



SAFETY DATA SHEET

In accordance with Regulation (EC) No 1907/2006 (REACH) and Regulation (EU) 2020/878

Date of issuance: 05.01.2024 r	Issue: 02/2024
According to Regulation (EU) № 1907/2006 (REACH)	Supersedes issue: 05/2022

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1. Product identifier:

Commercial product name: **OXISEPT**

Unique Formula Identifier (UFI): S410-C09N-C00X-EFS6

1.2. Relevant identified uses of the mixture and uses advised against:

Preparation for disinfection of invasive and non-invasive medical instruments and high-level cold disinfection of thermo sensitive and thermo resistant medical devices.

Medical Device class II b.

1.3. Details of the supplier of the safety data sheet:

ZHIVAS Ltd, 36, Dondukov Blvd, 1000 Sofia, Bulgaria
Postal address: 14, Assen Yordanov Blvd., Sofia 1592
Telephone/Fax + 359 2 981 78 23
E- mail: zhivas@techno-link.com
+ 359 2 981 78 23 (Zhivas Ltd, Sofia)

1.4. Emergency telephone number:

2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture:

The product is classified as hazardous in accordance with the Regulation (EU) 1272/2008 (CLP) (and subsequent amendments).

Hazard class and hazard category

Eye Dam.1; H318

2.2 Label elements

Components on the label:

Peracetic acid "in situ"

Pictograms:



GHS05

Signal word: **Danger**

Hazard statements:

H318 Causes serious eye damage

Precautionary statements:

P280 Wear protective gloves/eye protection/face protection.

P305+351+338 + 310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. Immediately call a POISON CENTER/ doctor.

P301+P312- IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell.

**2.3. Other hazards**

-On the basis of the available data, it does not contain substances with PBT or vPvB properties in a percentage more than 0,1 %.

- Eco toxicological information: The mixture does not contain components considered to have endocrine disrupting properties under REACH Regulation Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

- Toxicological information: The mixture does not contain components that are considered to have endocrine disrupting properties under REACH Regulation, Article 57(f) or Commission Delegated Regulation (EU) 2017/2100, or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

3. COMPOSITION/ INFORMATION ON INGREDIENTS**3.2. Mixture**

The preparation is a dry mixture of oxygen based bleaching agent and anionic surfactants.

Further ingredients: activator for generation of peroxy acetic acid *in situ* (TAED), complexation agent, corrosion inhibitor, carbonates.

Hazardous ingredients:

Substance name	CAS No.	EC No.	Concentration g/100g	Classification (Reg.(CE) 1272/2008)
Sodium percarbonate* (Disodium carbonate, compound with hydrogen peroxide (2:3))	15630-89-4	239-707-6	20 < x < 50	Eye Damm.1;H318 Acute Tox.4;H302 Oxidizing solid; H272
Citric acid anhydros	77-92-9	201-069-1	< 15.0	Eye Irrit. 2; H 319
Sodium carbonate anhydrous	497-19-8	207-838-8	≤ 5.00	Eye Irrit. 2; H 319
1-Hydroxyethanediphosphonic acid sodium salt	29329-71-3	249-559-4	≤ 2.00	Acute Tox. 4; H 302 Eye Irrit. 2; H 319
Disodium methasilicate, Penthydrate	10213-79-3	229-912-9	< 1.00	Skin Corr. 1B; H314 STOT SE 3; H335 Corr. metals 1; H290
Sodium C14-16 alpha-olefin sulphonate	68439-57-6	270-407-8	< 0.50	Skin Irrit. 2; H315 Eye Dam.1; H318

The texts of H phrases are given in section 16.

4. FIRST AID MEASURES**4.1. Description of first aid measures****General information:**

In case of eye contact and ingestion with symptoms of irritation, immediately call for medical help. (When possible show the label).

Inhalation:

Take the subject out from dusty environment and blow nose. If respiratory symptoms persist, call a physician.

Eye contact:

Rinse eyes immediately with plenty of water for 10 - 15 minutes. Consult with an ophthalmologist.

Skin contact:

Rinse with running water.



