

MATERIAL SAFETY DATA SHEET

[In accordance with Regulation (EC) 1907/2006 (REACH), as amended]

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking**1.1 Product identifier**

Trade name: **TRISEPT MIX**

1.2 Relevant identified uses of the substance or mixture and uses advised against

Identified uses: product with virucidal, bactericidal, fungicidal activity for hygienic and surgical hand disinfection.

Uses advised against: none specified.

1.3 Details of the supplier of the safety data sheet

Manufacturer: **TARCHOMIŃSKIE ZAKŁADY FARMACEUTYCZNE "POLFA" SPÓŁKA AKCYJNA**

Address: Ul. A. Fleminga 2, 03-176 Warsaw, Poland

Phone number: +48 22 510 80 01

E-mail address of the competent person responsible for the Safety Data Sheet: bhp@polfatarchomin.com.pl

1.4 Emergency contact number

112 (emergency phone number), 998 (fire service), 999 (emergency service)

Section 2: Hazards Identification**2.1 Classification of the substance or mixture**

Flam. Liq. 2 H225, Eye Irrit. 2 H319

Highly flammable liquid and vapour. Causes eye irritation.

2.2 Label elements

Pictograms indicating type of hazard and signal word.



HAZARD

Hazard statements

H225 Highly flammable liquid and vapour.
H319 Causes eye irritation.

Precautionary statements

P102 Keep out of the reach of children.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
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+P313 If eye irritation persists: Get medical advice/attention.
P501 Dispose of contents/container to properly marked waste containers in accordance with national regulations.

2.3 Other hazards

This product does not contain any substances classified as PBT or vPvB according to Annex XIII of REACH Regulation.

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Section 3: Composition/Information on Ingredients

3.1 Substances
Not applicable.

3.2 Mixtures

| | | |
|---|---|------|
| CAS number: 64-17-5 EC number: 200-578-6 Index number: 603-002-00-5 Registration number: - | ethanol¹⁾ Flam. Liq. 2 H225, Eye Irrit. 2 H319 | <80% |
| CAS number: 56-81-5 EC number: 200-289-5 Index number: - Registration number: - | glycerol¹⁾ this substance is not classified as posing risk | ≤10% |

1 - The substance with occupational exposure limit defined at the national level.
For the full wording of H statements see section 16 of this SDS.

Section 4: First Aid Measures

4.1 Description of first aid measures

Skin contact: adverse health effects following exposure to this route should not be expected, the product is intended for hygienic hand disinfection. Should symptoms occur, consult a doctor, show the package or label.

Eye contact: rinse with copious amount of water for at least 15 minutes. Protect the non-irritated eye, remove contact lenses. Avoid a strong water jet - risk of mechanic corneal damage. Should symptoms occur, contact a doctor.

Ingestion: rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Consult a doctor, show the package or label.

Inhalation: move out the victim to fresh air, keep him/her warm and quiet. Should symptoms occur, consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

No adverse effects other than those resulting from the product classification are expected.

4.3 Indication of any immediate medical attention and special treatment needed

The decision on the method of rescue treatment is made by a physician after thorough assessment of the victim's condition. Treat symptomatically.

Section 5: Fire-fighting Measures

5.1 Extinguishing Media

Suitable extinguishing media: alcohol resistant extinguishing foam, extinguishing powder, carbon dioxide (CO₂), dispersed water jet. Adjust the extinguishing agent to the materials in the immediate environment.

Unsuitable extinguishing media: strong water jet - danger of fire spreading.

5.2 Special risks based on the substance or mixture

Harmful gases may be formed in a fire, including, but not limited to, carbon oxides and other unidentified thermal decomposition products. Avoid inhalation of combustion products, as they may pose a health hazard.

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5.3 Advice for firefighters

Wear general protection measures typical in the case of fire. Do not stay in the fire-endangered area without proper clothing resistant to chemicals and self-contained breathing apparatus. Do not allow extinguishing water to enter sewer, surface and ground water. Highly flammable liquid and vapour. Cool the containers at risk of fire from a safe distance with dispersed water jet. Collect used extinguishing agents.

Section 6: Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Limit the access of third persons to the affected area until respective cleaning operations are finished. In the case of large releases, isolate the affected area. Ensure that the effects of the failure are eliminated by trained staff only. Use personal protective equipment. Avoid contact with eyes. Avoid breathing vapors. Ensure adequate ventilation. Keep away from any sources of ignition, extinguish open fire, do not smoke. Prevent electrostatic discharge.

6.2 Environmental precautions

Do not discharge to sewage systems, surface and ground water. If larger amounts of the mixture are released, steps should be taken to prevent spreading in the natural environment. Notify appropriate emergency services.

6.3 Methods and materials for containment and cleaning up

Cover up the leak spillage with liquid absorbent material (e.g. sand, earth, silica) and place in labelled containers. Dike larger spillages and pump them off. Treat the collected material as waste. Clean and ventilate the contaminated area well. Do not use sparking tools.

6.4 Reference to other sections

For product waste handling, see section 13 of the SDS. Personal protective equipment - see section 8 of this SDS.

Section 7: Handling and Storage of Substances and Mixtures

7.1 Precautions for safe handling

Observe the safety and hygiene regulations. Avoid eye contact. Do not breathe vapor. Use appropriate personal protective measures. Refer to the Safety Data Sheet or information on the label. Do not eat, drink or smoke while working. Wash hands before break and after work. Use as intended. Important! Risk of slipping on the released product. Do not use sparking tools.

7.2 Safe storage conditions, including any incompatibilities

Store in a dry and cool place, keep away the product containers from direct sunlight. Keep away from food, foodstuffs and animal feed. Do not store with incompatible materials (see subsection 10.5). Keep away from heat and ignition sources. Temperature in the storage room should not exceed 25°C.

7.3 Specific end use(s)

There is no information on uses other than those mentioned in subsection 1.2.

Section 8: Exposure Control/Personal Protective Measures

8.1 Control parameters

| Substance | TLV-TWA | TLV-STEL | TLV-CL | BLV |
|---|------------------------|----------|--------|-----|
| Ethanol [CAS 64-17-5] | 1900 mg/m ³ | — | — | — |
| glycerol – inhalable fraction [CAS 56-81-5] | 10 mg/m ³ | — | — | — |

Legal basis: Journal of Laws, item 1286, as amended

Recommended monitoring procedures

Observe the procedures for monitoring concentrations of hazardous components in the air and for air

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purity control at workplace - if available and justifiable at the specific workplace - in accordance with the applicable Polish or European standards with consideration to exposure place conditions and relevant method of measurement adapted to occupational conditions. The procedure, type and frequency of tests and measurements should comply with the requirements contained in the Regulation of the Minister of Health of 2 February 2011 (Journal of Laws 2011 No. 33, item 166, as amended).

8.2 Exposure controls

Follow general health and safety rules. Do not eat, drink or smoke while working. Wash your hands thoroughly before break and after you stop work. Avoid eye contact. Remove contaminated clothing and wash before reuse. General and/or local ventilation should be provided in the workplace in order to maintain concentrations of harmful agents in air below the pre-defined acceptable limits. If, during the work processes, there is a risk of clothing inflammation on a worker, emergency showers allowing to wash the whole body and separate eye showers should be installed not more than 20 m horizontally from the workplaces where the processes are performed. Use personal protective equipment.

Hand and body protection:

None required. In case of prolonged or repeated contact with the product, wear protective gloves if the risk assessment suggests that it is necessary. Select the glove material individually at the workplace. The glove material must be impermeable and resistant to the effects of the product. The material should be selected with consideration to breakthrough times, penetration rate and degradation. Moreover, the selection of suitable gloves is not related to material only, but also on other quality parameters, and varies depending on the manufacturer. The exact breakthrough time must be obtained from the manufacturer of the gloves and adhered to. It is recommended that gloves be changed regularly and replaced immediately if any sign of wear, damage, or change in appearance (color, flexibility, shape) occurs.

Eye protection:

Wear protective eyewear if at risk of eye contamination.

Respiratory protection:

None required if proper ventilation is ensured. In the event of high concentration of vapours, malfunctions or limits exceeding the maximum permissible concentrations, use appropriate respiratory equipment with an appropriate organic vapour absorbent (AX type). Personal protective equipment used must comply with the requirements of Regulation (EU) 2016/425. Personal protective equipment should be selected taking into account the concentration and form of substances in the workplace, exposure routes, exposure times and activities performed by an employee. The employer shall be obliged to ensure protective measures which meet all quality requirements, including their maintenance and cleaning.

Environmental exposure control

Avoid release to the environment, do not discharge into the sewer. Any emissions from ventilation systems and process equipment should be checked in order to determine their compliance with environmental protection laws.

