Justification Document for the Selection of a CoRAP Substance

– Update –

Substance Name (public name):	Disodium 4,4'-bis[(4,6-dianilino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate
EC Number:	205-117-2
CAS Number:	133-66-4
Authority:	Italian CA
Date:	21/03/2017
	20/03/2018 (1. Update)

Cover Note

This document has been prepared by the evaluating Member State given in the CoRAP update.

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1 IDENTITY OF THE SUBSTANCE

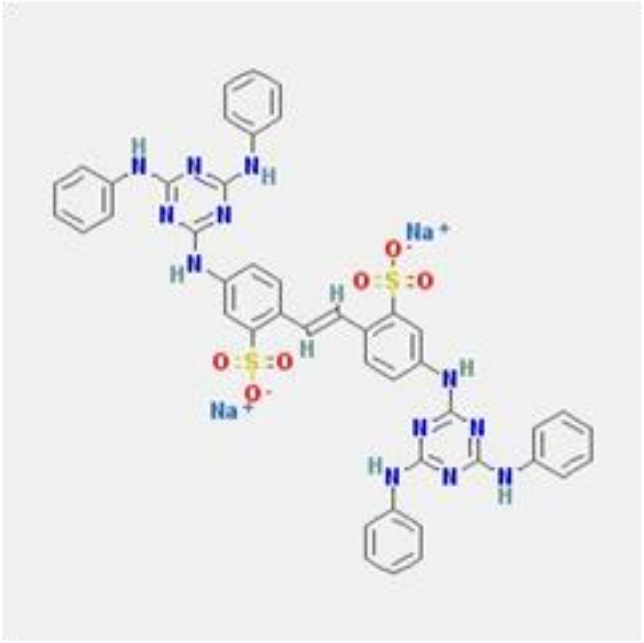
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Disodium 4,4'-bis[(4,6-dianilino-1,3,5-triazin-2-yl)amino]stilbene-2,2'-disulphonate
IUPAC name (public):	disodium 2,2'-ethene-1,2-diylbis{5-[(4,6-dianilino-1,3,5-triazin-2-yl)amino]benzenesulfonate}
Index number in Annex VI of the CLP Regulation:	/
Molecular formula:	C38H36N14O8S2Na2
Molecular weight or molecular weight range:	926.9
Synonyms:	*Fluorescent Brightener 9*

Type of substance ☒ Mono-constituent ☐ Multi-constituent ☐ UVCB

Structural formula:



1.2 Similar substances/grouping possibilities

Has read-across been used by the registrant for the concern related endpoints? ☒ Yes ☐ No

Is the substance a member of a category? ☐ Yes ☒ No

The registrant identified the registered substance as "belonging to the family of stilbene fluorescent whitening agents" (SFWA) and also provided four analogue substances (CAS RN 16090-02-1, 13863-31-5, 4404-43-7, 16470-24-9) belonging to the same category to fill the data gaps of the target substance. However, the information on the SFWA and the justification provided in the submitted document is not sufficient to conclude if the target substance can be included within the category and for establishing a clear basis for the analogue approach justification.

2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA		☐ Risk Management Option Analysis (RMOA)
REACH Processes	Evaluation	☐ Compliance check, Final decision
		☐ Testing proposal, Final decison
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII[1]
Harmonised C&L		☐ Annex VI (CLP) (see section 3.1)
Proce sses unde r other		☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009

[1] Please specify the relevant entry.

	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation	☐ Dangerous substances Directive Directive 67/548/EEC (NONS)
	☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☐ Other (provide further details below)

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

The Harmonised Classification is not available.

3.1.2 Self classification

- In the registration:

  Not Classified

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:

  Aquatic Chronic 3 H412

  Eye Irrit. 2 H319

  Skin Irrit. 2 H315

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[2]

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site		
☒ Full registration(s) (Art. 10)	☐ Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
☐ 1 – 10 tpa	☒ 10 – 100 tpa	☐ 100 – 1000 tpa
☐ 1000 – 10,000 tpa	☐ 10,000 – 100,000 tpa	☐ 100,000 – 1,000,000 tpa
☐ 1,000,000 – 10,000,000 tpa	☐ 10,000,000 – 100,000,000 tpa	☐ > 100,000,000 tpa
☐ <1 . . . . . >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		☐ Confidential
This substance has 1 active registration under REACH, 1 Joint Submission.		

