SAFETY DATA SHEET



This safety data sheet was created pursuant to the requirements of: The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020 and The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 No. 720

Issuing Date 26-Apr-2021 Revision Date 15-Apr-2021 Revision Number 1

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name Sterets Tisept Sachets

Synonyms None

Other information This product is a medicinal product and is regulated under The Human Medicines

Regulations 2012 No. 1916. This SDS is provided for information purposes.

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

Recommended use Antimicrobial preparation with cleansing properties for general antiseptic purposes

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

Molnlycke Health Care Medlock Street Oldham OL1 3HS United Kingdom

For further information, please contact

E-mail address Antiseptics.UK@molnlycke.com

1.4. Emergency telephone number

Emergency telephone +44 161 621 2121 (9am-5pm) GMT

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP]

2.2. Label elements

Hazard statements

Not classified

2.3. Other hazards

Toxic to aquatic life.

SECTION 3: Composition/information on ingredients

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3.1 Substances

Not applicable

3.2 Mixtures

Full text of H- and EUH-phrases: see section 16

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation Remove to fresh air.

Rinse thoroughly with plenty of water, also under the eyelids. Eye contact

Skin contact Wash skin with soap and water.

Clean mouth with water and drink afterwards plenty of water. Ingestion

4.2. Most important symptoms and effects, both acute and delayed

Symptoms No information available.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the

surrounding environment.

No information available. Unsuitable extinguishing media

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Specific/special fire-fighting

measures

Fires need to be assessed to determine appropriate protocols and safety measures for firefighting, including establishing safe zones, extinguishing media to be used, firefighter

protection, and actions to control or extinguish the fire.

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

Specific use(s).

No information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering controls Ensure adequate ventilation, especially in confined areas.

Personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection No special protective equipment required.

Skin and body protectionNo special protective equipment required.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

Environmental exposure controls No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state
Colour
Odour

Colour
Odour

Colour
C

Odour threshold No information available

 Property
 Values

 Melting point / freezing point
 No data available

Initial boiling point and boiling

No data available

No data available

range

Flammability No data available

Flammability Limit in Air

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point
Autoignition temperature
Decomposition temperature
pH
No data available

pH (as aqueous solution) No data available Kinematic viscosity No data available **Dynamic viscosity** No data available Water solubility Soluble in water Solubility(ies) No data available Partition coefficient No data available Vapour pressure No data available Relative density No data available **Bulk density** No data available **Liquid Density** No data available Vapour density No data available

Particle characteristics

Particle Size No data available
Particle Size Distribution No data available

Explosive propertiesNo information available. **Oxidising properties**No information available.

9.2. Other information

VOC No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity None under normal use conditions.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materialsNone known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon monoxide. Carbon dioxide (CO2). para-Chloroaniline.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.

Numerical measures of toxicity

Based on available data, the classification criteria are not met

Component Information

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation

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

Serious eye damage/eye irritation

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

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.

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

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

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

STOT - single exposure Based on available data, the classification criteria are not met.

STOT - repeated exposureBased on available data, the classification criteria are not met.

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

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity The product contains a substance which is toxic to aquatic organisms.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

Mobility Soluble in water.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment The product does not contain any substance(s) classified as PBT or vPvB.

12.6. Other adverse effects

Other adverse effects No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

<u>IMDG</u>

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicableMarine pollutantNot applicable

14.6 Special Precautions for Users

Special Provisions None

14.7 Maritime transport in bulk according to IMO instruments

No information available

RID

14.1 UN numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

ADR

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special Precautions for Users

Special Provisions None

IATA

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Environmental hazards
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special Precautions for Users

Special Provisions None **Note:** None

SECTION 15: Regulatory information

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

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV). This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII).

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

Contact supplier for inventory compliance status

15.2. Chemical safety assessment

Chemical Safety Report No information available

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Method Used
Calculation method

Key literature references and sources for data used to compile the SDS

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

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This material safety data sheet complies with the requirements of UK REACH

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet