



SAFETY DATA SHEET

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

Date of issuance: 05.05.2022	Issue: 07/2022
According to Regulation (EU) № 1907/2006 (REACH)	Supersedes issue: 06/2018

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

1.1. Product identifier:

Commercial name: **ZHIVASEPT FOAM**

Unique Formula Identifier (UFI): **8800-90DP-A000-T1XJ**

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

Ready to use solution for hygienic and surgical disinfection of hands and skin

1.3. Company identification:

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,

Internet: www.zhivas.com

1.4. Emergency telephone :

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 classes and hazard categories:

Eye Irrit. 2 ; H 319

2.2 Label elements

Hazard-determining components of labelling:

Chlorhexidine digluconate

Pictograms:



Signal word: Warning

Hazard statements:

H319 – Causes serious eye irritation.

Precautionary statements:

P102-Keep out of reach of children.

P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+313 If eye irritation persists: Get medical advice/attention.

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 %.
- Ecotoxicological 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. Mixtures

The mixture is an aqueous solution of chlorhexidine digluconate and alkylpolyglycoside. It contains as well certain harmless ingredients such as skin softeners, fragrance and coloring agent.

Substance name	CAS №	EC №	Concentration. g/100g	Classification Reg.(CE)1272/2008
Chlorhexidine digluconate	18472-51-0	242-354-0	0.8	Eye Dam.1,H 318 Aquatic Acute 1; H400 Aquatic Chronic1; H411

For the wording of the listed hazard statements refer to section 16.

4. FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation:

Not needed.

Eye contact:

Rinse immediately with plenty of water - also under the eyelids - for 15 - 20 minutes. Consult with an ophthalmologist.

Skin contact:

Not applicable.

Ingestion:

Rinse the mouth with plenty of water (if only the person is conscious). 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. Irritating to eyes.
Eye contact:	Not applicable.
Skin contact:	Ingestion of this material may cause symptoms such as nausea, vomiting, gastric distress.
Inhalation:	Not applicable.
4.3. Indication of any immediate medical attention and special treatment needed:	In case of eye contact and ingestion with symptoms of irritation, immediately call for medical help.

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media:	CO ₂ , fire extinguishing dust. The product is not flammable
5.2. Special hazards, arising from the preparation itself	In case of fire, toxic gases may be formed: CO, CO ₂ . 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, protective equipment and emergency procedures:	Not necessary. Avoid direct contact with the eyes.
6.2. Environmental precautions:	Should not be released in large quantities in the environment. The small releases can be diluted with plenty of water. 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:	Wash with water.
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	Follow the operating instructions as specified on the label. Avoid direct contact with the eyes. Do not allow disposal of the mixture into the environment.
7.2. Conditions for safe storage, including any incompatibilities	Store in well closed original package, in dry and well ventilated premises, at temperatures between 0°C and 35 °C. Do not expose to direct sunlight.
7.3. Specific end uses	Non

**8. EXPOSURE CONTROLS/ PERSONAL PROTECTION****8.1. Exposure limit values**

Limit values for some ingredients in the air of the work environment – Not applicable

8.2. Exposure controls

General protective measures: No further data, see item 7.

Hygiene measures: General ventilation is recommended

Respiratory protection: Not applicable.

Hand protection: Not applicable

Eye protection: Goggles

Body protection: Protective clothing.

9. CHEMICAL AND PHYSICAL PROPERTIES**9.1. Information on basic physical and chemical properties**

Physical state:	Viscose liquid
Form:	Transparent
Colour:	Of dye used (typically light-blue)
Odour:	Of the of fragrance used
Odour threshold	No data
pH (as supplied)	5,5 – 7,0 (20° C)
Boiling point	Above 95 °C
Flash point	Not applicable
Flamability	Not applicable
Explosive properties	Non explosive
Oxidizing properties	No
Vapours pressure	No data
Density , 20 °C	1,010 g/cm ³
Solubility in organic solvents	Miscible with acetone, benzene, methanol, ethanol
Solubility in water	Fully soluble
Viscosity	No data

9.2. Other information – none**10. STABILITY AND REACTIVITY**

10.1. Reactivity	Reacts with organic matter
10.2. Chemical stability	Stable under recommended storage conditions.
10.3. Possibility of hazardous reactions	Not expected.
10.4. Conditions to avoid:	High temperatures over 40 °C, sources of heat and direct sunlight
10.5. Incompatible materials:	Strong oxidizers and acids.
10.6. Hazardous decomposition products:	Not expected, if followed the instructions for use.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

LD50 oral, rat > 2000 mg/kg body weight.

LD50 dermal, rat > 2000 mg/kg body weight.

May cause irritation of the eyes

No sensitization of skin.

11.2. Additional information

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

12.1 Ecotoxicity:	Not classified as dangerous for the environment.
12.2. Persistence and degradability:	All ingredients are biodegradable.
12.3. Bioaccumulative potential	Bioaccumulation is not expected.
12.4. Mobility in soil:	Upon penetration into the soil, it might be expected that underground waters will be reached; Do not allow access to water sources.
12.5. Results of PBT and vPvB assessment:	No data
12.6. Endocrine disrupting properties	The mixture does 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. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods	Do not discharge into drains or the environment; dispose to an authorized waste collection point. 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 be disposed of together with household garbage. Do not discharge into drains or the environment; dispose to an authorized waste collection point. European waste catalogue 18 01 06 - chemicals consisting of or containing dangerous substances (from humane healthcare)
13.2. Contaminated packaging:	Empty packaging: 15.01.02 –plastic packaging. Empty packaging: Rinse with water

14. TRANSPORT INFORMATION

14.1 UN Number	Not applicable
14.2 UN proper shipping name	Non
14.3 Transport hazard class(es)	Non hazardous
14.4 Packaging 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 substance or 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;

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.

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 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):

- H315 Causes serious skin irritation
- H318 Causes serious eye damage
- H400 Very toxic to aquatic organisms
- H411 Toxic to aquatic life with long lasting effects.