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| Section 9: Physical and Chemical Properties |
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9.1 Information on basic physical and chemical properties

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|--|---------------------------|
| Physical form: | liquid |
| Colour: | colourless |
| Odour: | characteristic, alcoholic |
| Odour threshold: | not determined |
| pH: | not determined |
| Melting/freezing point | not determined |
| Initial boiling point / boiling range: | > 35°C |
| Ignition temperature: | < 23°C |
| Rate of evaporation: | not determined |
| Flammability (solid, gas): | not applicable |

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| Upper/lower explosive limit: | not determined |
| Vapour pressure: | not determined |
| Vapour density: | not determined |
| Density: | approx. 1 g/cm ³ |
| Solubility: | not determined |
| Partition coefficient: n-octanol / water: | not determined |
| Auto-ignition temperature: | not determined |
| Decomposition temperature: | not determined |
| Explosive properties: | not demonstrated |
| Oxidising properties: | not demonstrated |
| Viscosity: | not determined |

9.2 Other information

No results of additional tests available.

Section 10: Stability and Reactivity**10.1 Reactivity**

Reactive product, does not undergo dangerous polymerization. See also subsections 10.3 – 10.5.

10.2 Chemical stability

The product is stable when used and stored correctly.

10.3 Possibility of hazardous reactions

No hazardous reactions are known.

10.4 Conditions to avoid

Avoid direct sunlight, heat sources and fire.

10.5 Incompatible materials

Strong oxidants.

10.6 Hazardous decomposition products

None known.

Section 11: Toxicological Information**11.1 Information on toxicological effects****Toxicity of ingredients**Ethanol [CAS 64-17-5]

| | |
|-------------------------------------|----------------------|
| LD ₅₀ (oral, rat): | > 6,200-17,800 mg/kg |
| LD ₅₀ (skin, rabbit): | > 20,000 mg/kg |
| LC ₅₀ (inhalation, rat): | > 8,000 mg/l/4h |

Toxicity of the mixtureAcute toxicity

Based on the available data, the classification criteria are not met.

Skin corrosion/irritation

Based on the available data, the classification criteria are not met.

Serious eye damage/eye irritation

Causes eye irritation.

Sensitising effects to the respiratory system or skin

Based on the available data, the classification criteria are not met.

Germ cell mutagenicity

Based on the available data, the classification criteria are not met.

Carcinogenic effects

Based on the available data, the classification criteria are not met.

Reproductive toxicity

Based on the available data, the classification criteria are not met.

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Toxicity to target organs - single exposure

Based on the available data, the classification criteria are not met.

Toxicity to target organs - repeated exposure

Based on the available data, the classification criteria are not met.

Risk due to aspiration

Based on the available data, the classification criteria are not met.

Symptoms related to physical, chemical and toxicological properties

Skin contact: in the case of prolonged contact, skin redness, drying, cracking, defatting is possible.

Eye contact: redness, tearing, irritation.

Ingestion: nausea, vomiting, balance and coordination disorders, alcohol intoxication-like symptoms.

Inhalation: If the vapour concentration is high, the product may cause headache, dizziness.

Section 12: Ecological Information

12.1 Toxicity

Toxicity of ingredients

Ethanol [CAS 64-17-51]

| | | |
|--------------------|------------------|---|
| Fish toxicity: | LC ₅₀ | > 8,140 mg/l/48h/ <i>Leuciscus idus</i> |
| Daphnia toxicity: | EC ₅₀ | 9,268-14,221 mg/l/48h/ <i>Daphnia magna</i> |
| Algae toxicity: | EC ₅₀ | >5,000 mg/l/16h/ <i>Scenedesmus quadricauda</i> |
| Bacteria toxicity: | EC ₅₀ | >6,500 mg/l/16h/ <i>Pseudomonas putida</i> |

Toxicity of the mixture

The product is not classified as hazardous to the environment.

12.2 Stability and degradability

Ingredient data:

Ethanol [CAS-64-17-51]

it is biodegradable in 89% within 14 days.

Data of the European Chemicals Agency

12.3 Bioaccumulative potential

Ingredient data:

Ethanol [CAS-64-17-51]

log Po/w = -0.31; BCF = 3.

Data of the European Chemicals Agency

12.4 Mobility in soil

The mobility of the components of the mixture depends on their hydrophilic and hydrophobic properties as well as on the abiotic and biotic conditions of soil, including its structure, climate conditions, season of the year and soil organisms.

12.5 Results of PBT and vPvB assessment

This product does not contain any substances classified as PBT or vPvB according to Annex XIII of REACH Regulation.

12.6 Other adverse effects

The mixture is not classified as hazardous to the ozone layer. The possibility of other harmful effects of the individual components of the mixture on the environment should be considered (e.g. the ability to interfere with the hormonal metabolism, the effect on the increase of global warming).

