



Justification Document for the Selection of a CoRAP Substance

– UPDATE –

Substance Name (public name): sodium 3-nitrobenzene sulphonate

EC Number: 204-857-3

CAS Number: 127-68-4

Authority: Health & Safety Authority, Ireland

Date: 22/03/2016
22/03/2022 (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):	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 ₆ H ₅ NO ₅ S.Na
Molecular weight or molecular weight range:	225
Synonyms:	Benzenesulfonic acid, 3-nitro-, sodium salt

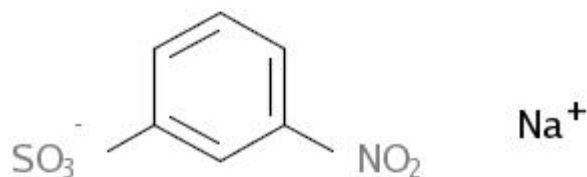
Type of substance

Mono-constituent

Multi-constituent

UVCB

Structural formula:



2 OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Table: Completed or ongoing processes

RMOA	<input type="checkbox"/> Risk Management Option Analysis (RMOA)	
REACH Processes	Evaluation	<input checked="" type="checkbox"/> Compliance check
		<input type="checkbox"/> Testing proposal
		<input type="checkbox"/> CoRAP and Substance Evaluation
	Authorisation	<input type="checkbox"/> Candidate List
		<input type="checkbox"/> Annex XIV
Restriction	<input type="checkbox"/> Annex XVII ¹	
CLH	<input checked="" type="checkbox"/> Annex VI (CLP) (see section 3.1)	
Processes under other EU legislation	<input type="checkbox"/> Plant Protection Products Regulation Regulation (EC) No 1107/2009	
	<input type="checkbox"/> Biocidal Product Regulation Regulation (EU) 528/2012 and amendments	
Previous legislation	<input type="checkbox"/> Dangerous substances Directive 67/548/EEC (NONS)	
	<input type="checkbox"/> Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	<input type="checkbox"/> Assessment	
	<input type="checkbox"/> In relevant Annex	
Other processes/ EU legislation	<input type="checkbox"/> Other (provide further details below)	
Further details	A compliance check decision was issued in January 2017, which included requests for <i>in vitro</i> gene mutation studies, a sub-chronic toxicity study (90-day), a screening reproductive/developmental toxicity study and a pre-natal developmental toxicity study. The compliance check process was concluded in August 2021.	

¹ Please specify the relevant entry.

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:
 - A number of notifications have concluded the substance is "not classified"

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

None.

4 INFORMATION ON (AGGREGATED) TONNAGE AND USES²

4.1 Tonnage and registration status

Table: Tonnage and registration status

From ECHA dissemination site *		
<input checked="" type="checkbox"/> Full registration(s) (Art. 10)	<input type="checkbox"/> Intermediate registration(s) (Art. 17 and/or 18)	
Tonnage band (as per dissemination site)		
<input type="checkbox"/> 1 - 10 tpa	<input type="checkbox"/> 10 - 100 tpa	<input type="checkbox"/> 100 - 1000 tpa
<input checked="" type="checkbox"/> 1000 - 10,000 tpa	<input type="checkbox"/> 10,000 - 100,000 tpa	<input type="checkbox"/> 100,000 - 1,000,000 tpa
<input type="checkbox"/> 1,000,000 - 10,000,000 tpa	<input type="checkbox"/> 10,000,000 - 100,000,000 tpa	<input type="checkbox"/> > 100,000,000 tpa
<input type="checkbox"/> <1 >+ tpa (e.g. 10+ ; 100+ ; 10,000+ tpa)		<input type="checkbox"/> Confidential
One joint submission with eight active registrants		

*the total tonnage band has been calculated by excluding the intermediate uses, for details see the Manual for Dissemination and Confidentiality under REACH Regulation (section 2.6.11):
https://echa.europa.eu/documents/10162/22308542/manual_dissemination_en.pdf/7e0b87c2-2681-4380-8389-cd655569d9f0

² Accessed October 2021

4.2 Overview of uses

Table: Uses

Part 1:

