	(m: 1, f: 1)	(m: 1)	(m: 1, a: 2)	(m: 1, f: 1)	

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 16 May 2022.

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