

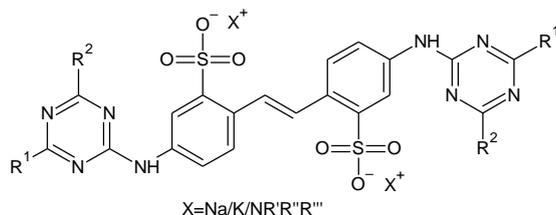
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

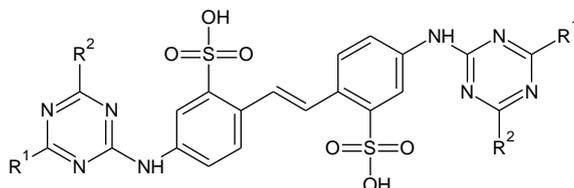
Date: 5 September 2022

Group Name: Ditriazine stilbenesulfonic acid dyes

General structure:



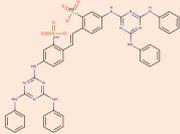
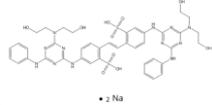
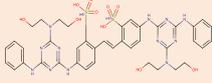
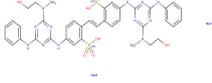
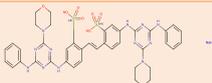
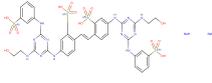
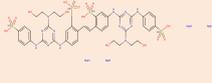
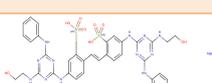
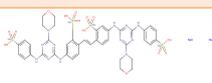
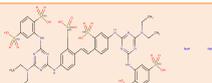
and



Revision history

<i>Version</i>	<i>Date</i>	<i>Description</i>
1.0	21 October 2022	

Substances within this group:

EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) ¹
205-117-2	133-66-4	Disodium 4,4'-bis[(4,6-dianilino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate		C&L notification
224-073-5	4193-55-9	Disodium 4,4'-bis[6-anilino-[4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, >1000
224-548-7	4404-43-7	4,4'-bis[4-[bis(2-hydroxyethyl)amino]-6-anilino-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonic acid		OSII or TII
237-600-9	13863-31-5	Disodium 4,4'-bis[[6-anilino-4-[(2-hydroxyethyl)methylamino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, 10-100
240-245-2	16090-02-1	Disodium 4,4'-bis[(4-anilino-6-morpholino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate		Full, 100-1000
240-400-4	16324-27-9	Tetrasodium 4,4'-bis[[4-[(2-hydroxyethyl)amino]-6-(m-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, not (publicly) available
240-521-2	16470-24-9	Tetrasodium 4,4'-bis[[4-[bis(2-hydroxyethyl)amino]-6-(4-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate]		Full, >1000
241-883-4	17958-73-5	Disodium 4,4'-bis[[4-anilino-6-[(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		C&L notification
248-420-5	27344-06-5	Disodium 4,4'-bis[[4-anilino-6-[(2-carbamoyl)ethyl(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, 100-1000
249-323-0	28950-61-0	Tetrasodium 4,4'-bis[[4-morpholino-6-(p-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, not (publicly) available
255-217-5	41098-56-0	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-(diethylamino)-1,3,5-triazine-4,2-diy]imino]]bis(benzene-1,4-disulphonate)		Full, 100-1000

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>

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EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1
257-827-7	52301-70-9	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diy]imino]]bis(benzene-1,4-disulphonate)		Full, 10-100
267-097-1	67786-25-8	Tetrasodium 4,4'-bis[[4-[bis(2-hydroxypropyl)amino]-6-[(4-sulphonatophenyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate		Full, >1000
273-468-9	68971-49-3	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diy]imino]]bis(benzene-1,4-disulphonate)		Full, 100-1000
275-031-8	70942-01-7	Potassium sodium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, >1000
275-279-7	71230-67-6	Dipotassium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Full, not (publicly) available
279-087-4	79135-87-8	Hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[(2-cyanoethyl)[2-(2-hydroxyethoxy)ethyl]amino]-1,3,5-triazine-4,2-diy]imino]]bis[benzene-1,4-disulphonate]		Full, not (publicly) available
405-280-1	76508-02-6	A mixture of: hexasodium 2,2'-vinylenebis(((3-sulfonato-4,1-phenylene)amino(6-(N-(2-cyanoethyl)-N-(2-hydroxypropyl)amino)-1,3,5-triazine-4,2-diy)amino)benzene-1,4-disulfonate); hexasodium trans-4-[4-[N-(2-cyanoethyl)-N-(2-hydroxypropyl)amino]-6-(2,5-disulfonatoanilino)-1,3,5-triazin-2-ylamino]-4'-[6-(2,5-disulfonatoanilino)-4-[N-(2-hydroxypropylamino)-1,3,5-triazin-2-ylamino]stilbene-2,2'-disulfonate]; hexasodium trans-4-[4-[N-(2-carbamoyl)ethyl)-N-(2-hydroxypropyl)amino]-6-(2,5-disulfonatoanilino)-1,3,5-triazin-2-ylamino]-4'-[6-(2,5-disulfonatoanilino)-4-[N-(2-cyanoethyl)-N-(2-hydroxypropylamino)-1,3,5-triazin-2-ylamino]stilbene-2,2'-disulfonate		NONS

ASSESSMENT OF REGULATORY NEEDS

EC/List number	CAS number	Substance name and/ or Substance name acronyms	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) 1
476-880-9	-	Producto P0310		Full, not (publicly) available
476-900-6	-	Brightener 0503E		Full, not (publicly) available
609-336-8*	371756-75-1	1,4-Benzenedisulfonic acid, 2,2'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis(2-hydroxypropyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis-, sodium salt (1:6)		Full, not (publicly) available
619-874-5	42355-78-2	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-(diethylamino)-6-[[4-sulfo(phenyl)amino]-1,3,5-triazin-2-yl]amino]-, sodium salt (1:4)		Full, not (publicly) available
700-932-4	-	Leucophor 1111X		Full, not (publicly) available
Not (publicly) available (Reaction mass X)	-	Reaction mass of all possible isomers of Disodium 2,2'-ethenediylbis[5-({4-[bis(2-hydroxyalkyl)amino]-6-({4-[(2-hydroxyethyl) substituted]phenyl}amino)-1,3,5-triazin-2-yl}amino)benzenesulfonate]		Full, not (publicly) available
800-181-3*	371756-75-1	1,4-Benzenedisulfonic acid, 2,2'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis(2-hydroxypropyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis-, sodium salt (1:6)		Full, not (publicly) available
Not (publicly) available	-	P-1057		Full, not (publicly) available
Not (publicly) available	-	P-1401		Full, not (publicly) available
942-661-6	-	Reaction mass of Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-[bis(2-hydroxyethyl)amino]-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt and Benzenesulfonic acid, 5-[[4-[bis(2-hydroxyethyl)amino]-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-2-[2-[4-[[4-[(2-hydroxyethyl)amino]-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-2-sulfo(phenyl)ethenyl]-, disodium salt		Full, not (publicly) available

*) Duplicate registrations

This table does not contain group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

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

Foreword

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

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

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g., assessment done under REACH/CLP or other EU legislation, or can be generated in some cases (e.g., further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process, but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult the ECHA website².

² <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
RMOA	Regulatory management options analysis
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of the "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 amino substituents R^1 and R^2 as shown in the figure 1. This specific group includes the substances that are members of the optical brighteners category named "Stilbene Fluorescent Whitening Agents (SFWA)", created by the registrants and, additionally, some other substances very similar in terms of the R^1 and R^2 moieties. Other triazine-stilbenes, with higher variability at R^1 and R^2 , will be addressed in another group.

