



SAFETY DATA SHEET

Date of issuance: 14.07.2024	Issue: 01/2024
According to Regulation (EC) No 1907/2006 (REACH)	Supersedes issue:

1. IDENTIFICATION OF THE PREPARATION AND THE COMPANY

- 1.1. Product identifier:** Commercial product name: **ALDESEPT MD (AER)**
Medical device class IIb
- 1.2. Relevant identified uses of the mixture and uses advised against:** ALDEHYDE BASED CONCENTRATE FOR DISINFECTION OF INVASIVE AND NON-INVASIVE MEDICAL INSTRUMENTS AND CHEMO THERMAL REPROCESSING OF ENDOSCOPES.
- 1.3. Company identification:** 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,
Internet: www.zhivas.com
- 1.4. Emergency telephone :** Hospital for active treatment and emergency medicine "N.I.Pirogov"
Tel: +359 2 9154409
E-mail: poison_centre@mail.orbitel.bg
<http://www.pirogov.bg>

2. HAZARDS IDENTIFICATION

- 2.1 Classification of the mixture:** The product classification is in accordance with Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 1272/2008, Annex VI (CLP).

Acute Tox 4 (oral); H 332
Acute Tox 4 (inhaled.); H332
Eye Dam.1; H318
Resp.Sens.1; H334
STOT SE 3; H335
Skin Sens.1; H317
Aquatic acute,1: H400

- 2.2 Label elements:**
Classification Reg.(CE)1272/2008:
Pictograms:



GHS 07



GHS 08



GHS 09

Signal word

Danger!

Hazard statements:

H332 – Harmful is inhaled
H302 – Harmful is swallowed
H335 – May cause respiratory irritation
H318 – Causes serious eye damage
H334 – May cause allergy or asthma symptoms or breathing difficulties if inhaled
H317 – May cause an allergic skin reaction
H400 – Very toxic to aquatic life

**Precautionary statements:**

P102 – Keep out of reach of children
P261 – Avoid breathing the vapors.
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305+P351+P338 – IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P301+P310 – IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician.
P302+P332+P313 IF ON SKIN: If skin irritation occurs: Get medical advice/attention
P273 – Avoid release to the environment.

2.3. Other hazards

None.

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

The mixture is an aqueous solution of glutaraldehyde, ethyl alcohol, and corrosion inhibitor.
It contains certain quantities of harmless additions: fragrance.

Component	CAS №	EC №	Concentration g/100g	Pictogram	Classification (Reg.(CE) 1272/2008)
Ethyl alcohol	64-17-5	200-578-6	20.0	 	Flam.Liq.2; H225 Eye irrit.2; H319
Glutaraldehyde	111-30-8	203-856-5	10.0	  	Acute Tox. 4 (*); H332 STOT SE 3 (*); H335 Skin Irrit.2,(*); H315 Eye Dam.1,(*) H318 Skin Sens. 1; H317 Aquatic Acute 1; H400

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

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

Inhalation: Take the subject out into fresh air. Maintain normal body temperature. If symptoms persist call a physician.

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

Skin contact: Immediately take off the contaminated clothes. Wash the contaminated areas thoroughly with soap and water. Wash the working clothes before using them again.

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: 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: In case of eye contact and ingestion with symptoms of irritation, immediately call for medical help.

**5. FIRE-FIGHTING MEASURES**

- 5.1. Extinguishing media:** Water spray, CO₂, dry powder..
- 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:** Take the precautions customary for handling chemicals. Avoid direct contact with skin and eyes.
- 6.2. Environmental precautions:** Should not be released in the environment.
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:** Absorb by means of suitable inert materials (sand, sawdust or soil). The contaminated material should be collected mechanically for subsequent disposal. Wash with water and detergent.
- 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 and skin.
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, at temperature between 5°C and 35°C. Do not expose to direct sunlight. Do not store with strong oxidizers and acids.
- 7.3. Specific end uses** For professional use only

8. EXPOSURE CONTROLS/ PERSONAL PROTECTION**8.1. Exposure limit values****Limit values for some ingredients in the air of the work environment**

Ingredient	CAS No	EC No	Limit values in workplace air
Glutaraldehyde	111-30-8	203-856-5	UK: 0,7 mg/m ³ (15 minutes); 5 mg/m ³ (8 hours)
Ethyl alcohol	64-17-5	200-578-6	1000 mg/m ³ (8 hours)

8.2. Exposure controls

- General protective measures:** No further data, see item 7.
- Hygiene measures:** General and local ventilation is recommended in order to control limit values of Ethanol and Glutaraldehyde in the air of the workplace
- Respiratory protection:** In case of exceeding the limit values for work environment – use filter respiratory devices.
- Hand protection:** Use suitable protective gloves resisting to solvents (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 soap and water.