4.2 Overview of uses

This substance is used in the following products: washing & cleaning products and textile treatment products and dyes.

This substance is used for the manufacture of: textile, leather or fur.

Release to the environment of this substance is likely to occur from industrial use: formulation of mixtures and in the production of articles. Other release to the environment of this substance is likely to occur from: indoor use (e.g. machine wash liquids/detergents, automotive care products, paints and coating or adhesives, fragrances and air fresheners), outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment).

This substance can be found in products with material based on: fabrics, textiles and apparel (e.g. clothing, mattress, curtains or carpets, textile toys).

[2] *The dissemination site was accessed in August 2017.*

Table: Uses

Part 1:

☒ Manufacture	☒ Formulation	☒ Industrial use	☒ Professional use	☒ Consumer use	☒ Article service life	☐ Closed system

Part 2:

	Use(s)
Uses as intermediate	
Formulation	Formulation of Preparations and/or Settings Manufacture of Cleaning and Maintenance Products
Uses at industrial sites	Textile Finishing
Uses by professional workers	Institutional and industrial uses of cleaning and maintenance products (ERC 8a: Wide dispersive indoor use of processing aids in open systems; ERC 8b: Wide dispersive indoor use of reactive substances in open systems)
Consumer Uses	Consumer uses of cleaning and maintenance products (ERC 8a; ERC 8b) Service life stage of textile products (ERC 10a: Wide dispersive outdoor use of long-life articles and materials with low release; ERC 11a: Wide dispersive indoor use of long-life articles and materials with low release)
Article service life	Service life stage of textile products (ERC 10a; ERC 11a)

Part 3: There is high potential for exposure of

☒ Humans	☒ Environment

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

☒ Article 44(2) (refined prioritisation criteria for substance evaluation)

☐ Article 45(5) (Member State priority)

5.2. Selection criteria met

☐ Fulfils criteria as CMR/ Suspected CMR

☐ Fulfils criteria as Sensitiser/ Suspected sensitiser

☐ Fulfils criteria as potential endocrine disrupter

☒ Fulfils criteria as PBT/vPvB / Suspected PBT/vPvB

☐ Fulfils criteria high (aggregated) tonnage (*tpa > 1000*)

☒ Fulfils exposure criteria

☐ Fulfils MS's (national) priorities

5.3 Initial grounds for concern to be clarified under Substance Evaluation

Hazard based concerns		
CMR ☐ C ☐ M ☐ R	Suspected CMR[1] ☐ C ☐ M ☐ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[3]	
☐ PBT/vPvB	☒ Suspected PBT/vPvB[1]	☐ Other (please specify below)
Exposure/risk based concerns		
☒ Wide dispersive use	☐ Consumer use	☐ Exposure of sensitive populations
☐ Exposure of environment	☐ Exposure of workers	☐ Cumulative exposure
☐ High RCR	☐ High (aggregated) tonnage	☐ Other (please specify below)
PBT assessment *Persistence assessment*		

[3] CMR/Sensitiser: known carcinogenic and/or mutagenic and/or reprotoxic properties/known sensitising properties (according to CLP harmonized or registrant self-classification or CLP Inventory)
Suspected CMR/Suspected sensitiser: suspected carcinogenic and/or mutagenic and/or reprotoxic properties/suspected sensitising properties (not classified according to CLP harmonized or registrant self-classification)
Suspected PBT: Potentially Persistent, Bioaccumulative and Toxic

The Registrants considered the substance to be persistent in the environment.

The following studies on ready biodegradability were reported: 1) episuite BIOWIN, resulting as not readily biodegradable; 2) OECD 301A (old version) based on a read-across with a structural analogue substance (CAS n° 16470-24-9), the degradation was 1.2% after 28 d (DOC removal). The substance was concluded by the Registrants to be not readily biodegradable.