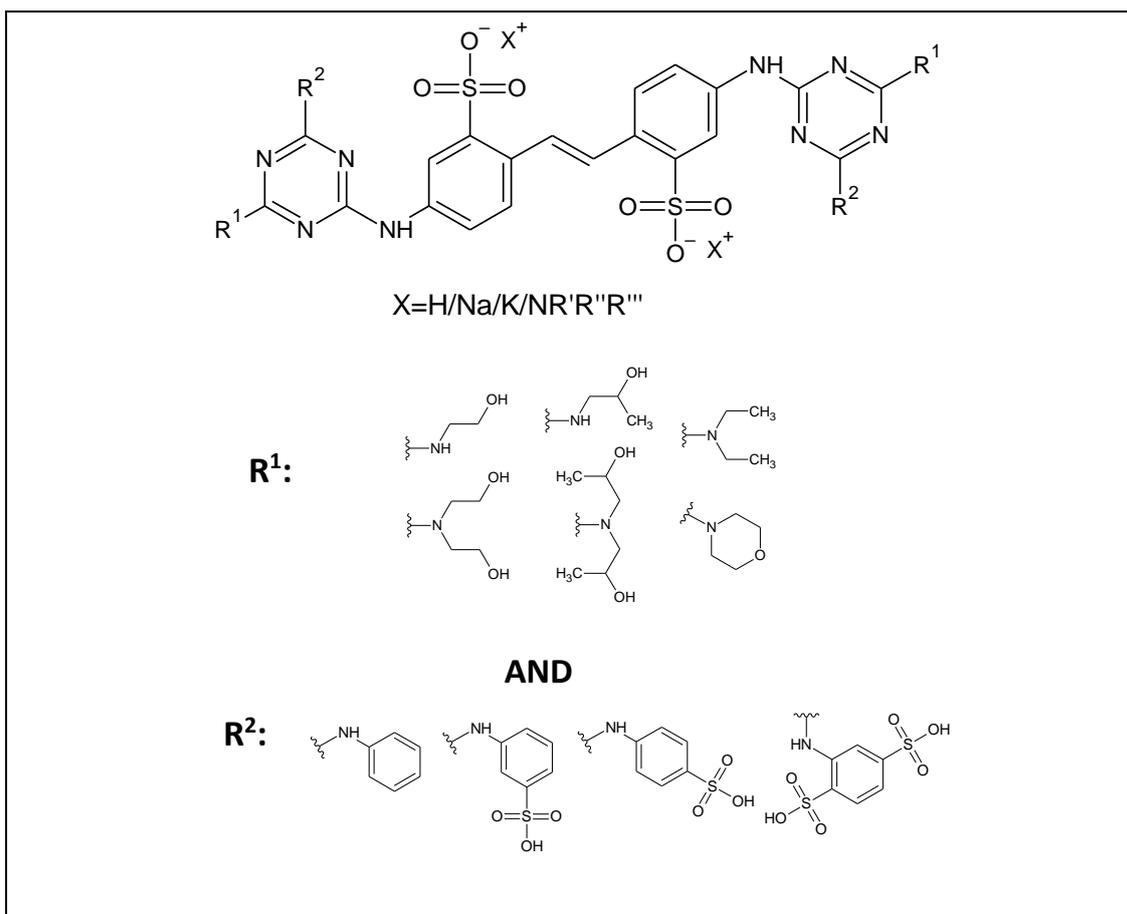


Fig 1: Examples of ditriazine stilbenedisulfonic acid dyes belonging to this group. The common pattern across the substances is the presence of an alkylamine as R^1 and an aniline or sulfonated aniline as R^2 on the triazine rings.

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.

These substances are used in coatings, inks, paper products, textiles, and washing and cleaning products. The substances remain present in the final articles (such as textiles and paper), as they are adsorbed and aggregated in the matrix due to forces attracting dyes and fibres in various forms, including hydrogen bonds and Van der Waals forces. This binding is important for their function as optical brighteners. The binding affinities depend on the different substituents. A minor use in adhesives, also there as optical brightener, has been identified, further resulting in inclusion into matrices such as paper. The uses are wide-dispersive, and exposure of professionals and consumers, as well as of the environment, is likely.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted and no quantitative exposure assessment is performed at this stage.

