MINISTRY
OF HUMAN CAPACITIES

Justification Document for the Selection of a CoRAP Substance

Substance Name (public name):	sodium chlorite
EC Number:	231-836-6
CAS Number:	7758-19-2
Authority:	Hungarian REACH Competent Authority
Date:	19/03/2019

Cover Note

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

Table of Contents

1 IDENTITY OF THE SUBSTANCE

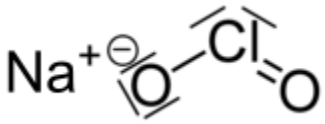
1.1 Other identifiers of the substance

Table: Other Substance identifiers

EC name (public):	sodium chlorite
IUPAC name (public):	sodium chlorite
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	$NaClO_2$
Molecular weight or molecular weight range:	90.442 g/mol
Synonyms:	Chlorous acid, sodium salt Natriumchlorit

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

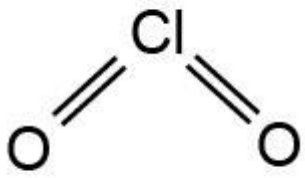
Structural formula:



1.2 Similar substances/grouping possibilities

EC number:	233-162-8
EC name (public):	Chlorine dioxide
CAS number:	10049-04-4
CAS name (public):	-
IUPAC name (public):	-
Index number in Annex VI of the CLP Regulation:	-
Molecular formula:	ClO_2
Molecular weight or molecular weight range:	67,45 g/mol
Synonyms:	Chlordioxid chlorine dioxide Chlorine dioxide, water solution

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
		☐ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restriction	☐ Annex XVII[1]
CLH	☐ 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 legislation	☐ Dangerous substances Directive 67/548/EEC (NONS)	
	☐ Existing Substances Regulation 793/93/EEC (RAR/RRS)	
(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment	
	☐ In relevant Annex	
Other processes/ EU legislation	☐ Other (provide further details below)	
Further details	None of the above mentioned processes are in progress or have been completed.	

[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

There is no harmonised classification for this substance.

3.1.2 Self classification

- In the registration:
    - Ox. Solid 1 H271
    - Acute Tox. 2 H310
    - Acute Tox. 3 H301
    - Skin Corr. 1B H314
    - STOT RE 2 H373
    - Aquatic Acute 1 H400
    - Aquatic Chronic 2 H412

- The following hazard classes are in addition notified among the aggregated self classifications in the C&L Inventory:
    - Eye Dam. 1 H318
    - Aquatic Chronic 3 H412
    - Acute Tox. 3 H311
    - Acute Tox. 2 H330
    - Acute Tox. 4 H302
    - Acute Tox. 4 H332
    - Skin Corr. 1C H314
    - STOT SE 3 H371
    - Skin Irrit. 2 H315
    - Carc. 1B H350
    - Not Classified

3.1.3 Proposal for Harmonised Classification in Annex VI of the CLP

HU MSCA has no information about any proposal for harmonised classification regarding this substance.

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
The substance has a full joint registration with four active registrants. Furthermore the substance has an intermediate registration as well, with one registrant.		

*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

4.2 Overview of uses

Part 1:

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

Part 2:

	Use(s)
Uses as intermediate	Used in synthesis as TII under SCC (PROC 1,3, SU24)
Formulation	Formulation stage (ERC 2; PROC 1, 3, 5, 8a, 8b, 9, 15; PC 8, 21, 26, 34, 37, 0)

[2] *The dissemination site was accessed 16/08/2018.*

Uses at industrial sites	Industrial oxidant (ERC 6a; PROC 1, 2, 3, 4; PC 0) Industrial bleaching for textile (ERC 6b; PROC 1, 2, 3, 5, 8a, 8b; PC 34) Industrial laboratory reagent (ERC 6b; PROC 15; PC 21) Industrial paper pulp bleaching (ERC 6b; PROC 1, 2, 3, 4, 5, 8a, 8b, 9, 15, 21, PC26) Bioethanol production (ERC 6b; PROC 0) Refractory binder for lining of blast furnaces and other applications (ERC 4, PROC 4, 8a; PC 0) Industrial water treatment (ERC 6b, 7; PROC 2; PC37)
Uses by professional workers	Professional bleaching: Market sector cleaners: Formulation of cleaning products (ERC 2; PROC 14,13; PC 35) Professional bleaching: market sector cleaners: brushing application (ERC 8b; PROC 10; PC 35) Professional bleaching: market sector cleaners: end-use stage: cleaning outdoors (ERC 8e; PROC 10; PC 35) Professional bleaching: Market sector cleaners: end-use stage: brushing application (ERC 8b; PROC 10; PC 35)
Consumer Uses	Consumer end-use stage: cleaning outdoors (ERC 8e; PC 35) Consumer end-use stage: cleaning indoors (ERC 8b; PC 35)
Article service life	-

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[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)

[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

Sodium chlorite is professionally used mostly in correlation with paper pulp and textile bleaching and waste water treatment. During the manufacture of the substance itself, sodium chlorite is used in closed systems, however, exposure is likely to occur during batch processes (PROC 5), therefore, exposure of the workers to the substance cannot be excluded.
In addition, the substance is used as a washing and cleaning agent by professionals and consumers. According to SPIN database, the uses indicate very probable exposure of consumers, occupational workers and waste water (Use index: 5).

According to the available data sodium chlorite and chlorine dioxide (read-across substance) were positive in two in vitro studies (mammalian cell gene mutation assay with and without metabolic activation [chlorine dioxide] and chromosome aberration test [sodium chlorite] without metabolic activation), and was mutagenic in Salmonella typhimurium TA100.
In the CSR several in vivo studies are available and one positive result was observed in an in vivo micronucleus assay in somatic cells exposed by the intraperitoneal route. Other in vivo studies, mostly via oral administration, presented negative results. However in these studies no cytotoxicity was observed and the dosing concentrations were quite low, thus the results shall not be considered as unambiguous.

In a developmental toxicity study Long-Evans rat pups were exposed ad libitum to chlorine dioxide from postnatal day 1 to 20. Forebrain weight and protein content were decreased on post natal day 21 and 35, as were the DNA content on day 35 and the number of dendritic spines on cerebral cortical pyramidal cells. Histopathological examinations revealed no gross lesions in the brain.

In an experimental study Long-Evans rats were given access to 0, 1, 10, 100 and 500 ppm sodium chlorite in deionised water ad libitum as drinking water. Decreases in serum T3 and T4 were observed on Postnatal Days 21 and 40 in male and female pups exposed to 100 ppm chlorite. A significant increase in the percentage of abnormal sperm morphology and decrease in sperm direct progressive movement were observed for adult males at chlorite levels of 100 or 500 ppm. Although in another study 35, 70 and 300 ppm sodium chlorite were given to Sprague-Dawley rats but there was no change in the thyroid hormon levels.

The available data on developmental studies and mutagenic properties are contradictory, and the positive findings raise a concern regarding the substance that warrants further clarification. Overall, the concerns for developmental toxicity and mutagenicity for this substance have not been clarified based on available data.

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)
In order to clarify the concerns identified further information on mutagenic and developmental toxicological properties of the substance may be necessary.	

5.5. Potential follow-up and link to risk management

☒ Harmonised C&L	☐ Restriction	☐ Authorisation	☐ Other (provide further details)
Depending on the outcome of the substance evaluation a proposal for harmonised classification is a possible risk management measure.			