



SAFETY DATA SHEET

Date of issuance: 10.06.2022	Issue: 02/2022
According to Regulation (EU) № 1907/2006 (REACH)	Supersedes issue: new

1. IDENTIFICATION OF THE MIXTURE AND THE COMPANY

- 1.1. Product identifier:** Commercial name: **ZHIVASEPT FOAM 4 %**
- 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 :** Emergency Medical Institute Pirogov: + 359 2 91 54 409 (Sofia, Bulgaria)

2. HAZARDS IDENTIFICATION

- 2.1 Classification of the mixture:** The product is classified according to Regulation (EC) No.1272/2008:

Eye Irrit. 2 ; H 319

2.2 Label elements

Active ingredient shown on the label:
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

**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	4.0	Eye Dam 1; H318 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.
Eye contact: Irritating to eyes.
Skin contact: Not applicable.
Ingestion: 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: CO₂, 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, CO₂.
In case of burning of the PE package the following toxic gases may be formed: CO, CO₂, 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 Wash with water.

containment and cleaning up:

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:	Red-Carmoisine
Odour:	Of the of fragrance used-Oceanic
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
Relative 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 below 0 °C and above 35 °C, sources of heat and direct sunlight
10.5. Incompatible materials:	No data
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 product does not contain substances classified as carcinogenic, mutagenic and toxic for reproduction.

No evidence of neurotoxicity.

No data from epidemiological studies on the impact of the drug on humans.

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	This mixture contains no substance considered to be endocrine disruptor
12.7. Other adverse effects:	No data

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	None
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);

ESIS : European chemical Substances Information System

GESTIS Stoffdatenbank, 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 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.

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

Hazard statements (GHS):

- H319 Causes serious eye irritation.
- H318 Causes serious eye damage
- H400 Very toxic to aquatic organisms
- H411 Toxic to aquatic life with long lasting effects.