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

Based on currently available information, there is a need for EU regulatory risk management – harmonised classification for reproductive and developmental toxicity hazards, and eventual restriction, due to the potential for release and exposure of the substances containing disulfonated aniline (EC 255-217-5, EC 257-827-7, EC 273-468-9, EC 279-087-4, EC 405-280-1, P-1057, 476-880-9, 609-336-8 and its duplicate 800-123-7) (subgroup 1).

The SFWA category has undergone comprehensive compliance checks with following data generation and has therefore overall good data availability; some data generation is however still ongoing, so that final conclusions cannot be drawn

for all endpoints. However, existing studies may justify the classification of the disulphonated aniline -containing substances as Repr. 1B or 2. Effects observed include testes atrophy (EC 255-217-5), decreased number of implantations and corpora lutea (EC 257-827-7), decreased fertility index, also leading to lower number of dams with live born pups, affected mean number of pups/litter (EC 273-468-9). For the latter two substances, the effects were however not observed in either the dose-range finding or main OECD 422 studies. For the time being, the worst case of classification as Repr. 1B is assumed for the strategy. For the non-SFWA group members, data availability is limited. The dossiers rely on read-across adaptations for many endpoints. Based on the structural similarity of the non-SFWA category members, the assumption of potential reproductive and developmental toxicity hazard can be extended to these other disulfonated group members.

Compliance check is suggested for the disulfonated non-SFWA group members EC 476-880-9, 609-336-8, 800-181-3, as well as EC 279-087-4 which, in addition to disulfonation, has a different substituent from the SFWA category members, to clarify and confirm their potential reproductive and developmental toxicity hazard, if applicable.

The reproductive and developmental toxicity hazard potential will be re-evaluated after data generation.

Furthermore, the substances fulfil the P/vP screening criteria and are expected to be mobile in the environment. The potential persistency and mobility will also be re-evaluated after potential generation of higher-tier simulation data and adsorption/desorption data via compliance check.

The first step of the regulatory risk management action, should the hazard be confirmed, would be the harmonised classification (CLH) as Repr. 1B/2, which can be initiated after data is available from the on-going studies and those that may still be requested under the follow-up process.

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.

Almost all of these substances are used in products used in a professional setting as well as by consumers (as listed in Annex 2). Professional and consumer uses are considered as widespread (at many sites and by many users). Professional users operate often with relatively low levels of operational controls and risk management measures but with often 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, **restriction of the substances as such or in mixtures** 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 Sustainability³ which aims to extend to professional users under REACH

³ European Commission, *Chemical Strategy for Sustainability Towards a Toxic-Free Environment*, available at <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

the level of protection granted to consumers.

These substances are also incorporated in articles, where they have a technical function. It is thus proposed that a restriction be considered also on the use in articles for the substances with reproductive toxicity. In relation to such a restriction, it should be noted that (some of) 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 sieve⁴. The number of sulfonic acid groups affects the affinity of the FWA for cellulose and thus the migration potential⁵. 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 FCM⁶. 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. For textiles, the already existing restriction entry 72 could possibly be made use of.

Based on currently available information, there is currently no need for EU regulatory risk management for any of the group substances that are not disulfonated (subgroups 2a and 2b), as no hazards justifying such measures were identified.

None of the substances in the entire group are likely to have any of the hazards of skin sensitisation, respiratory sensitisation, mutagenicity or repeated dose toxicity. The non-/mono-sulfonated substances in subgroup 2 are also unlikely to have the reproductive and developmental toxicity hazards.

However, for the SFWA category substances EC 240-245-2, 224-073-5 and 248-420-5, the CCH process is still ongoing to clarify the potential aquatic toxicity. here is currently not sufficient information to have a holistic view of the available long-term fish toxicity information for all the members of the SFWA category, but potential long-term aquatic toxicity hazard is expected.

⁴ 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.

⁵ 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.

⁶ 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

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also have been considered. When new information (e.g., on hazards through evaluation processes, or on uses) will become available, the document will be updated and conclusions and actions revisited.

