

<b>TECHNICAL FILE</b> 	<b>Oosafe® Disinfectant</b> <b>Technical File Code : OODIS</b> Initial Issue Date: 01.07.16	<b>Oosafe® Disinfectant</b> <b>SAFETY DATA SHEET</b> <b>Document no. OODIS-06.2</b>
	Current Issue No.: 15 Issue Date: 01.05.2024	Revision No.: 07 Revision Date: 01.06.2025

# MATERIAL SAFETY DATA SHEET

Oosafe® Disinfectant for Medical Device



Revision No: 07; Date: 01.06.2025

According to Regulation (EC) No 1907/2006 (REACH) as amended

## SECTION 1: Identification of the Substance/Mixture and of the Company / Undertaking

### 1.1. Product identifier

**Substance /Mixture Name:** Oosafe® Disinfectant

**Substance number:** OOMD-00050; OOMD-00250; OOMD-01000; OOMD-05000; OOMD-10000; OOMDW-120

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

**Mixture's intended use:** Disinfectant for medical devices and equipment.

**In the following product types:** Disinfectant for medical devices.

**Mixture uses advised against:** The product should not be used in ways other than those referred in Section 1.

### 1.3. Details of the supplier of the safety data sheet

**Manufacturer: Sparmed Aps**

Ryttermarken 2, DK-3520, Farum, Denmark

Ph: +4539402503

**Competent person responsible for the safety data sheet: ra@sparmed.dk**

### 1.4. Emergency telephone number

**Danish Poison Line: +45 82 12 12 12**

**Additional information:** Tel. +45 39 40 25 03

In case of emergency, call the national/local Poisoning Information Centre or Toxicology Information Centre.

European emergency number (can be called free from the entire territory of the EU): 112.

## SECTION 2: Hazards Identification

### 2.1. Classification of the substance or mixture

**Classification of the mixture in accordance with Regulation (EC) No 1272/2008**

The mixture is classified as dangerous.

Aquatic Chronic 3, H412

**Most serious adverse effects on human health and the environment**

Harmful to aquatic life with long lasting effects.

### 2.2. Label elements

**Hazardous substances:**

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides

**Hazard statements:** H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements:**

P102 Keep out of reach of children.

P273 Avoid release to the environment.

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P501 Dispose of contents/container to in accordance with local/regional/national/international regulations.

### 2.3. Other hazards

The product does not contain any persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) components in concentrations greater than or equal to 0.1% (Annex XIII of Regulation (EC) No 1907/2006).

The product does not contain any substances with endocrine disrupting properties in concentrations greater than or equal to 0.1% in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

Requirements in the food industry:

- After the prescribed exposure time rinse the disinfected surfaces, equipment, tools, and containers several times with drinking water
- Do not treat food directly
- Treat only smooth (non-absorbent and non-porous) materials

## SECTION 3: Composition/Information on Ingredients

### 3.2. Mixtures

#### Chemical characterization

**Active substance:** Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides

**Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**

Identification numbers	Substance name	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
CAS: 68391-01-5 EC: 269-919-4	Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides	0.27	Acute Tox. 4, H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	

Full text of all classifications and hazard statements is given in the section 16.

## SECTION 4: First Aid Measures

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

<b>General advice:</b>	No special measures required.
<b>If inhaled:</b>	Supply fresh air. Consult doctor in case of complaints.
<b>If on skin:</b>	Generally, the product does not irritate the skin. Consult the doctor in case of complaints.
<b>If in eyes:</b>	Rinse immediately with plenty of water, also under the eyelids, for 10 minutes. Consult a doctor if irritation persists.
<b>If swallowed:</b>	Rinse mouth and drink plenty of water. Never induce vomiting or give anything by mouth to an unconscious person.

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

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<b>If inhaled:</b>	Not expected.
<b>If on skin:</b>	Not expected.
<b>If in eyes:</b>	Not expected.
<b>If swallowed:</b>	Not expected.

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

**Treatment:** | No further relevant information available. Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

<b>Suitable extinguishing media:</b>	Water spray, dry powder, foam.
<b>Unsuitable extinguishing media:</b>	No further relevant information. For safety reasons, do not use a full water jet as this may spread the fire.