Section 13: Waste Management

13.1 Waste treatment methods

Recommendations for the mixture: do not discharge to the sewage system. Do not store on municipal landfill. Dispose of in accordance with the applicable regulations. The waste code should be assigned at the site where it is produced.

Recommendations concerning the used packages: transfer the package to the authorised company. Do not mix with other waste. The waste code should be assigned at the site where it is produced.

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EU legal acts: Directives of the European Parliament and of the Council: 2008/98/EC as amended, 94/62/EC, as amended, the National Legislation: Journal of Laws of 2013, item 21, as amended; Journal of Laws of 2013, item 888, as amended

Section 14: Transport Information

14.1 UN number

Land transport: 1170
 Marine transport: 1170
 Air transport: 1170



14.2 Proper UN shipping name

Land transport: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
 Marine transport: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
 Air transport: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)

14.3 Transport hazard class(es)

Land transport: 3
 Marine transport: 3
 Air transport: 3

14.4 Packing group

Land transport: II
 Marine transport: II
 Air transport: II

14.5 Environmental hazards

The mixture poses no environmental hazard as per transport regulations.

14.6 Special safety precautions for users

During handling, wear personal protective equipment as specified in section 8. Avoid sources of ignition.

14.7 Bulk transport according to Annex II of the MARPOL agreement and in accordance with the IBC code

Not applicable.

Section 15: Regulatory Information

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

The Act of 25 February 2011 on Chemical Substances and Their Mixtures (Journal of Laws 2011 No. 63, item 322, as amended). Regulation of the Minister of Family, Labour and Social Policy of 12 June 2018 on Maximum Permissible Concentration and Intensity of Agents Harmful to Health in the Working Environment (Journal of Laws 2018, item 1286, as amended).

European agreement ADR concerning international road transport of hazardous goods.

Waste Act of 14 December 2012, (Journal of Laws 2013, item 21, as amended).

The Act of 13 June 2013 on the Management of Packaging Materials and Packaging Waste (Journal of Laws 2013, item 888, as amended).

Regulation of the Minister of Climate of 2 January 2020 on Waste Catalogue (Journal of Laws 2020, item 10).

Regulation of the Minister of Health of 2 February 2011 on Testing and Measuring Harmful Factors in the Work Environment (Journal of Laws 2011 No. 33, item 166, as amended).

1907/2006/EC Regulation 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, as amended.

1272/2008/EC Regulation 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, as amended.

2015/830/EU Commission Regulation of 28 May 2015 amending Regulation (EC) No. 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction

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of Chemicals (REACH).

2008/98/EC Directive of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, as amended.

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

European agreement ADR concerning international road transport of hazardous goods.

2016/425/EU Regulation of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

15.2 Chemical Safety Assessment

No safety assessment is required for the mixture.

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| Section 16: Other Information |
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Full wording of H statements from section 3 of the SDS

H225 Highly flammable liquid and vapour.

H319 Causes eye irritation.

Abbreviations and acronyms

TLV-TWA Threshold Limit Value-Time Weighted Average

TLV-STEL Threshold Limit Value-Short-Term Exposure Limit

TLV-CL Threshold Limit Value-Ceiling Limit

BLV Biological Limit Value

PBT Persistent, bio-accumulative and toxic substance

vPvB Very persistent and very bio-accumulative substances

Flam. Liq. 2 Flammable liquid category 2

Eye Irrit. 2 Eye irritant category 2

Training

Before starting the handling of the product, the user should learn the OHS regulations applicable to handling chemicals, in particular appropriate workplace training on the substance should be provided. In accordance with ADR contract, persons involved in transport of hazardous materials should be properly trained in the duties performed (general, workplace and safety training).

Key references and data sources

The SDS has been developed on the basis of data sheets for individual ingredients, literature data, web-based databases, knowledge and experience, taking into account currently applicable laws and regulations.

Procedures used to classify the mixture

The classification was performed on the basis of ingredient data sheets and data on hazardous components content by means of calculation based on the guidelines of Regulation 1272/2008/EC (CLP), as amended.

Additional information

Date of issue: 13/03/2020

Version: 1.0/PL

SDS issued by: "THETA" Doradztwo Techniczne

The above information is based on the currently available data characterising the product and the experience and knowledge possessed in this respect by the manufacturer. However, they should not be regarded as a qualitative characterisation of the product or guarantee of its specific properties. They should be regarded as an aid for safe handling in product transport, storage and application. It does not exempt the user from responsibility in case of misuse of the above information or from compliance with any legal regulations which may be applicable in this matter.

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