Ingestion: Rinse the mouth with plenty of water, drink 1 – glasses of water. Do not induce vomiting. If symptoms persist, call a physician

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

Principal routes of exposure:

Oral:	Ingestion may cause irritation to mucous membranes.
Eye contact:	Irritating to eyes.
Skin contact:	May cause irritation by skin contact.
Ingestion:	Ingestion of this material may cause symptoms such as nausea, vomiting, gastric distress.
Inhalation:	Inhalation may cause irritation.

4.3. Indication of any immediate medical attention and special treatment needed: none

Treatment:	Treat symptomatically
Protection of first-aiders:	None
Notes to physician:	None

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media:	Suitable for all regular extinguishing materials.
5.2. Special hazards, arising from the preparation itself	None known. In case of burning of the PE package the following toxic gases may be formed: CO, CO ₂ , light hydrocarbons.
5.3. Advice for firefighters	Standard protective equipment should be worn by fire-fighters. In the event of a large fire toxic fumes containing oxides of carbon may be formed, which would necessitate the use of a self contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions:	Avoid direct contact with skin and eyes. Refer to protective measures, listed in sections 7 and 8.
6.2. Environmental precautions:	Should not be released in the environment (e.g. into the sewer system). If the product contaminates the environment inform respective authorities and proceed according to the local legislation
6.3. Methods and material for containment and cleaning up:	Remove mechanically, wash away residue with plenty of water. The contaminated material should be collected for subsequent disposal.
6.4. Reference to other sections:	Refer to protective measures, listed in sections 7 and 8

7. HANDLING AND STORAGE

7.1. Precautions for safe handling	Avoid dust formation. Avoid direct contact with the skin and eyes. Do not allow disposal of the preparation into the environment. Do not use near possible sources of ignition
7.2. Conditions for safe storage, including any incompatibilities	Store in well closed original package, in dry and well ventilated premises, away from sources of ignition at temperature not exceeding 35°C. Do not expose to direct sunlight.
7.3. Specific end uses	For professional use only

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION



8.1. Exposure limit values

DNEL/DMEL and PNEC values:

Derived no-effect levels (DNEL)

For the mixture: There are no available data on the mixture itself.

DNEL Values for the components of the mixture:

Component	Limit value type (End use)	Exposure route	Exposure frequency	Limit value (DNEL)
Sodium carbonate anhydrous	Consumer, local impact	Inhalation	Long-term (repeated)	10 mg/m ³
Sodium metasilicate pentahydrate	Consumer, systemic impacts	Inhalation	Long-term (repeated)	6,22 mg/m ³
Disodium hydrogen phosphate anhydrous	Consumer, systemic impacts	Inhalation	Long-term (repeated)	4,07 mg/m ³
Disodium carbonate, compound with hydrogen peroxide (2:3)	Consumer, local impact	Inhalation	Long-term (repeated)	5 mg/m ³

The predicted no-effect concentration (PNEC) There are no available data on the mixture itself

8.2. Exposure controls

- General protective measures:** Good hygiene practice, no further data, see item 7.
- Hygiene measures:**
 - Store work clothing separately
 - Avoid contact of the preparation
 - Change contaminated clothes immediately
- Respiratory protection:** Use filter respiratory devices.
- Hand protection:** Use suitable protective gloves made of nitril rubber or butyl rubber
- Eye protection:** Fully tight goggles
- Body protection:** Protective clothing. Wash off any dirt that gets onto skin with lots of water.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	granules
Colour:	white (the colour of the used chemical TAED)
Odour:	None
pH (1 % solution in water)	8.0 –9.0 (20° C)
Boiling point	Not applicable
Flash point	Not applicable
Flamability	Not applicable
Explosive properties	Not explosive
Oxidizing properties	Yes, oxidizing solid of class 5.1 (by heating over 35 °C or after contact with water)
Vapours pressure	No data
Density (bulk) , 20 °C	0.8– 1.05 g/cm ³
Solubility in organic solvents	No data
Solubility in water	Fully soluble
Partition coefficient	Not applicable
Viscosity	Not applicable
Vapour density	Not applicable
Evaporation rate	Not applicable

