Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	sodium 3-nitrobenzene sulphonate
EC Number:	204-857-3
CAS Number:	127-68-4
Authority:	IE MSCA
Date:	22/03/2016

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

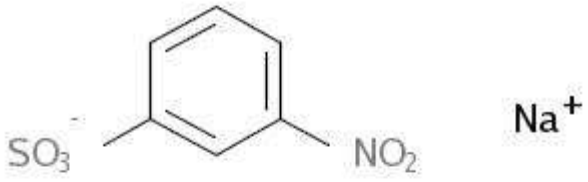
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	Sodium 3-nitrobenzene sulphonate
IUPAC name (public):	Sodium 3-nitrobenzene sulfonate
Index number in Annex VI of the CLP Regulation:	609-048-00-2
Molecular formula:	$C_6H_5NO_5S.Na$
Molecular weight or molecular weight range:	225
Synonyms:	Benzenesulfonic acid, 3-nitro-, sodium salt

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

Structural formula:



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
		☐ CoRAP and Substance Evaluation
	Authorisa-tion	☐ Candidate List
		☐ Annex XIV
	Restric-tion	☐ Annex XVII
Harmonised C&L	☒ Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legisla-tion	☐ 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 process es/ EU legisla-tion	☐ Other (provide further details below)	
Further details		

3 HAZARD INFORMATION (INCLUDING CLASSIFICATION)

3.1 Classification

3.1.1 Harmonised Classification in Annex VI of the CLP

Table: Harmonised classification

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
609-048-00-2	sodium 3-nitrobenzenesulphonate	204-857-3	127-68-4	Skin Sens. 1 Eye Irrit. 2	H317 H319		

3.1.2 Self classification

- In the registration:
  - Skin sensitisation 1; H317: May cause an allergic skin reaction
  - Eye irritation 2; H319: Causes serious eye irritation

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
  - "Not classified"

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES[1]

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
One joint submission with four active registrations		

[1] *Dissemination site was accessed on 22/09/2015*

4.2 Overview of uses

Table: Uses

Part 1:

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

Part 2:

	Use(s)
Formulation	• Oxidative hair-dyes formulation • Formulation of substance
Uses at industrial sites	• Dye Intermediate • Electroplating agent • Catalysts in Organic synthesis • Chemical for metal surface treatment • Chemical for metal surface coating • Chemical for textile coating
Article service life	Textiles outdoor; textiles indoor; vehicles; machinery, mechanical appliances; electrical/electronic articles; stone, plaster, cement, glass and ceramic articles; rubber articles; fabrics, textiles and apparel; metal articles; paper articles

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 (why the substance qualifies for being in CoRAP)

☒ 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[2] ☐ C ☐ M ☒ R	☐ Potential endocrine disruptor
☐ Sensitiser	☐ Suspected Sensitiser[2]	
☐ PBT/vPvB	☐ Suspected PBT/vPvB[2]	☒ 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)

[2] 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

A weight of evidence approach is used to address the repeated dose toxicity, developmental toxicity and fertility endpoints. For the repeated dose toxicity endpoint, the registration data includes a 28-day repeated dose toxicity study in rats, QSAR estimates and results from a published study in which rats and dogs were treated with a formulation containing 2.25% sodium 3-nitrobenzene sulphonate for 28-days and 2 years, respectively. Further review of the available data is required to determine if the DNEL(s) identified are robust and whether the data is adequate for the purposes of classification and labelling. As part of the weight of evidence approach for the reproductive toxicity endpoint, the registration data includes QSAR estimates, results from published studies examining the effects of 2.25% sodium 3-nitrobenzene sulphonate on rats and rabbits during gestation and a read-across to data on nitrobenzene (EC 202-716-0). Nitrobenzene has a harmonized classification on Annex VI to CLP as Repr. 1B H360F. The lack of developmental toxicity seen with nitrobenzene is used to support the conclusion that no additional developmental toxicity study with sodium 3-nitrobenzene sulphonate is required but the classification of nitrobenzene as Repro. 1B H360F (testicular toxicity) is not considered relevant due to the lack of effects observed in the 28-day repeated dose toxicity study in rats with sodium 3-nitrobenzene sulphonate. Therefore, no classification for effects on fertility is assigned in the registration data. Further review of the available data and the appropriateness of a read-across to nitrobenzene is required in order to determine whether further data to address the reproductive toxicity endpoint is needed. The registration data reports a use in the formulation of oxidative hair dyes. However no corresponding exposure scenario for professional or consumer end use of hair dyes is reported in the registration dossiers. Further review is required to determine whether all relevant lifecycle stages are reported in the registration dossiers.

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 ED potential	☐ Other (provide further details below)
Following the evaluation of the existing data, further information may be requested to address the repeated dose toxicity, developmental toxicity and fertility endpoints. Further information may be requested to address potential missing exposure scenarios relating to end use of hair dye formulations.	

5.5. Potential follow-up and link to risk management

☐ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
To be confirmed once the evaluation is completed.			