

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

### 1.1. Product identifier

# otosil ES-1.1 | MSI – 40 ShoreA

UFI 9X84-3WC5-JW0S-CMGA

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

Relevant identified uses: Manufacture.  
Uses advised against: Private households (= general public).

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

#### Manufacturer

pro3dure medical GmbH  
Am Burgberg 13  
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10  
Telefax: +49 (0)2374 920050-50

#### Supplier

pro3dure medical GmbH  
Am Burgberg 13  
D 58642 Iserlohn

Telephone +49 (0)2374 920050-10  
Telefax: +49 (0)2374 920050-50

#### Information contact

pro3dure medical GmbH

Information telephone +49 (0)2374 920050-10  
Information telefax +49 (0)2374 920050-50  
E-mail (competent person) info@pro3dure.com  
Website www.pro3dure.com

### 1.4. Emergency telephone number

pro3dure medical GmbH  
This number is serviced during office hours.

Telephone +49 (0)2374 920050-10

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008:  
Identification is not obligatory. Please observe the information on the safety data sheet at all times.

### 2.2. Label elements

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms

Signal word: -

Hazard statements: -

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Precautionary statements:

-

**Special labelling of particular preparations:**

none

## 2.3. Other hazards

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## SECTION 3: Composition / information on ingredients

### 3.1. Substances

not applicable

### 3.2. Mixtures

This mixture contains no substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH at a concentration of  $\geq 0.1\%$ .

(Full text of H- and EUH-statements: see section 16.)

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## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**General information:** First aider: Pay attention to self-protection!  
**In case of inhalation:** Provide fresh air. Seek medical attention if problems persist.  
**Following skin contact:** After contact with skin, wash immediately with plenty of water and soap. In case of skin irritation, consult a physician.  
**After eye contact:** In case of contact with eyes, rinse immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Subsequently consult an ophthalmologist.  
**After ingestion:** Rinse mouth immediately and drink plenty of water. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.

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

erythema (redness)

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

Treat symptomatically.

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## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

**Suitable extinguishing media** Co-ordinate fire-fighting measures to the fire surroundings.  
**Unsuitable extinguishing media** Co-ordinate fire-fighting measures to the fire surroundings.

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

Not readily flammable

### 5.3. Advice for firefighters

**General information**

Co-ordinate fire-fighting measures to the fire surroundings.

**Special protective equipment for fire-fighters:**

In case of fire: Wear self-contained breathing apparatus.

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## SECTION 6: Accidental release measures

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

Remove persons to safety. Remove all sources of ignition. Provide adequate ventilation. Wear personal protection equipment.

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

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

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

### 6.4. Reference to other sections

Safe handling: see section 7 Personal protection equipment: see section 8 Disposal: see section 13

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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

**Advices on safe handling**

No special measures are necessary.

**Precautions against fire and explosion:**

No special fire protection measures are necessary.

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

**Requirements for storage rooms and vessels**

Keep in a cool, well-ventilated place. Do not keep the container sealed.

**Hints on joint storage**

Do not store together with: Acids alkalines Powdered metals Release of: Hydrogen

### 7.3. Specific end use(s)

Observe instructions for use.

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

**occupational exposure limit value**

Substance:	CAS-No.:		Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m <sup>3</sup> ]	Limitation of exposure peaks:	Remark:

**Substance with a common (EC) occupational exposure limit value.**

Substance:	CAS-No.:		Source:	Occupational exposure limit value:[ppm]	Occupational exposure limit value:[mg/m <sup>3</sup> ]	Limitation of exposure peaks:	Remark:

### DNEL-/PNEC-values

#### DNEL value

Substance:	CAS-No.:	DNEL/DMEL
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#### PNEC Value

Substance:	CAS-No.:	PNEC
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#### Additional information

none

## 8.2. Exposure controls

#### Occupational exposure controls:

Technical measures and the application of suitable work processes have priority over personal protection equipment.

#### General protection and hygiene measures:

When using do not eat, drink, smoke, sniff. Wash hands before breaks and after work. Apply skin care products after work. Wash contaminated clothing prior to re-use.

#### Personal protection equipment

Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500.

#### Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

#### Hand protection

Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: Butyl rubber.

#### Eye/face protection

Eye glasses with side protection

#### Body protection:

Wear suitable protective clothing.