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

Physical state:	Liquid
Form:	Transparent
Colour:	Colourless
Odour:	odourless
Odour threshold	No data
pH 1 % - solution	5.5 – 7.0 (20° C)
Boiling point	About 100° C
Flash point	Not applicable
Flamability	Not applicable
Explosive properties	Product is not explosive
Oxidizing properties	No
Relative density , 20 °C	1.01 – 1.03 g/cm ³
Solubility in organic solvents	Well soluble in acetone, benzene, methyl and ethyl alcohol
Solubility in water	Fully miscible
Partition coefficient	Not applicable
Viscosity	Not applicable
Vapour density	No data

9.2. Other information none

10. STABILITY AND REACTIVITY

10.1. Reactivity	Reacts with proteins and lipids.
10.2. Chemical stability	Stable under recommended storage conditions.
10.3. Possibility of hazardous reactions	Not expected, if followed the instructions for use.
10.4. Conditions to avoid:	high temperatures above 50°C, sources of heat and direct sunlight
10.5. Incompatible materials:	Strong oxidizers and alkalis.
10.6. Hazardous decomposition products:	Toxic gases: nitrous fumes, carbon oxides.

11. TOXICOLOGICAL INFORMATION

Toxicological properties of the preparation were not investigated. The preparation is classified by conventional method.

Acute toxicity:

LD50 oral, rats, > 2000 mg/kg bw

LD50 dermal, rats, > 2000 mg/kg bw.

Harmful if swallowed and after skin contact

Risk of serious damage to eyes;

Possible sensitization if inhaled and after skin contact.



12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:	Classified under the conventional method Dangerous for the environment. Very toxic to aquatic organisms. Chemical oxygen demand (COD) : 490 g/kg Biotical degradation – very good > 91%.
12.2. Persistence and degradability:	Moderate potential for bioaccumulation.
12.3. Bioaccumulative potential	Upon penetration into the soil, it might be expected that underground waters will be reached; Do not allow access to water sources.
12.4. Mobility in soil:	Unknown to product
12.5. Results of PBT and vPvB assessment:	No data
12.6. Other adverse effects:	

13. DISPOSAL 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 be discharged 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 15 01 10* - packing containing dangerous substances
13.2. Contaminated packaging:	Empty packaging should be taken to an approved waste handling site for recycling or disposal.

14. TRANSPORT INFORMATION

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

14.1 UN Number	- 3082
14.2 UN proper shipping name	- Environmentally hazardous substance, liquid, n.o.s
14.3 Transport hazard class(es)	- 9
14.4 Packaging group	- III
14.5 Environmental hazards	-
Labeling in acc. with ADR, p.5.2.1.8	
Labeling in acc. with RID, p.5.2.1.8	
Labeling in acc. with IMDG, p.5.2.1.6.3	
Classification of dangerous products acc. P. 2.9.3. of IMDG	Yes 
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

For quantity up to 5L

15. REGULATORY INFORMATION

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:**
- Regulation (EC) № 1907/2008 of the European Parliament concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).
 - Regulation (EC) № 453/2010 amending Regulation (EC) № 1907/2008 of the European Parliament concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Annex.



- Regulation (EC) № 1271/2008 of the European Parliament on classification, labeling and packaging of substances and mixtures.
- Regulation (EO) 648/2004 concerning detergents.
- Directive 1999/45/EC of the European Parliament on the approximation of laws, regulations and administrative provisions - relating to the classification, labeling and packaging of substances and mixtures.
- European Directive 76/79/EIO relating to restrictions on the marketing and use of certain dangerous substances and preparations.
- ECB - ESIS- European chemical information system, IUCLD.
- Council Directive 98/24/EC on the protection of the health and safety of workers and the risks related to chemical agents at work.
- Commission Directive 2000/39/EC establishing a first list of indicative limit values for occupational exposure for the 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.
- Council Directive 89/656/EEC on the minimum health and safety of workers in the use of personal protective equipment at the workplace.
- Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste. • Directive 2000/60/CE for Establishing a framework for Community action in the field of water policy.
- European Directive 91/689/SEE hazardous waste.
- European Directive 94/62/SE packaging and waste.
- European Directive 1999/31/SE Landfill of waste
- According to Directive 94/33/EC, juveniles are only allowed to handle this product as long as all effects of dangerous substances are prevented.

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.

List of relevant Hazard statements (GHS), referred in section 3.

H225	Highly flammable
H301	Toxic if swallowed
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause skin sensitization
H318	Causes serious damage to eyes
H319	Causes serious eye irritation
H331	Toxic if inhaled
H332	Harmful if inhaled
H335	May cause respiratory irritation
H336	May cause drowsiness and dizziness
H400	Very toxic to aquatic life

GHS-Pictograms in section 3:

 Exclamation mark (GHS07)	 Flame (GHS 02)	 Environment (GHS 09)	 Corrosion (GHS 05)
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