#### 5.2. Special hazards arising from the substance or mixture.

**In case of fire or due to heat:** | Toxic fire extinguishing gases may be formed.

#### 5.3. Advice for firefighters

<b>Special protective equipment for firefighters:</b>	Wear self-contained breathing apparatus. Do not breathe combustion or explosion gases.
<b>Additional information:</b>	Use water spray to cool unopened containers.

### SECTION 6: Accidental Release Measures

#### 6.1. Personal precautions, protective equipment, and emergency procedures

**Personal precautions:** | Not required.

#### 6.2. Environmental precautions

**To protect the environment:** | Dilute the product thoroughly with water.

#### 6.3. Methods and material for containment and cleaning up.

**Clean-up:** | Collect with absorbent material (sand, diatomaceous earth, acid binders, universal binders, sawdust).

#### 6.4. Reference to other sections

For information on personal protective equipment, see Section 8.  
For disposal information, see Section 13.

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## SECTION 7: Handling and Storage

### 7.1. Precautions for safe handling

<b>Advice for safe handling:</b>	No special measures are required.
<b>Fire and explosion protection measures:</b>	No special measures are required.

### 7.2. Conditions for safe storage, including any incompatibilities.

<b>Storage requirements for storage rooms and containers:</b>	Keep containers tightly closed.
<b>Information about storage in one common storage facility:</b>	No further relevant information available.
<b>Further information on storage conditions:</b>	Keep away from heat and direct sunlight.

### 7.3. Specific end use(s) :

Disinfectant for surfaces, objects and instruments.

## SECTION 8: Exposure Controls/Personal Protection

### 8.1. Control parameters.

<b>Occupational exposure:</b>	The product does not contain any relevant quantities of materials with critical values that must be monitored at the workplace.
<b>Other information of limit values:</b>	If a hazardous substance not regulated by a limit value, the employer is obliged to reduce the level of exposure to the lowest level that can be expected according to scientific and technical standards, at which level, according to the current state of science, the hazardous substance has no harmful effects on health.

### 8.2. Exposure controls

<b>General protective and hygienic measures:</b>	The general rules and precautionary measures for handling chemicals should be observed.
<b>Eye/face protection:</b>	Not necessary under normal use.
<b>Skin protection:</b>	Not necessary under normal use.
<b>Respiratory protection:</b>	Not necessary under normal use.
<b>Thermal hazard</b>	Not known
<b>Environmental exposure controls</b>	To protect the environment, dilute the product thoroughly with water.

## SECTION 9: Physical and Chemical Properties

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## 9.1. Information on basic physical and chemical properties

<b>Physical state:</b>	Liquid
<b>Colour:</b>	Colourless
<b>Odour:</b>	Without fragrance
<b>Melting point/freezing point</b>	0°C (approximate value)
<b>Boiling point or initial boiling point and boiling range</b>	100°C (approximate value)
<b>Flammability</b>	Non-flammable
<b>Lower and upper explosion limit</b>	Not determined
<b>Flash point:</b>	Not determined
<b>Auto-ignition temperature</b>	Not determined
<b>Decomposition temperature</b>	Not determined
<b>pH</b>	7-8.5 (0.27% solution at 20 °C) (2,7 mg/g)
<b>Kinematic viscosity:</b>	Not determined
<b>Solubility in water:</b>	Soluble in water
<b>Partition coefficient n-octanol/water (log value)</b>	Not determined
<b>Vapour pressure:</b>	Not determined
<b>Density and/or relative density</b>	1 g/cm <sup>3</sup> at 20 °C (approximate value)
<b>Relative vapour density:</b>	Not determined
<b>Particle characteristics:</b>	Not determined

Not determined ~ the manufacturer has not carried out tests on certain parameters of the product, or the results of the tests were not available when the data sheet was issued.

## SECTION 10: Stability and Reactivity

### 10.1. Reactivity

Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

### 10.2. Chemical stability

Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

### 10.3. Possibility of hazardous reactions

No hazardous reactions are known.

### 10.4. Conditions to avoid

Keep away from heat and direct sunlight. Does not decompose when used as directed.

### 10.5. Incompatible materials

No incompatible materials are known.

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known. No hazardous decomposition products are known.

## SECTION 11: Toxicological Information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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Toxicological data:

#### Acute toxicity

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Acute oral toxicity: 1000 mg/kg - Harmful if swallowed.