9.2. Other information – None



10. STABILITY AND REACTIVITY

10.1. Reactivity	Reacts with water forming peracetic acid in the solution. The process is irreversible.
10.2. Chemical stability	Stable under recommended storage conditions. Keep dry.
10.3. Possibility of hazardous reactions	Reacts with burning materials and acids; heat released
10.4. Conditions to avoid:	High humidity by the storage
10.5. Incompatible materials:	Burning materials, acids, water, chlorine containing substances
10.6. Hazardous decomposition products:	Not expected, if followed the instructions for use and storage conditions.

11. TOXICOLOGICAL INFORMATION

11.1. Information on the toxicological effects

(a) acute toxicity;

Acute toxicity of the mixture::

Acute oral toxicity

LD₅₀ oral (calculated) – 2732 mg/kg body weight.

Acute dermal toxicity

LD₅₀ dermal (calculated) > 2000 mg/kg body weight

Acute inhalation toxicity

No data available

The mixture is not classified on acute toxicity.

Acute toxicity of ingredients:

Sodium percarbonate:

LD₅₀ oral,(Rat - male and female) - 1.034 mg/kg (US-EPA)

LD₅₀ Dermal (Rabbit - male and female) - > 2.000 mg/kg (US-EPA)

Sodium percarbonate is classified - acute oral toxicity, Category 4 based on the criteria of the CLP Regulation (EC) No 1272/2008.

Existing animal data on acute toxicity of Sodium percarbonate show that it exhibits local irritation effects in the gastrointestinal and respiratory tracts and on the skin.

1-Hydroxyethanediphosphonic acid sodium salt

LD₅₀ oral (Rat) - 1100 mg/kg

(b) skin corrosion/irritation;

The mixture is not classified.

Data on ingredients:

A human patch test performed with sodium percarbonate (York et al. 1996) and a valid and reliable skin irritation test performed with rabbits Glaza 1990c) shows that sodium percarbonate is not irritating to the skin.

Disodium methasilicate, Pentahydrate (Skin Corr. 1B; H314) in concentration <1% according to the criteria of the CLP Regulation (table 3.2.3) does not lead to classification of the mixture.

(c) serious eye damage/irritation;

In the test on rabbit eye with Sodium percarbonate (BASF data), eye corrosion was observed.

The mixture contains Sodium percarbonate in concentration 36 %, and lead to classification - Serious eye damage, cat.1.

(d) respiratory or skin sensitization; EN_SDS_OXISEPT_06_2022

A valid GLP guideline study was conducted with guinea pigs in which sodium
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percarbonate was not a skin sensitizer.

The mixture does not contain allergens above the established general/specific limits and it is not classified.

(e) germ cell mutagenicity;

Data on the mutagenicity of sodium percarbonate are not available but it is likely that any test results for sodium percarbonate will be similar to those of hydrogen peroxide due to the release of hydrogen peroxide in aqueous media.

The available studies on hydrogen peroxide, most of them, in particular the in vivo studies, were performed according to OECD guidelines and GLP, are not in support of significant genotoxicity/mutagenicity under in vivo conditions. Therefore sodium percarbonate is also unlikely to have any in vivo genotoxic potential.

The mixture does not meet the classification criteria for this hazard class.

(f) carcinogenicity;

Carcinogenicity studies with animals and sodium percarbonate are not available.

The mixture does not meet the classification criteria for this hazard class.

(g) reproductive toxicity;

In conclusion, the available information supports the view that sodium percarbonate and its dissociation products hydrogen peroxide and sodium carbonate do not act as reproductive toxicants or may reach the developing foetus under the conditions of human exposure. It can thus be concluded that the substances should not be considered as reproductive or developmental toxicants.

The mixture does not meet the classification criteria for this hazard class

(h) STOT-single exposure;

The respiratory irritation can be explained by the elevated particle concentration in the breathing air and the formation of hydrogen peroxide and sodium carbonate from the dissociation of sodium percarbonate in the upper respiratory tract. The RD50 was approximately 700 mg/m³.