#### Environmental exposure controls

refer to chapter 7. No further action is necessary.

#### Consumer exposure controls

refer to chapter 7. No further action is necessary.

#### Exposure Scenario:

Skin contact

## SECTION 9: Physical and chemical properties

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

#### Appearance

Physical state:	viscous
Colour:	-
Odour:	odourless
Odour threshold:	No data available

#### Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:				No data available

<b>Initial boiling point and boiling range:</b>			No data available
<b>Flammability:</b>			No data available
<b>lower flammability or explosive limits:</b>	74 Vol-%		Hydrogen
<b>Upper flammability or explosive limits:</b>	4 Vol-%		Hydrogen
<b>Flash point:</b>	>	150 °C	No data available
<b>Ignition temperature:</b>	>	200 °C	No data available
<b>Decomposition temperature:</b>			No data available
<b>pH:</b>			No data available
<b>Kinematic viscosity:</b>	°C	Pa*s	No data available
<b>Water solubility (g/L):</b>			No data available
<b>Partition coefficient: n-octanol/water:</b>			No data available
<b>Vapour pressure:</b>			No data available
<b>Density:</b>	1,01	g/mL	No data available
<b>Relative density:</b>			No data available
<b>Particle properties:</b>			No data available

## 9.2. Other information

none

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## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

### 10.2. Chemical stability

With proper storage and handling the product is stable.

### 10.3. Possibility of hazardous reactions

May generate flammable hydrogen gas. Avoid contact with water, alcohols, acidic, basic, or oxidizing materials. Potential for exothermic hazard.

### 10.4. Conditions to avoid

heat. Keep away from sources of ignition - No smoking.

### 10.5. Incompatible materials

Oxidizing agent Acid. Alkalis (alkalis). metal.

### 10.6. Hazardous decomposition products

Hydrogen.

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## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

There are no data available on the preparation/mixture itself.

<b>M-factor:</b>	-	<b>Acute toxicity (dermal):</b>	> 5000 mg/kg
<b>Acute toxicity (oral):</b>	> 5000 mg/kg	<b>Acute toxicity (inhalativ):</b>	17.34 mg/L

### Acute toxicity

Substance:	CAS-No.:	Toxicological information
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#### Skin corrosion/irritation:

There are no data available on the preparation/mixture itself.

#### Serious eye damage/irritation:

There are no data available on the preparation/mixture itself.

#### Respiratory or skin sensitisation:

There are no data available on the preparation/mixture itself.

#### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

##### Carcinogenicity:

No information available.

##### Germ cell mutagenicity:

No information available.

##### Reproductive toxicity:

No information available.

#### STOT-single exposure:

No information available.

#### STOT-repeated exposure:

No information available.

#### Aspiration hazard:

There are no data available on the preparation/mixture itself.

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## SECTION 12: Ecological information

### 12.1. Toxicity

There are no data available on the preparation/mixture itself.

#### Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
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### 12.2. Persistence and degradability

There are no data available on the mixture itself.

### 12.3. Bioaccumulative potential

There are no data available on the mixture itself.

### 12.4. Mobility in soil

There are no data available on the mixture itself.

### 12.5. Results of PBT and vPvB assessment

There are no data available on the mixture itself.



#### 14.6. Special precautions for user

##### Land transport (ADR/RID)

transport category: - tunnel restriction code: -  
Special provisions: - Limited quantity (LQ): -

##### Sea transport (IMDG)

EmS-No: -  
Special provisions: - Limited quantity (LQ): -

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

Remark -

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### SECTION 15: Regulatory information

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

##### EU legislation

**Information on Regulation (EC) No 166/2006 establishing a European Pollutant Release and Transfer Register:**  
No information available.

**Regulation (EC) No. 1005/2009 on substances that lead to the depletion of the ozone layer:**  
No information available.

**Regulation (EC) No. 648/2004 (Detergents regulation)**  
No information available.

**Regulation (EC) No 850/2004 [POP-Regulation]:**  
No information available.

**Regulation (EU) No 649/2012 on the export and import of dangerous chemicals:**  
No information available.

**Use restriction according to REACH annex XVII, no.:**  
No information available.

##### National regulations

Observe in addition any national regulations!