Acute inhalative toxicity: no data available

Acute dermal toxicity: no data available

Route of exposure	Parameter	Value	Exposure time	Species	Sex	Value determination
Oral	ATE	192308 mg/kg				Calculation of value

#### Skin corrosion/irritation

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution): Causes severe skin burns.

#### Serious eye damage/irritation

Product: Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution): Causes serious eye damage.

#### Respiratory or skin sensitisation

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

#### Germ cell mutagenicity

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

#### Carcinogenicity

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

#### Reproductive toxicity

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

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#### Toxicity for specific target organ - single exposure

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

#### Toxicity for specific target organ - repeated exposure

Product: Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

NOAEL (oral, rat - 90 days): 391 mg/kg, dietary (Method: OECD 408)

#### Aspiration hazard

Product:

Based on available data the classification criteria are not met.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution):

Based on available data the classification criteria are not met.

#### More information

The product is a preparation for which there is no experimentally determined toxicity data.

### 11.2. Information on other hazards

#### Endocrine disrupting properties

The product does not contain any substances with endocrine disrupting properties in concentrations greater than or equal to 0.1% in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

#### Other information

The product is not classified as dangerous according to Regulation (EC) No 1272/2008. To the best of our knowledge and available information, it does not cause any adverse effects under the specified conditions of use and handling.

## SECTION 12: Ecological Information

### 12.1. Toxicity

Product: Harmful to aquatic life with long lasting effects.

**Toxicity to fish:** | No further relevant information available.

Information on active substance:

Quaternary ammonium compounds, benzyl-C12-18-alkyldimethyl, chlorides (regarding a 50% solution): Very toxic to aquatic life with long lasting effects.

### 12.2. Persistence and degradability

There is no further relevant information.

### 12.3. Bioaccumulative potential

There is no further relevant information.

### 12.4. Mobility in soil

There is no further relevant information.

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### 12.5. Results of PBT and vPvB assessment

The product does not contain any persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) components in concentrations greater than or equal to 0.1% (Annex XIII of Regulation (EC) No 1907/2006).

### 12.6. Endocrine disrupting properties

The product does not contain any substances with endocrine disrupting properties in concentrations greater than or equal to 0.1% in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### 12.7. Other adverse effects

There is no further relevant information.

## SECTION 13: Disposal Considerations

### 13.1. Waste treatment methods

<b>Product:</b>	Dispose it according to the waste disposal code indicated and in accordance with local/regional/national/international regulations.
<b>Contaminated packaging:</b>	Partially or completely emptied packaging should be rinsed with clean water and then treated and disposed of with household waste or taken to a recycling collection point.

### Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.  
Decision 2000/532/EC establishing a list of wastes, as amended.

### Waste type code

07 06 01\* aqueous washing liquids and mother liquors

(\*) - Hazardous waste according to Directive 2008/98/EC on hazardous waste

## SECTION 14: Transport Information

<b>14.1. UN number or ID number</b>	not subject to transport regulations
<b>14.2. UN Proper shipping name</b>	not relevant
<b>14.3. Transport hazard class(es)</b>	not relevant
<b>14.4. Packing group</b>	not relevant
<b>14.5. Environmental hazards</b>	not relevant
<b>14.6. Special precautions for user</b>	not relevant
<b>14.7. Maritime transport in bulk according to IMO instruments</b>	not applicable

## SECTION 15: Regulatory Information

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

- Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).
- Regulation (EC) No. 1272/2008 of the European Parliament and of the Council as amended.
- Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, as amended.

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- Named dangerous substances - ANNEX I None of the ingredients is listed.
- Seveso category This product is not subject to Seveso directive dispositions.
- Regulation (EU) 2019/1021 on persistent organic pollutants (POP): The mixture does not contain substances identified as POP.
- List of Substances Subject to Authorisation (ANNEX XIV): The product does not contain any substance included in annex XIV.
- Regulation (EC) No 1907/2006 ANNEX XVII Conditions of restriction: No restrictions are known
- Regulation (EU) No 649/2012 (PIC) There are no substances listed in this regulation.
- Regulation (EU) 2019/1148 - Explosive precursors: The mixture does not contain explosives precursors in concentrations equal to or greater than 1%.
- Substances of very high concern (SVHC) according to REACH, Article 59: The mixture does not contain SVHC substances in concentration equal to or greater than 0.1% by weight.
- Regulation (EU) 2024/590: substances that deplete the ozone layer: The mixture does not contain substances that deplete the ozone layer.

