


<p>TECHNICAL FILE</p>  <p>GOosafe in IVF Laboratories</p>	<p><b>Oosafe® Disinfectant</b></p> <p><b>Technical File Code: OODIS</b></p> <p>Initial Issue Date: 01.07.16</p>	<p><b>Oosafe® Disinfectant</b></p> <p><b>SAFETY DATA SHEET</b></p> <p><b>Document no. OODIS-06.2</b></p>
	<p>Current Issue No.: 11</p> <p>Issue Date: 13.06.2019</p>	<p>Revision No.: 04</p> <p>Revision Date: 20.10.2020</p>



# SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

**Oosafe® Disinfectant**

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

### 1.1. Product identifier

Product name: Oosafe® Disinfectant;

Product 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

Use of the substance: Disinfectant for medical devices, surfaces and equipment

In the following product type: Disinfectant for medical devices

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

Sparmed Aps  
Ryttermarken 2, DK-3520, Farum, Denmark

### 1.4. Emergency telephone number

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

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

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No. 1272 / 2008**

Hazard categories: Hazardous to the aquatic environment – Aquatic chronic 3.

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

### 2.2. Label elements

Hazard Pictogram(s): -

Signal word(s): -

Hazard statement(s):


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

Precautionary statement(s):

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

**P273** Avoid release to the environment.

**P501** Dispose of contents in accordance with local regulation.

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### **2.3. Other hazards**

According to regulation (EC) No. 1907/2006 (REACH) this substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## **SECTION 3: Composition/information on ingredients**

### **3.1. Mixtures**

#### **Chemical characterization**

Aqueous disinfectant with 0.26% concentration of the active ingredient.

#### **Active ingredients\_**

<b>Name</b>	<b>Product identifier</b>	<b>Classification at a concentration of ca. 50%</b>
Quaternary ammonium compounds, benzyl-C12-16-alkyldimethyl-,chlorides	(CAS-no.) 68424-85-1 (EC-no.) 270-325-2	Acute Tox.; 4; H302 Skin Corr.; 1B, H314 Aquatic Acute; 1; H400 Aquatic Chronic; 1; H410

For the full text of the H-Statements, see Section 16.

## **SECTION 4: First aid measures**

### **4.1. Description of first aid measures**


General advice:	No special measures required. Consult doctor if any complaint arises.
Inhalation:	The product should not cause breathing problems. Supply fresh air if needed. If breathing difficulty arises, get medical advice.
Skin contact	The product does not irritate the skin. Consult a doctor in case of complaints.
Eye contact	Remove contact lenses if present. Rinse with plenty of water, also under the eyelids, for ten minutes. opened eye for 10 minutes under running water. Consult a doctor if irritation persists.
Ingestion:	Rinse mouth and drink plenty of water. Never induce vomiting or give anything by mouth to an unconscious person. Consult a doctor if complaint arise.

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

No further relevant information available. Consult doctor if any complaint should arise.

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

Treat symptomatically.

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## SECTION 5: Fire-fighting measures

### **5.1. Extinguishing media**

Suitable extinguishing media: Dry powder, water spray, foam.

Unsuitable extinguishing media: None known.

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

Special firefighting hazards: Heating or fire can release toxic gas.

### **5.3. Advice for fire-fighters**

Special protective equipment for firefighters: In the event of fire, wear usual protective clothing and face covering.

Additional information: Use water spray to cool unopened containers. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

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

Not required. Ventilate area if needed.

### **6.2. Environmental precautions**

Do not allow to enter sewers/surface or ground water.

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

Clean released product with water and mop or absorb with liquid-binding material.

### **6.4. Additional information**

For disposal consideration, see Section 13.

## SECTION 7: Handling and storage


### **7.1. Precautions for safe handling**

Reduce the release of the mixture to the environment by avoiding spills and keeping away from drains.

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

Requirements for storage areas and containers: Keep containers tightly closed. To maintain product quality, keep away from heat and direct sunlight.

**7.3. Specific end use(s)** Disinfectant for medical devices, surfaces, and equipment.

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Contains no substances with occupational exposure limit values.

### 8.2. Exposure controls

#### Personal protective equipment

Appropriate engineering controls: No special exposure control measure required.

Individual protection measures such as personal protective equipment: The general rules and precautionary measures for handling chemicals should be observed. No other special personal protective equipment required.