##### Restrictions of occupation

none

##### Other regulations, restrictions and prohibition regulations

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#### 15.2. Chemical Safety Assessment

**For this preparation a chemical safety assessment has been carried out.** no  
For this substance a chemical safety assessment has not been carried out.



## SECTION 16: Other information

**Relevant H- and EUH-phrases (Number and full text):**  
**Hazard statements**

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**Training advice**

Observe instructions for use.

**Recommended restrictions of use:**

refer to chapter 1.

**Further remarks:**

none

**Documentation of changes:**

Changes compared to version 4:

12.6 Information added.

Changes compared to version 3:

3.2 Recalculation of concentrations

5 Revised

6.1 Revised

8.2 Revised

12.5 Revised

16 Documentation of changes introduced

16 List of abbreviations inserted.

**Key literature references and sources for data**

Data arise from reference works and literature.

### Abbreviations and acronyms

AC: Artikelkategorie (Article Category)

ACGIH: Rat für Arbeitsschutz und Gefahrstoffe, Amerika (American Conference of Government Industrial Hygienists)

ADN: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf Binnengewässern (Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)

ADR: Europäisches Übereinkommen über die internationale Beförderung gefährlicher Güter auf der Straße (Accord européen relatif transport des marchandises dangereuses par route)

AGW: Arbeitsplatzgrenzwert

AOX: Adsorbierbare organisch gebundene Halogene (Adsorbable Organic halogen compounds)

Bw: Körpergewicht (Body weight)

CMR: Stoffe klassifiziert als Krebserzeugend, Mutagen oder Reproduktionstoxisch (Carcinogenic, Mutagenic, toxic for Reproduction)

CSR: Stoffsicherheitsbericht (Chemical Safety Report)

DIN: Deutsches Institut für Normung / Deutsche Industrienorm

DNEL: Grenzwert, unterhalb dessen der Stoff keine Wirkung ausübt (Derived No Effect Level)

DPD: Zubereitungsrichtlinie / Richtlinie 1999-45-EC (Dangerous Preparations Directive)

DSD: Stoffrichtlinie / Richtlinie 67-548-EC (Dangerous Substances Directive)

DU: Nachgeschalteter Anwender (Downstream User)

EC50: Wirksame Konzentration 50% (Effective Concentration 50%)

ECHA: Europäische Chemikalienagentur

EN: Europäische Norm

EWC/EWL: Europäischer Abfallartenkatalog (European Waste Catalogue)

IATA: Verband für den internationalen Lufttransport (International Air Transport Association)

IBC: Großpackmittel (Intermediate Bulk Container)

ICAO: Internationale Zivilluftfahrt-Organisation (International Civil Aviation Organization)

IMDG Code: Gefahrgutvorschriften für den internationalen Seetransport (International Maritime Dangerous Goods Code)

IMO: Internationale Seeschiffahrts-Organisation (International Maritime Organization)

ISO: Internationale Normungsorganisation (International Standards Organisation)

LC50: Lethale (Tödliche) Konzentration 50%

LD50: Lethale (Tödliche) Dosis 50%

LEV: Lokale Absaugung (Local exhaust ventilation)

MAK: Maximale Arbeitsplatzkonzentration – DFG

n.a.: nicht anwendbar

n.b.: nicht bestimmt

OEL: Arbeitsplatzgrenzwert (Occupational Exposure Limit)

PBT: persistent, bioakkumulierbar, giftig (persistent, bioaccumulative, toxic)

PNEC: Abgeschätzte Nicht-Effekt-Konzentration (Predicted No Effect Concentration)

PPE/PSA: Persönliche Schutzausrüstung (Personal Protective Equipment)

REACH: Registrierung, Bewertung und Zulassung von Chemikalien (Registration, Evaluation and Authorization of Chemicals)

RID: Gefahrgutvorschriften für den Transport mit der Eisenbahn (Règlement International concernant le transport de marchandises dangereuses par chemin de fer)

STEL: Grenzwert für Kurzzeitexposition (Short-term Exposure Limit)

SVHC: Stoff sehr hoher Besorgnis (Substance of Very High Concern)

TLV: Arbeitsplatzgrenzwert (Threshold Limit Value)

VOC: Flüchtige organische Kohlenwasserstoffe (Volatile Organic Compounds)

vPvB: sehr persistent, sehr bioakkumulierbar (very persistent, very bioaccumulative)

dw: Trockenmasse (dry weight)