<input type="checkbox"/> Manufacture	<input checked="" type="checkbox"/> Formulation	<input checked="" type="checkbox"/> Industrial use	<input checked="" type="checkbox"/> Professional use	<input type="checkbox"/> Consumer use	<input checked="" type="checkbox"/> Article service life	<input type="checkbox"/> Closed system
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Part 2:

	Use(s)
Uses as intermediate	-
Formulation	Formulation of the substance
Uses at industrial sites	Intermediate; electroplating agent; catalyst; metal surface treatment; textile coating
Uses by professional workers	Textiles
Consumer Uses	-
Article service life	Textiles, machinery, mechanical appliances, electrical/electronic articles; electrical batteries and accumulators; metal articles

5. JUSTIFICATION FOR THE SELECTION OF THE CANDIDATE CoRAP SUBSTANCE

5.1. Legal basis for the proposal

- Article 44(2)
 Article 45(5)

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 <input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> R	Suspected CMR ¹ <input type="checkbox"/> C <input type="checkbox"/> M <input checked="" type="checkbox"/> R	<input type="checkbox"/> Potential endocrine disruptor
<input type="checkbox"/> Sensitiser	<input type="checkbox"/> Suspected Sensitiser ³	
<input type="checkbox"/> PBT/vPvB	<input type="checkbox"/> Suspected PBT/vPvB ¹	<input type="checkbox"/> Other (please specify below)
Exposure/risk based concerns		
<input type="checkbox"/> Wide dispersive use	<input type="checkbox"/> Consumer use	<input type="checkbox"/> Exposure of sensitive populations
<input type="checkbox"/> Exposure of environment	<input checked="" type="checkbox"/> Exposure of workers	<input type="checkbox"/> Cumulative exposure
<input type="checkbox"/> High RCR	<input checked="" type="checkbox"/> High (aggregated) tonnage	<input type="checkbox"/> Other (please specify below)
In the 90-day oral repeated dose toxicity study with sodium 3-nitrobenzene sulphonate, an increase in absolute testes weight was observed in the mid and high dose groups. The registration dossier includes a valid data waiver for the screening		

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

reproductive/developmental toxicity study (Annex VIII, section 8.7.1) and therefore no data addressing effects on fertility is available. No concern for developmental toxicity was identified from the pre-natal developmental toxicity study in rats with sodium 3-nitrobenzene sulphonate.

Sodium 3-nitrobenzene sulphonate is structurally similar to nitrobenzene (EC 202-716-0), which has a harmonized classification as Repr. 1B H360F due to effects on male fertility. No concern for developmental toxicity has been identified for nitrobenzene. In a previous version of the registration dossier, the registrants of sodium 3-nitrobenzene sulphonate applied a "negative" read-across from nitrobenzene to address effects on development. However, no "positive" read-across from nitrobenzene to address effects on fertility was applied.

The registration data reports industrial and professional uses of sodium 3-nitrobenzene sulphonate. In addition, use in a number of article types is reported.

A further review of the available data is required in order to determine whether further data is needed to clarify the concern for reproductive toxicity (effects on fertility) for sodium 3-nitrobenzene sulphonate.

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

<input checked="" type="checkbox"/> Information on toxicological properties	<input type="checkbox"/> Information on physico-chemical properties
<input type="checkbox"/> Information on fate and behaviour	<input type="checkbox"/> Information on exposure
<input type="checkbox"/> Information on ecotoxicological properties	<input type="checkbox"/> Information on uses
<input type="checkbox"/> Information ED potential	<input type="checkbox"/> Other (provide further details below)
Following the evaluation of the existing data, further information may be requested to address reproductive toxicity (effects on fertility).	

5.5. Potential follow-up and link to risk management

<input checked="" type="checkbox"/> Harmonised C&L	<input type="checkbox"/> Restriction	<input type="checkbox"/> Authorisation	<input type="checkbox"/> Other (provide further details)
Where the concern for reproductive toxicity (effects on fertility) is verified, the need for harmonized classification and labelling will be assessed.			