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
Subgroup 1 Disulfonated optical brighteners In SFWA category: 255-217-5 257-827-7 273-468-9 Outside category: 279-087-4 405-280-1 P-1057 476-880-9 609-336-8 800-181-3	Known or potential hazard for reproductive toxicity	Potential hazard for mobility as the substances screen for P/vP criteria and are potentially mobile	Optical brighteners High potential for exposure of consumers, e.g., from use in washing and cleaning products, potential for exposure of humans and the environment from, e.g., use in textiles.	Need for EU RRM: Restriction Justification: Uses by professionals and uses in certain types of articles best managed by restriction	First step: CCH For EC 476-880-9, 609-336-8, 800-181-3 and 279-087-4 Next steps (if hazard confirmed): CLH Restriction
Subgroup 2a Other SFWA category members (not disulfonated)	No hazard or unlikely hazard	Potential hazard for aquatic toxicity to be confirmed via on-going data generation	Optical brighteners High potential for exposure of	Currently not possible to assess the regulatory needs	First step: No action

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Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
224-073-5 224-548-7 237-600-9 240-245-2 240-400-4 240-521-2 241-883-4 248-420-5 249-323-0 267-097-1 275-031-8 619-874-5		for EC 224-073-5, 248-420-5 and 240- 245-2 No hazard or unlikely hazard for the other substances	consumers, e.g., from use in washing and cleaning products, potential for exposure of humans and the environment from, e.g., use in textiles.	Justification: CCHs on-going for SFWA category	Next steps (if hazard confirmed): No action
Subgroup 2b Other substances outside category (not disulfonated) 205-117-2 275-279-7 476-900-6 700-932-4 Reaction mass X P-1401 942-661-6	No hazard or unlikely hazard	No hazard or unlikely hazard	Optical brighteners High potential for exposure of consumers, e.g., from use in washing and cleaning products, potential for exposure of humans and the environment from, e.g., use in textiles.	Currently no need for EU RRM Justification: No identified hazards justifying EU-level RRM	First step: No action Next steps (if hazard confirmed): No action

Annex 1: Overview of classifications

Data extracted on 5 April 2022

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers, therefore the number may differ from the C&L inventory which displays number of notifiers.

EC/ List No	CAS number	Substance name	Harmonised classification	Classification in registrations ⁷	Classification in C&L notifications ⁸
205-117-2	133-66-4	disodium 4,4'-bis[(4,6-dianilino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate			Skin Irrit. 2 H315[1 out of 8] Aquatic Chronic 3 H412[1 out of 8] Eye Irrit. 2 H319[2 out of 8]
224-073-5	4193-55-9	disodium 4,4'-bis[6-anilino-[4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		-	Eye Irrit. 2 H319[2 out of 24]
224-548-7	4404-43-7	4,4'-bis[4-[bis(2-hydroxyethyl)amino]-6-anilino-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonic acid			Eye Irrit. 2 H319[1 out of 6]
237-600-9	13863-31-5	disodium 4,4'-bis[[6-anilino-4-[(2-hydroxyethyl)methylamino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		-	

⁷ The column gives the classifications in registrations received under REACH. Additional classifications in intermediate and in inactive registrations (if any) are annotated and displayed last. For each classification the table includes information on the hazard category, the hazard statement and any available information on specific effects (relevant for reproductive toxicity), specific concentration limits, M-Factors and affected organs. Two classifications differing in any of these aspects are considered different and are repeated in the table. The columns "Classifications in registrations" and "Classifications in C&L notifications" are empty if there are no Registrations/C&L notifications (hazard is unknown). The value '-' is displayed on the same columns when there are (relevant) submissions but they do not contain self-classifications (substance is not hazardous).

⁸ The column gives the additional classifications not found in registrations but found in active or inactive C&L notifications (without distinguishing them). For each classification this column also provides the number of C&L notifications that contain the classification out of the total number of C&L notifications received for the substance. A single C&L notification file submitted by a group of notifiers is only counted once. Therefore, the numbers may differ from the dissemination site which counts number of notifiers.