Eye/face protection: Not required

Skin protection: Not required

Respiratory protection: Not required

Thermal hazards: Not required

Environment exposure controls: Do not pour product down the rain.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Appearance: Liquid, colourless

Odour: Odourless

Odour threshold: No data available

pH: 7.0 – 8.5 (20 °C), concentration: 2.6 mg/g

Melting point/ range: approx. 0°C

Boiling point/ range: approx. 100°C

Flash point: no data available

Evaporation rate: no data available

Flammability (solid, gas): no data available

Upper/lower explosive limits: no data available


Vapor pressure: no data available

Vapor density: no data available

Relative density: no data available

Density: ca. 1g/cm<sup>3</sup> (20°C)

Solubility: completely miscible in water (20°C)

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Partition coefficient:	not applicable
Auto-ignition temperature:	no data available
Decomposition temperature:	no data available
Viscosity, dynamic:	approx. 3mPa.s (20°C)
Explosive properties:	no data available, not explosive
Oxidising properties:	no data available

## SECTION 10: Stability and reactivity

<b><u>10.1. Reactivity</u></b>	Stable under normal conditions.
<b><u>10.2. Chemical stability</u></b>	Stable under recommended storage conditions.
<b><u>10.3. Possibility of hazardous reactions</u></b>	No hazardous reactions known.
<b><u>10.4. Conditions to avoid</u></b>	No decomposition under normal conditions. Avoid heat and direct sunlight.
<b><u>10.5. Incompatible materials</u></b>	Oxidising agents, strong acids, and strong bases.
<b><u>10.6. Hazardous decomposition products</u></b>	No hazardous decomposition products known. No decomposition if used as directed.

## SECTION 11: Toxicological information


### **11.1. Information on toxicological effects**

#### **Toxicological data concerning the mixture**

Acute toxicity:	No data available
Skin corrosion/irritation:	No data available
Serious eye damage/irritation:	No data available
Respiratory/skin sensitization:	No data available
Germ cell mutagenicity:	No data available
Carcinogenicity:	No data available
Reproductive toxicity:	No data available
STOT-single exposure:	No data available
STOT-repeated exposure:	No data available
Aspiration hazard:	No aspiration toxicity classification

#### **Additional Toxicological information:**

The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. When used and handled with regard to specifications, the products do not have any harmful effects according to our experience and the information provided to us.

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## SECTION 12: Ecological information

### 12.1. Toxicity

Toxicity to fish: No data available.

### 12.2 Persistence and degradability

Biodegradability: No data available.

### 12.3. Bioaccumulative potential

Bioaccumulation: No data available.

### 12.4. Mobility in soil

Behaviour in environmental compartments: No data available

### 12.5. Results of PBT and vPvB assessment

Assessment: This mixture contains no substance considered to be persistent, bioaccumulating and toxic (PBT).  
This mixture contains no substance considered to be very persistent and very bioaccumulating (vPvB).

### 12.6. Other adverse effects

Additional ecological information: No data available on the product itself.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product: Smaller quantities can be disposed with household waste

Contaminated Packaging:

P501 Partially empty or empty container/packaging should be rinsed with water and can be disposed of together with household waste or brought to a recycling collection point.

## SECTION 14: Transport information

IATA/IMDG/ADR/RID/DOT/TDG

### 14.1. UN number

Not applicable.

### 14.2. UN Proper shipping name


Not applicable.

### 14.3. Transport hazard class

Not applicable.

### 14.4. Packing group

Not applicable.

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#### **14.5. Environmental hazards**

No.

#### **14.6. Special precautions for the user**

None.

#### **14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

### **SECTION 15: Regulatory information**

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

This safety datasheet complies with the requirements of Regulation (EC) No 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830, and Regulation (EC) No. 1272/2008.

##### **National legislation**

No additional information available.

##### **Classification according to Industrial Safety and Health Regulation (GHS and BetrSichV)**

Oosafe® Disinfectant does not require classification in accordance with the regulation for GHS qualification and for BetrSichV.

#### **15.2. Chemical safety assessment**


Not required.

### **SECTION 16: Other information**

##### **Data sources:**

Regulation (EC) No 1272/2008 of the European Parliament 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.

Changes in this new version were only based on updating Material Safety Data Sheet to Regulation (EU) 2015/830.

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#### Full text of H-Statements

H302	Harmful if swallowed
H314	Causes severe skin burns and 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

#### Full test of P-Statements

P102	Keep out of reach of children.
P273	Avoid release to the environment
P501	Dispose of content in accordance with local regulations

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, however they are no assurance of product properties and do not justify a contractual legal relationship. This version replaces all previous versions. 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.



Manufacturer:  
**SparMED ApS**  
Ryttermarken 2, DK-3520 Farum, Denmark  
Tel.: +45 39 40 25 03  
Fax: +45 39 40 25 64  
e-mail: [info@sparmed.dk](mailto:info@sparmed.dk)  
[www.sparmed.dk](http://www.sparmed.dk)

<b>PREPARED BY:</b> ☐	<b>APPROVED BY:</b> ☐
Regulatory Affairs Assistant ☐	Regulatory Affairs Officer ☐
<b>SIGNATURE:</b> ☐ 	<b>SIGNATURE:</b> ☐ 