

SAFETY DATA SHEET

which is not required by the Art. 31. or 32. of the Regulation (EC) No. 1907/2006

Trade name: **Solumium® Oral** Date of print: 12/10/2019
 Revision date: 11/10/2019
 Version: 2.5. / EN

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier **Solumium® Oral**

1.2. Relevant identified uses of the substance or mixture and uses advised against

Antimicrobial solution for the treatment and prevention of skin and mucous membrane infections. Medical device.

1.3. Details of the supplier of the safety data sheet

Manufacturer and supplier: Solumium Kft.
 Address: 1118 Budapest, Rozmaring u. 19.
 E-mail address for the competent person responsible for the safety data sheet: info@solumium.com, noszti@t-online.hu
 Phone +36-1-3194323 (8:00-16:00) +36-20-470-0597

1.4. Emergency telephone number

Emergency telephone number:

<http://apps.who.int/poisoncentres/>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to **Regulation (EC) No. 1272/2008 (CLP)**: not classified

2.2. Label elements

Labeling according to Regulation (EC) No 1272/2008 [CLP]

No specific requirement

2.3. Other hazards

The mixture does not meet persistent (P), bioaccumulation (B) and toxicity (T) criteria. The mixture is not PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

Name	EC-Nr.	CAS-Nr.	REACH registration Nu.	Content (%)	Classification according to 1272/2008 (CLP) ³	
					Hazard categories ¹	H-phrase(s) ¹
Chlorine dioxide...%	233-162-8	10049-04-4	Not available ²	≥0,03 and ≤0,035	Acute Tox.3* Skin Corr. 1B Aquatic Acute 1	H301 H314 H400

¹ – See Section 16 for the full text of the abbreviations declared above.

² – The manufacturing volume of the substance does not reach the limit for registration requirement

³ – Chlorine dioxide has been classified in 790/2009/EU which is the ATP 1 for the CLP regulation with a new index number 017-026-01-0. These classifications are shown above. Its concentration limits are given in the sections below.

*– so called minimum classification in the CLP regulation.

SECTION 4: First aid measures

4.1. Description of first aid measures

If inhaled: Remove to fresh air, seek medical attention.

On skin contact: No action is required.

On contact with eyes: No action is required.

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On ingestion: A single ingestion of a dilute solution containing less than 24 mg of chlorine dioxide does not pose an unacceptable risk. If a much larger quantity is swallowed, add 2-3 g of vitamin C (ascorbic acid) dissolved in a glass of water. The injured person should drink plenty of water. Do not induce vomiting. In case of complaints, seek medical advice.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms: When inhaling large quantities, cough, pale skin, headache, difficulty breathing.

Effects of excessive exposure: Bronchitis, pneumonia, pulmonary edema.

Hazards: Symptoms occur immediately.

4.3. Indication of any immediate medical attention and special treatment needed

Treatment: Treat according to symptoms.

SECTION 5: Firefighting measures

The product is not flammable, but as an oxidizer nourishes combustion.

5.1. Extinguishing media

Suitable extinguishing media: the same as for the source of the fire

5.2. Special hazards arising from the substance or mixture

When the solution is heated: Chlorine dioxide in the air.

5.3. Advice for firefighter

Special protective equipment: Wear ambient air-independent breathing apparatus and chemical protective clothing.

Further information: Keep containers cool by spraying with water if exposed to fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Respiratory protection should be used in the presence of vapours/fumes/spray.

6.2. Environmental precautions

Do not empty into drains. Do not discharge into the subsoil/soil.

6.3. Methods and material for containment and cleaning up

For large amounts: Pump off product. Neutralize it with adding ascorbic acid.

For residues: Pick up with absorbent material (e.g. sand, sawdust, general-purpose binder). Dispose of absorbed material with adding ascorbic acid solution.

The resulting solution or the absorbent material can be disposed.

6.4. Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

When handling heated product, vapours of the product should be ventilated.

7.2. Conditions for safe storage, including any incompatibilities

Store tightly closed in a cool place, protected from direct sunlight. Keep out of the sight and reach of children. The product may only be stored in the original sealed and properly labelled container.

7.3. Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

An occupational exposure level of 0.28 mg/m³ (0.1 ppmv) for 8 hours, and a short term of 0.84 mg/m³ (0.3 ppmv) have been assigned by OSHA. There is a DNEL value of 0.308 mg/m³ in the registration document. PNEC values for fresh water is 0,021 µg/L

8.2. Exposure controls

Respiratory protection: None

Hand protection: None

Eye protection: None

Body protection: None

General safety and hygiene measures: Do not breathe vapour/spray. Apply ventilation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Data refer to the product as a diluted aqueous solution.

- a) Appearance: liquid
- b) Color: yellow
- c) Odour: specific, like chlorine
- d) Odour threshold: 0.1 ppmv (for pure chlorine dioxide)
- e) pH-value: 4,5-5,5
- f) Melting point/freezing point: 0°C
- g) Boiling range: 100°C
- h) Flash point: not flammable
- i) Evaporation rate: no data
- j) Flammability (solid, gaseous): not flammable
- k) Ignitable, explosive range: not flammable
- l) Vapour pressure: $P = c \cdot \exp(12.732 - 3102/T)$, where P is the vapor pressure of chlorine dioxide in Hgmm above a solution with a c concentration of chlorine dioxide in g/L, and T is the absolute temperature in Kelvin. Ishi, G. Chemical Engineering (Japan) **22(3)** (1958)
- m) Vapour density: no data
- n) Density: 1,00 g/cm³
- o) Solubility: see the formula by Ishi above
- p) Partition coefficient n-octanol/water: no data
- q) Self-ignition temperature: not flammable
- r) Decomposition temperature: no data
- s) Viscosity: same as water
- t) Explosive properties: chlorine dioxide can decompose with a puff in the gas phase if its concentration is above 10 % (v/v) and can detonate when its concentration is above 40 % (v/v), therefore accumulating chlorine dioxide above an aqueous solution shall be avoided.
- u) Oxidizing properties: oxidizing

9.2. Other information

Not applicable.

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SECTION 10: Stability and reactivity

10.1. Reactivity

Oxidizing organic matter.

10.2. Chemical stability

The product is stable if stored and handled as prescribed/indicated.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

Under fire or when heated the product evolves gaseous chlorine dioxide which is toxic.

10.5. Incompatible materials

Substance that can be oxidized.

10.6. Hazardous decomposition products

No hazardous decomposition products if stored and handled as prescribed/indicated.

SECTION 11: Toxicological information

Information is related to pure chlorine dioxide. Specific concentration limits for the aqueous solutions of chlorine dioxide are given from the 1. ATP as well as from the registration document.

11.1. Information on toxicological effects

Acute toxicity – oral:

Rats LD50 = 94 mg/kg

0.3-0.4 mg/kg chlorine dioxide when consumed by healthy adults caused no harmful effect. In the registration solutions of 0.6-2.0% are classified as Acute Tox. 3, however, according to the LD50 measured Solumium Oral solution need not to be classified.

Acute toxicity – inhalation as a solution:

Rats LC50 = 6830 mg/m³ (4h)

11.2. Irritation/Corrosion

Skin corrosion/Skin irritation: Aqueous solutions of $\geq 5\%$ are classified as Skin Corr. 1B, and those of $1\% \leq C < 5\%$ as Skin Irrit. 2 according to the 1. ATP. In the registration document solutions of 1-2% are considered as Skin Irrit. 2.

Eye damage/Irritation: Solutions of $3\% \leq C < 5\%$ are classified as Eye Dam. 1 and those of $0,3\% \leq C < 3\%$ as Eye Irrit. 2 according to the 1. ATP. In the registration document solutions of 0.6-2% are not considered as irritative to eye at all, based, however, negative tests performed in more diluted, 10-20 ppm solutions.

11.3. Sensitization: Not classified

11.4. Mutagenicity: Not classified. Based on available data, the classification criteria are not met.

11.5. Carcinogenicity: Not classified. Based on available data, the classification criteria are not met.

11.6. Reproductive toxicity: Not classified. Based on available data, the classification criteria are not met.

11.7. STOT-single exposure: Pure chlorine dioxide is not classified, however, in the 1. ATP aqueous solutions of $\geq 3\%$ are classified as STOT SE 3.

11.8. STOT-repeated exposure: Not classified.

11.9. Aspiration hazard: Not classified due to lack of data.

11.10. Toxicokinetic: No data

11.11. Genetic toxicity: Not classified. Based on available data, the classification criteria are not met.

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16.1. Indication of changes The measures required for the eyes and skin were modified/eased and the form was adapted to the Hungarian Correction of Commission regulation 2015/830.

16.2. Abbreviations and acronyms

Carc.: Carcinogenicity

CAS number: Chemical Abstracts Service number

CLP: Classification Labelling Packaging Regulation

CSR: Chemical Safety Report

DNEL: Derived No Effect Level

EC: European Commission

EC number: EINECS and ELINCS number

EC50: Half maximal effective concentration

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

Irrit.: Irritation

LC50: Lethal concentration, 50 %

LD50: Median Lethal dose

PBT: Persistent, Bioaccumulative and Toxic

PNEC: Predicted No Effect Concentration

REACH: The Registration, Evaluation, Authorization and Restriction of Chemicals

Resp.: Respiratory

Sens.: Sensitization

STOT: Specific Target Organ Toxicity

STOT SE: Specific target organ toxicity — single exposure

STOT RE: Specific target organ toxicity — repeated exposure

Tox.: Toxicity

vPvB: Very Persistent and Very Bioaccumulative

16.3. Key literature references and sources for data 1. ATP, Adaptation to the Technical Progress of the CLP regulation. Registration document published on the website of the European Chemical Agency.

16.4. Full text of abbreviations

H- Phrases

H301	Toxic if swallowed
H314	Cause sever skin burns and eye damage
H400	Very toxic to aquatic life

Hazard classes

Acute Tox. 3	Acute Toxicity 3
Aquatic Acute	Hazardous to the aquatic environment
Eye Irrit. 2	Serious eye irritation 2
Skin Irrit. 1B	Skin irritation 1B
STOT SE 2	Specific target organ toxicity – single exposure 2