(i) STOT-repeated exposure;

As it is expected that repeated dose toxicity of sodium percarbonate will mainly be mediated by hydrogen peroxide, no observed adverse effect levels can be defined on the basis of its hydrogen peroxide content. Based on the 90-day drinking water study according to OECD guidelines and GLP with hydrogen peroxide and catalase deficient mice, the predicted NOAEL of sodium percarbonate would be 308 ppm .

The mixture does not meet the classification criteria for hazard class STOT SE and STOT RE.

(j) aspiration hazard.

Not relevant.

11.2 Information on other hazards

The mixture does not contain components considered to have endocrine disrupting properties under REACH, Article 57(e) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1 % or higher.

12. ECOLOGICAL INFORMATION

Available data for **sodium percarbonate**.

12.1 Toxicity

Acute toxicity Fish: 96hr-LC50 = 70.7mg/l(*Pimephales promelas*)

Invertebrates: 48hr-EC = 4.9mg/l(*Daphnia magna*)

Algae: 72hr-EC50 = 7.7mg/l(*Crupina vulgaris*)

Chronic toxicity Invertebrates: 48d-NOEC =2.0mg/l(*Daphnia magna*)

Algae:72hr-NOEC = 0.3mg/l(*Crupina vulgaris*)

12.2 Persistence and degradability

Based on a log Kow -1.57 sodium percarbonate is not expected to persistence

12.3 Bioaccumulative potential

No bioaccumulation of sodium percarbonate or its dissociation products sodium carbonate and hydrogen



	peroxide is expected.
12.4 Mobility in soil	Volatilisation of hydrogen peroxide from surface waters and moist soil is expected to be very low, while it is expected to be highly mobile in soil.
12.5 Results of PBT and vPvB assessment	Not relevant
12.6. Endocrine disrupting properties	The mixture do not contain components that are considered to have endocrine disrupting properties under REACH Regulation Article 57(e) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
12.7 Other adverse effects	No other adverse environmental impacts are expected (such as ozone destruction, potential for photochemical ozone creation, potential for global warming).

13. DISPOASL CONSIDERATIONS

13.1. Waste treatment methods	Disposal should be in accordance with the local, state or national legislation Contain, absorb and transfer to disposable container. Dilute with plenty of water. Clean thoroughly. Do not discharge into drains or the environment; dispose to an authorized waste collection point.
13.2. Contaminated packaging:	Rinse with water. Empty packaging should be taken to an approved waste handling site for recycling or disposal The cleaned packaging is disposed as not dangerous wastes.

14. TRANSPORT INFORMATION

To be transported in closed transport vehicles, separated from food and drinks.

14.1. UN Number	Not applicable
14.2. UN proper shipping name	Not applicable
14.3. Transport hazard class	Not hazardous for any type of transport
14.4. Packing group	No data
14.5. Environmental hazards	No data
14.6. Special precautions for user	Not applicable
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the mixture

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006



REGULATION (EU) 2020/878, amending the annex II of Regulation (EC) 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH);

REGULATION (EC) No 648/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 March 2004 on detergents

DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

ESIS : European chemical Substances Information System

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste

15.2. Chemical safety assessment

For this mixture a chemical safety assessment has not been carried out.

For this mixture a chemical safety assessment has not been carried out.

16. OTHER INFORMATION

The information given corresponds to the current state of our knowledge and experience of the product, and is not exhaustive. This applies to product, which conforms to the specification unless otherwise stated. In this case of combinations and mixtures one must make sure, that no new dangers can arise.

In any case the user is not exempt from observing all legal, administrative and regulatory procedures, relating to the product, personal hygiene and protection of human welfare and the environment.

Section 1.1: Added Unique Formula Identifier (UFI)

SDS updated according to the requirements of Regulation (EU) 2020/878

Hazard statements (GHS) in section 3:

- H290 May be corrosive to metals
- H302 Harmful if swallowed
- H314 Causes severe skin burns and eye damage
- H318 Causes severe eye damage
- H319 Causes serious eye irritation
- H335 May cause respiratory irritation