

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

1.1. Product identifier

otosil SL-1 | MSI

UFI AJJE-NWM1-MW0N-A7MF

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:
Flam. Liq. 2, H225; Aquatic Acute 1, H400; Aquatic Chronic 1, H410

2.2. Label elements

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

Hazard pictograms



GHS02, GHS09
Warning

Signal word:

Hazard statements:

H225 Highly flammable liquid and vapour.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 Keep container tightly closed.
P240 Ground and bond container and receiving equipment.
P241 Use explosion-proof electrical equipment.
P242 Use non-sparking tools.
P243 Take action to prevent static discharges.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+361+353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P370+378 In case of fire: Use carbon dioxide to extinguish.
P391 Collect spillage.
P403+235 Store in a well-ventilated place. Keep cool.

Special labelling of particular preparations:

none

2.3. Other hazards

No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition / information on ingredients

3.1. Substances

not applicable

3.2. Mixtures

Mixture related information

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Hexamethyldisiloxane	107-46-0	not applicable	60-80 %	Flam. Liq. 2, H225; Aquatic Acute 1, H400; Aquatic Chronic 1, H410	M = 1 ATE (dermal) = > 2000 mg/kg ATE (oral) = > 5000 mg/kg ATE (inhalativ) = 15956 ppm
Catalyst			<1 %	Repr. 2, H361; Aquatic Chronic 3, H412	

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

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: Provide fresh air. Seek medical attention if problems persist.
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 flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist. Consult an ophthalmologist.
After ingestion: Rinse mouth thoroughly with water. Do NOT induce vomiting. Call a physician immediately. Call a physician immediately.

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

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

Provide fresh air.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Carbon dioxide (CO₂) Dry extinguishing powder Foam Water spray jet
Unsuitable extinguishing media Full water jet

5.2. Special hazards arising from the substance or mixture

Combustible Vapours can form explosive mixtures with air.

5.3. Advice for firefighters

General information

In case of fire may be liberated: Carbon dioxide (CO₂) Carbon monoxide Do not allow run-off from fire-fighting to enter drains or water courses. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for fire-fighters:

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not breathe vapour/aerosol. Avoid contact with skin and eyes. Provide adequate ventilation. Keep away from sources of ignition - No smoking.

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

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advices on safe handling

Provide adequate ventilation as well as local exhaustion at critical locations. Store in a well-ventilated place. Keep container tightly closed.

Precautions against fire and explosion:

Only use the material in places where open light, fire and other flammable sources can be kept away.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep the packing dry and well sealed to prevent contamination and absorption of humidity.

Hints on joint storage

none

7.3. Specific end use(s)

Observe instructions for use.

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/m³]	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/m³]	Limitation of exposure peaks:	Remark:

DNEL-/PNEC-values

DNEL value

Substance:	CAS-No.:	DNEL/DMEL

PNEC Value

Substance:	CAS-No.:	PNEC

Additional information

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8.2. Exposure controls

Occupational exposure controls:

Provide adequate ventilation as well as local exhaust at critical locations. 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

Respiratory protection necessary at: aerosol or mist formation Suitable respiratory protection apparatus: Filtering device (full mask or mouthpiece) with filter:

Hand protection

Suitable material: Tested protective gloves are to be worn: DIN-/EN-Norms: EN ISO 374 Suitable material: NBR (Nitrilkautschuk) / >0,11mm / >480h / -
Unsuitable material:

Eye/face protection

Eye glasses with side protection

Body protection:

lab coat

Environmental exposure controls

Do not allow to enter into surface water or drains.

Consumer exposure controls

refer to chapter 7. No further action is necessary.

