ZHIVAS Ltd.

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SAFETY DATA SHEET

Date of issuance:**20.03.2016** r	Issue**: 04/2016**
According to Regulation (EC) **No 453/2010**	Supersedes issue: **03/2015**

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1. Product identifier: Commercial product name: **OXISEPT**

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, Asen Jordanov Blvd., Sofia 1592
Telephone/Fax + 359 2 981 78 23
E- mail: zhivas@techno-link.com

1.4. Emergency telephone number: + 359 2 981 78 23 Sofia, Bulgaria

2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture: The classification and labeling is in accordance with Regulation (EC) No. 1272/2008, Annex VI (CLP)

Hazard class and hazard category

Oxidizing solid 2; H272
Eye Irrit. 2; H319
Skin Irrit. 2; H315
STOT SE3, H 335

2.2 Label elements

Pictograms:

GHS02

GHS07

Signal word: **Warning**

Hazard statements:
H272 May intensify fire; oxidiser.
H319 Causes serious eye irritation.
H315 Causes skin irritation.
H335 May cause respiratory irritation.

Precautionary statements:

P210 Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P280 Wear protective gloves/eye protection/face protection.
P302+352 IF ON SKIN: Wash with plenty of water.
P305+351+338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing
P403+233 Store in a well-ventilated place. Keep container tightly closed.

2.3. Other hazards **No**

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), complexion agent, corrosion inhibitor, carbonates.

Hazardous ingredients:

Substance name	CAS No.	EC No.	Concen-tration, g/100g	Classification (Reg.(CE) 1272/2008)
Sodium percarbonate* (Disodium carbonate, compound with hydrogen peroxide (2:3)	15630-89-4	239-707-6	30.00	Eye Damm.1;H318 Acute Tox.4;H302 Oxidizing solid; H272
Sodium carbonate anhydrous	497-19-8	207-838-8	60.50	Eye Irrit. 2; H319
Disodium methasilicate, Pent hydrate	10213-79-3	229-912-9	2.00	Skin Corr. 1B; H314 STOT SE 3; H335
Sodium C14-16 alpha-olefin sulphonate	68439-57-6	270-407-8	2.00	Skin Irrit. 2; H315 Eye Dam.1; H318
Phosphonate (etidronic acid, tetrasodium salt)	29329-71-3	249-559-4	0.50	Acute Tox. 4; H 302 Eye Irrit. 2; H 319

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/m³
Sodium metasilicate pentahydrate	Consumer, systemic impacts	Inhalation	Long-term (repeated)	6,22 mg/m³
Disodium hydrogenphosphate anhydrous	Consumer, systemic impacts	Inhalation	Long-term (repeated)	4,07 mg/m³
Disodium carbonate, compound with hydrogen peroxide (2:3)	Consumer, local impact	Inhalation	Long-term (repeated)	5 mg/m³

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 nitryl rubber or butyl rubber

Eye protection: Fully tight goggles

Body protection: Protective clothing. Wash off any durt that gets onto skin with lots of water.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state:	Solid powder
Colour:	Light green, light blue or white (the colour of the used chemical TAED)
Odour:	None
pH (1 % solution in water)	10,0 –11,0 (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 50 °C or after contact with water)
Vapours pressure	No data
Relative density (bulk) , 20 °C	0,95 – 0,98 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 – No

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.

10.6. Hazardous decomposition products: Not expected, if followed the instructions for use.

11. TOXICOLOGICAL INFORMATION

11.1. Information on the toxicological effects

(a) acute toxicity;	LD_{50} oral, white rats (evaluated) – < 2000 mg/kg body weight. It can be concluded that the existing animal data on acute toxicity show that sodium percarbonate exhibits local irritation effects in the gastrointestinal and respiratory tracts and on the skin. Systemic effects are not to be expected. Sodium percarbonate should be classified for acute oral toxicity, Category 4 based on the criteria of the CLP Regulation (EC) No 1272/2008.
(b) skin corrosion/irritation;	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.
(c) serious eye damage/irritation;	In test (BASF test) on rabbit eye corrosion, eye corrosion was observed.
(d) respiratory or skin sensitization;	A valid GLP guideline study was conducted with guinea pigs in which sodium percarbonate was not a skin sensitizer.
(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.
(f) carcinogenicity;	Carcinogenicity studies with animals and sodium percarbonate are not available.
(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.
(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 .
(j) aspiration hazard.	Not relevant.

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 Other adverse effects	None identified

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.
13.2. Contaminated packaging:	Do not discharge into drains or the environment; dispose to an authorized waste collection point. 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	1479
14.2. UN proper shipping name	Oxidizing solid, n.o.s., (sodium carbonate peroxyhydrate)
14.3. Transport hazard class	5.1
14.4. Packing group	III
14.5. Environmental hazards	No
14.6. Special precautions for user	Keep dry
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

Sodium Percarbonate (EC # 239-707-6 / CAS # 15630-89-4), disodium carbonate, compound with hydrogen peroxide (2:3) , Information for the Downstream Users (DUs) and DUs' Trade Associations on the Exposure Scenarios, use descriptors and Uses, Sodium Percarbonate REACH-Consortium, Brussels, 2010;

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;

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation 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 2000/39/EC - indicative occupational exposure limit values of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.;

Directive 89/656/EEC - use of personal protective equipment of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16 (1) of Directive 89/391/EEC) ;

DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy;

COMMISSION DIRECTIVE 2001/60/EC of 7 August 2001 adapting to technical progress Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations;

Council Directive 91/689/EEC of 12 December 1991 on hazardous waste;

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

DIRECTIVE 2008/112/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 amending Council Directives 76/768/EEC, 88/378/EEC, 1999/13/EC and Directives 2000/53/EC, 2002/96/EC and 2004/42/EC of the European Parliament and of the Council in order to adapt them to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste;

COUNCIL DIRECTIVE 94/33/EC of 22 June 1994 on the protection of young people at work;

GESTIS Stoffdatenbank, IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung;.

GESTIS DNEL-Datenbank, IFA Institut für Arbeitsschutz der Deutschen Gesetzlichen Unfallversicherung;

15.2. Chemical safety assessment

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 mast 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.

Hazard statements (GHS) in section 3:

H272 May intensify fire; oxidizer
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