The Registrants waived the simulation tests (water and sediment, soil), on the basis that the test substance would not be biodegradable in simulation tests either.

In conclusion, the substance is likely to be not readily biodegradable on the basis of the QSAR prediction, although its reliability is low, additionally the R-A justification is not acceptable, therefore the substance is potentially P or vP.

Bioaccumulation assessment

The Registrants submitted two different aquatic bioaccumulation studies: 1) QSAR estimation, the BCF value is = 10 L/Kg, however there is a lack of QSAR documentation; 2) experimental study carried on with an analogue substance (CAS n° 16090-02-1), that showed that tissue concentrations of the tested substance were too low to be quantified, however there is not adequate justification document for read-across. The substance was concluded by the Registrants to be not bioaccumulative.

The reliability of the QSAR prediction is low and the R-A justification is not acceptable, therefore no information is provided on bioaccumulation in aquatic organisms, moreover, based on the physicochemical property of the substance (Log Kow > 8, Log Koc > 5), a potential for terrestrial bioaccumulation cannot be excluded.

The substance fulfills the screening criterion of Log Kow greater than 4.5 (predicted Log Kow = 8.96), therefore bioaccumulation testing is needed.

In conclusion, the substance is potentially B or vB.

Toxicity assessment

The acute aquatic toxicity data were provided by the Registrans for all the three taxonomic groups, carried out with a structural analogue substance (CAS n° 16090-02-1). The results of the short-term tests didn't reveal any toxicity. Moreover, the Registrants provided only one long-term aquatic toxicity test based on a read-across with a structural analogue substance (CAS n° 16090-02-1) on Daphnia, which revealed a NOEC=1 mg/L.

The R-A justification is not acceptable, therefore there is a gap of information on the aquatic acute toxicity of the substance, as well as on the chronic toxicity.

Therefore, based on the information provided, is not possible to assess the real hazard of the substance to the aquatic organisms.

Exposure assessment

Taking into account that no hazard was identified, the exposure estimation is considered not necessary by the Registrants and is not reported in the registration dossiers. Consequently, all identified uses of the substance are assessed by the Registrants as safe for human health and the environment.

In section 3.7.3 of IUCLID, among the significant routes of exposure for environment, water and soil are checked by the Registrants, nevertheless potential releases are not reported. The substance has a wide dispersive use, therefore a potential for exposure/release due to the uses of the substance is expected. In particular, the reported use ERC 8a: Wide dispersive indoor use of processing aids in open systems - indicates indirect exposure to soil is likely (the substance is used in textile and laundry detergents).

5.4 Preliminary indication of information that may need to be requested to clarify the concern

☐ Information on toxicological properties	☐ Information on physico-chemical properties
☒ Information on fate and behaviour	☒ Information on exposure
☒ Information on ecotoxicological properties	☐ Information on uses
☐ Information on ED potential	☐ Other (provide further details below)

Based on the analysis of available data it can be concluded that both standard and non-standard information are needed to verify the initial concern as suspected PBT. These are specified below.

Only screening information are available for P assessment, that provide a conclusion as potentially P or vP, therefore the simulation tests (water and/or sediment/soil) are needed. Considering the physico-chemical properties of the substance (WS 140 mg/L, Log Kow > 8 and Log Koc > 5), both simulation testing in surface waters (OECD 309) and sediments (OECD 308) are proposed.

The substance is potentially B or vB, therefore a bioaccumulation test in fish (OECD TG 305) is needed as confirmatory data.

No reliable information is available on aquatic toxicity of the substance, therfore standard information requirements are needed. Moreover, based on the physico-chemical property of the substance (Log Kow > 8, Log Koc > 5) long-term tests with sediment dwelling species and/or terrestrial organisms may provide more useful information on the toxicity of the substance. However, depending on the outputs of the P and B assessment, the T criterion can then be considered.

Based on a wide dispersive use of the substance and on the potential for PBT properties, an exposure assessment is needed.

5.5 Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☒ Other (provide further details)

The potential regulatory outcome, following the clarification of the concern, could be to carry out an Annex XV for SVHC identification.