### National regulations (Denmark)

Administered by the Danish Environmental Protection Agency (Miljøstyrelsen)

### 15.2. Chemical safety assessment

It has not been prepared for the product, and its preparation is not necessary.

## SECTION 16: Other Information

### A list of standard risk phrases used in the safety data sheet

**H302** Harmful if swallowed.

**H314** Causes severe skin burns and eye damage.

**H318** Causes serious eye damage.

**H400** Very toxic to aquatic life.

**H410** Very toxic to aquatic life with long lasting effects.

**H412** Harmful to aquatic life with long lasting effects.

### Guidelines for safe handling used in the safety data sheet

**P102** Keep out of reach of children.

**P273** Avoid release to the environment.

**P501** Dispose of contents/container to in accordance with local/regional/national/international regulations.

### Other important information about human health protection

The information provided is intended only as a guide for safe handling, use, processing, storage, transportation and disposal.

### Key to abbreviations and acronyms used in the safety data sheet

**Acute Tox.** Acute toxicity

**ADR** European agreement concerning the international carriage of dangerous goods by road

**AGW** Occupational Exposure Limits

**Aquatic Acute** Hazardous to the aquatic environment

**Aquatic Chronic** Hazardous to the aquatic environment (chronic)

**BCF** Bioconcentration Factor

**CAS** Chemical Abstracts Service

**CLP** Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures

**EC** Identification code for each substance listed in EINECS

**EINECS** European Inventory of Existing Commercial Chemical Substances

**EmS** Emergency plan

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<b>EU</b>	European Union
<b>EuPCS</b>	European Product Categorisation System
<b>Eye Dam.</b>	Serious eye damage
<b>IATA</b>	International Air Transport Association
<b>IBC</b>	International Code for The Construction and Equipment of Ships Carrying Dangerous Chemicals
<b>ICAO</b>	International Civil Aviation Organization
<b>IMDG</b>	International Maritime Dangerous Goods
<b>IMO</b>	International Maritime Organization
<b>INCI</b>	International Nomenclature of Cosmetic Ingredients
<b>ISO</b>	International Organization for Standardization
<b>IUPAC</b>	International Union of Pure and Applied Chemistry
<b>log Kow</b>	Octanol-water partition coefficient
<b>MAK</b>	Maximum workplace concentration
<b>OEL</b>	Occupational Exposure Limits
<b>PBT</b>	Persistent, bioaccumulative and toxic
<b>PMT</b>	Persistent, mobile and toxic ppm Parts per million
<b>REACH</b>	Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>RID</b>	Agreement on the transport of dangerous goods by rail
<b>Skin Corr.</b>	Skin corrosion
<b>UN</b>	Four-figure identification number of the substance or article taken from the UN Model Regulations
<b>UVCB</b>	Substances of unknown or variable composition, complex reaction products or biological materials
<b>VOC</b>	Volatile organic compounds
<b>vPvB</b>	Very persistent and very bioaccumulative
<b>vPvM</b>	Very persistent and very mobile

#### Training guidelines

There are no known educational instructions.

#### Recommended restrictions of use

The product must not be used for purposes other than its intended purpose.

#### Information about data sources used to compile the Safety Data Sheet

Regulation (EC) No. 1907/2006 of the European Parliament and of the Council (REACH) as amended.

Regulation (EC) No. 1272/2008 of the European Parliament and of the Council as amended.

Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

#### More information

Classification procedure: calculation method based on Annex I to the CLP Regulation (EC) No 1272/2008

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#### Statement

The producer of the safety data sheet or the company supplying the data sheet - not knowing the circumstances of the use and handling of the product - cannot be held liable for any unforeseen damage, loss, injury, accident or similar events resulting from non-prescribed use. The person performing the activity is obliged to comply with all applicable legal regulations that apply to the activity carried out with the product. The producer of the safety data sheet or the company supplying the data sheet cannot be held liable for any unforeseen damage resulting from a modification of the safety data sheet and label provided to the Client that was not made by the producer of the safety data sheet.

#### Regulatory Affairs Department at Sparmed

Contact: [ra@sparmed.dk](mailto:ra@sparmed.dk)