ASSESSMENT OF REGULATORY NEEDS

240-245-2	16090-02-1	disodium 4,4'-bis[[4-anilino-6-morpholino-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		Aquatic Chronic 3 H412	
240-400-4	16324-27-9	tetrasodium 4,4'-bis[[4-[(2-hydroxyethyl)amino]-6-(m-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		-	
240-521-2	16470-24-9	tetrasodium 4,4'-bis[[4-[(2-hydroxyethyl)amino]-6-(4-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate]		Eye Irrit. 2 H319	
241-883-4	17958-73-5	disodium 4,4'-bis[[4-anilino-6-[(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	-	-	-
248-420-5	27344-06-5	disodium 4,4'-bis[[4-anilino-6-[(2-carbamoyl)ethyl](2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate		-	Acute Tox. 4 H302[1 out of 9] STOT Single Exp. 3 H335, affected organs: respiratory tract[1 out of 9] Skin Corr. 1B H314[1 out of 9] Acute Tox. 4 H312[1 out of 9]
249-323-0	28950-61-0	tetrasodium 4,4'-bis[[4-morpholino-6-(p-sulphonatoanilino)-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	-	-	-
255-217-5	41098-56-0	hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-(diethylamino)-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate)		-	-
257-827-7	52301-70-9	hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-morpholino-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate)	-	-	Eye Irrit. 2 H319[3 out of 13]

ASSESSMENT OF REGULATORY NEEDS

267-097-1	67786-25-8	tetrasodium 4,4'-bis[[4-[bis(2-hydroxypropyl)amino]-6-[(4-sulphonatophenyl)amino]-1,3,5-triazin-2-yl]amino]-stilbene-2,2'-disulphonate	-	-	-
273-468-9	68971-49-3	hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[bis(2-hydroxyethyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis(benzene-1,4-disulphonate)	-	-	-
275-031-8	70942-01-7	potassium sodium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	-	-	-
275-279-7	71230-67-6	dipotassium 4,4'-bis[6-anilino-4-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl]amino]stilbene-2,2'-disulphonate	-	-	-
279-087-4	79135-87-8	hexasodium 2,2'-[vinylenebis[(3-sulphonato-4,1-phenylene)imino[6-[(2-cyanoethyl)[2-(2-hydroxyethoxy)ethyl]amino]-1,3,5-triazine-4,2-diyl]imino]]bis[benzene-1,4-disulphonate]	-	-	-
405-280-1	76508-02-6	A mixture of: hexasodium 2,2'-vinylenebis[[(3-sulfonato-4,1-phenylene)amino(6-(N-(2-cyanoethyl)-N-(2-hydroxypropyl)amino)-1,3,5-triazine-4,2-diyl)amino)benzene-1,4-disulfonate]; hexasodium trans-4-[4-[N-(2-cyanoethyl)-N-(2-hydroxypropyl)amino]-6-(2,5-disulfonatoanilino)-1,3,5-triazin-2-ylamino]-4'-[6-(2,5-disulfonatoanilino)-4-[N-(2-hydroxypropylamino)-1,3,5-triazin-2-		Eye Irrit. 2 H319 [Article 10 (inactive)]	-

ASSESSMENT OF REGULATORY NEEDS

		ylamino]stilbene-2,2'-disulfonate; hexasodium trans-4-[4-[N-(2-carbamoylethyl)-N-(2-hydroxypropyl)amino]-6-(2,5-disulfonatoanilino)-1,3,5-triazin-2-ylamino]-4'-[6-(2,5-disulfonatoanilino)-4-[N-(2-cyanoethyl)-N-(2-hydroxypropylamino)-1,3,5-triazin-2-ylamino]stilbene-2,2'-disulfonate			
476-880-9	-	Producto P0310	-	-	-
476-900-6	-	Brightener 0503E	-	-	-
609-336-8*	-	609-336-8	-	-	-
619-874-5	42355-78-2	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-(diethylamino)-6-[(4-sulfophenyl)amino]-1,3,5-triazin-2-yl]amino]-, sodium salt (1:4)	-	-	-
700-932-4	-	Leucophor 1111X	-	-	-
Reaction mass X		Reaction mass of all possible isomers of Disodium 2,2'-ethene-diylbis[5-({4-[bis(2-hydroxyalkyl)amino]-6-({4-[(2-hydroxyethyl) substituted]phenyl}amino)-1,3,5-triazin-2-yl}amino)benzenesulfonate]	-	-	-
800-181-3*	371756-75-1	1,4-Benzenedisulfonic acid, 2,2'-[1,2-ethenediylbis[(3-sulfo-4,1-phenylene)imino[6-[bis(2-hydroxypropyl)amino]-1,3,5-triazine-4,2-diyl]imino]]bis-, sodium salt (1:6)	-	-	-
P-1057	-		-	-	-

ASSESSMENT OF REGULATORY NEEDS

P-1401	-		-	-	-
942-661-6	-	Reaction mass of disodium 2,2'-(E)-ethene-1,2-diylbis[5-(4-anilino-6-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl)amino]benzenesulfonate] and disodium 5-(4-anilino-6-[bis(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl)amino)-2-((E)-2-[4-(4-anilino-6-[(2-hydroxyethyl)amino]-1,3,5-triazin-2-yl)amino]-2-sulfonatophenyl]vinyl)benzenesulfonate	-	-	-

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

Data extracted on 18 February 2022

These substances are used as optical brighteners in coatings, inks, paper products, textiles, washing and cleaning products. They remain present in the final articles (such as textiles and paper), as they bind to the matrix, which is important for their function.

A minor use in adhesives, also there as optical brightener, has been identified, further resulting in inclusion into matrices such as paper.

The uses are wide-dispersive, and exposure of professionals and consumers is likely.

The use of optical brighteners in detergents is intended to enhance whiteness when the whitening agents used in the production of textiles slowly wash out.

EC/list number	224-073-5	224-548-7	237-600-9	240-245-2	240-400-4	240-521-2	248-420-5	249-323-0	255-217-5	257-827-7	267-097-1	273-468-9	275-031-8	275-279-7	279-087-4	476-880-9	476-900-6	609-336-8	619-874-5	700-932-4	Reaction mass X	800-181-3	P-1057	P-1401	942-661-6
PC 35: Washing and cleaning products	F, I, P, C, A		F, I, P, C, A	F, I, P, C, A		F, I, P, C, A	F, I, P, C		P, C	F	F, I, P, C, A	F, I, P, C, A	P, C, A					F, P, C, A						F, P, C, A	
PC 39: Cosmetics, personal care products				F																					
PC 24: Lubricants, greases, release products						F																			
PC 32: Polymer preparations and compounds	F, I, A								A																
PC 1: Adhesives, sealants									F, I, P, C																
PC 9a: Coatings and paints, thinners, paint removes	F, I			P, C, A	I	F, I, P, C, A	F, I, P, C		F, I, P, C		F, I, P, C, A	F, I, P, C	P, C, A						I						
PC 18: Ink and toners									F, I, P, C																
PC 26: Paper and board treatment products	F, I, A			F, I, P, C, A	F, I, A	F, I, P, C, A	F, I, A		F, I, P, C, A	F, I, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	I		F, I, P, C, A		F, I, P, C, A	F, I, A	F, I, A			F, I, P, C, A	F, I, P, C, A	F, I, A
PC 34: Textile dyes, and impregnating products	F, I, P, C, A		A	F, I, P, C, A	F, I, A	F, I, P, C, A	F, I, A	I	F, I, A	F, I, P, A	F, I, P, C, A	F, I, P, C, A	F, I, P, C, A	I	F, I, A	F, I, P, C, A		F, I, P, C, A			I		F, I, P, C, A	F, I, P, C, A	

ASSESSMENT OF REGULATORY NEEDS

PC 23: Leather treatment products				F, I					I															
PC 19: Intermediate	F	I																						
PC 30: Photo-chemicals									I															
no PC																								dye

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 11 March 2022

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