Exposure Scenario:

Skin contact Inhalation

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state: Liquid
Colour: clear
Odour: characteristic
Odour threshold: No data available

Safety relevant basis data

	parameter	Value	unit	Remark
Melting point/freezing point:		-59	°C	Hexamethyldisiloxane
Initial boiling point and boiling range:		101	°C	Hexamethyldisiloxane
Flammability:				No data available
lower flammability or explosive limits:				No data available
Upper flammability or explosive limits:				No data available
Flash point:	closed crucible	-6	°C	Hexamethyldisiloxane
Ignition temperature:				No data available
Decomposition temperature:				No data available
pH:				No data available
Kinematic viscosity:				No data available
Water solubility (g/L):				No data available
Partition coefficient: n-octanol/water:				No data available
Vapour pressure:	at 20°C.	44	hPa	Hexamethyldisiloxane
Density:	at 20°C.	0,764	g/cm ³	Hexamethyldisiloxane
Relative density:				No data available
Particle properties:				not applicable

9.2. Other information

none

SECTION 10: Stability and reactivity

10.1. Reactivity

Polymerises on contact with water, including moisture in the air.

10.2. Chemical stability

Moisture-sensitive.

10.3. Possibility of hazardous reactions

Polymerization.

10.4. Conditions to avoid

Humidity. Heat. Keep away from sources of ignition - No smoking.

10.5. Incompatible materials

Protect from moisture.

10.6. Hazardous decomposition products

In case of fire may be liberated: Carbon dioxide. Carbon monoxide.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

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

M-factor: -

Acute toxicity (dermal): -

Acute toxicity (oral): -

Acute toxicity (inhalative): -

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Hexamethyldisiloxane	107-46-0	LD50 oral (rat) > 5000 mg/kg LC50 inhalation (rat, 4 h) 15956 ppm LD50 dermal (rabbit) > 2000 mg/kg NOAEL (rat) 160 mg/kg

Skin corrosion/irritation:

Has degreasing effect on the skin.

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:

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

Germ cell mutagenicity:

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

Reproductive toxicity:

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

STOT-single exposure:

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

STOT-repeated exposure:

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

Aspiration hazard:

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

SECTION 12: Ecological information

12.1. Toxicity

May cause long lasting harmful effects to aquatic life.

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity
Hexamethyldisiloxane	107-46-0	LC50 (fish, 96 h) 0,46 mg/L EC50 (algae, 96 h) 0,22 mg/L

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.

12.6 Endocrine disruptive effect

There are no data available on the mixture itself.

12.7. Other adverse effects

Very toxic to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Appropriate disposal/Product:

Dispose of waste according to applicable legislation. Waste disposal according to directive 2008/98/EC, covering waste and dangerous waste. Must not be disposed together with household garbage.

Appropriate disposal / Package

Non-contaminated packages may be recycled. Handle contaminated packages in the same way as the substance itself.

List of proposed waste codes / waste designations according to EWC / AVV

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

SECTION 14: Transport information

14.1. UN number

UN No.: 1993

14.2. UN proper shipping name

Land transport (ADR/RID)

ENTZÜNDBARER FLÜSSIGER STOFF, N.A.G.

Hexamethyldisiloxan

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)
FLAMMABLE LIQUID, N.O.S.
Hexamethyldisiloxane

14.3. Transport hazard class(es)

Hazard label(s) / Label: 3

Classification code: / Classification Code: F1



14.4. Packing group

Packing group/ Packing Group: II

14.5. Environmental hazards

ADR/RID / IMDG / ICAO-TI / IATA-DGR:	Yes	No
Marine pollutant:	<input checked="" type="checkbox"/>	<input type="checkbox"/>

14.6. Special precautions for user

Land transport (ADR/RID)			
transport category:	2	tunnel restriction code:	D/E
Special provisions:	274, 601, 640D	Limited quantity (LQ):	1 L

Sea transport (IMDG)

EmS-No: F-E, S-E
Special provisions: 223 Limited quantity (LQ): 1 L

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

Remark -

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

No data available

Other regulations, restrictions and prohibition regulations

No data available

15.2. Chemical Safety Assessment

For this preparation a chemical safety assessment has been carried out.

For this substance a chemical safety assessment is not required.

SECTION 16: Other information

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

Hazard statements

H225	Highly flammable liquid and vapour.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Training advice

Observe instructions for use.

Recommended restrictions of use:

Reserved for industrial and professional use.

Further remarks:

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Documentation of changes:

Changes compared to version 4:

Change in product identifier.

Changes compared to version 2:

Formulation adjusted. Remaining SDS acutely adjusted according to new formulation. Version 3 is skipped to align the version-number with the German version.

Changes compared to version 1:

1.1	UFI-code added
8.2	revised

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)