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

1.1. Product identifier

otosil ES-1.1 | MSI – 60 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:
-
Precautionary statements:

-

Special labelling of particular preparations:
none

2.3. Other hazards
-

SECTION 3: Composition / information on ingredients

3.1. Substances
not applicable

3.2. Mixtures
This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH:

Composition/information on ingredients

Substance:	CAS-No.:	REACH-no.:	Concentration:	Classification: EC 1272/2008 (CLP):	M, ATE, Note
Decamethylcyclopentasiloxane	541-02-6		0,1 %	-	ATE (dermal) = >2000 mg/kg ATE (oral) = >5000 mg/kg ATE (inhalativ) = 8,67 mg/L
Dodecamethylcyclohexasiloxane	540-97-6		0,1 %	-	ATE (dermal) = 2000 mg/kg ATE (oral) = > 2000 mg/kg
Octamethylcyclotetrasiloxane	556-67-2		0,1 %	Flam. Liq. 3, H226; Repr. 2, H361; Repr. 2, H361f; Aquatic Chronic 4, H413	ATE (dermal) = > 2375 mg/kg ATE (oral) = 4800 mg/kg ATE (inhalativ) = 36 mg/L

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

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.

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.

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

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.

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
Octamethylcyclotetrasiloxane	556-67-2	worker inhalativ long-term, systemic 73 mg/m³ worker inhalativ short-term, systemic 73 mg/m³ worker inhalativ long-term, local 73 mg/m³ worker inhalativ short-term, local 73 mg/m³ population inhalativ short-term, local 13 mg/m³ population inhalativ short-term, systemic 13 mg/m³ population inhalativ long-term, local 13 mg/m³ population inhalativ long-term, systemic 13 mg/m³ population oral long-term, systemic 3,7 mg/kg bw/day population oral short-term, systemic 3,7 mg/kg bw/day
Dodecamethylcyclohexasiloxane	540-97-6	worker inhalativ long-term, local 1,22 mg/m³ population inhalativ long-term, local 0,3 mg/m³ population inhalativ short-term, local 1,5 mg/m³
Decamethylcyclopentasiloxane	541-02-6	worker inhalativ long-term, systemic 97,3 mg/m³ worker inhalativ long-term, local 24,2 mg/m³ population inhalativ long-term, systemic 17,3 mg/m³ population inhalativ long-term, local 4,3 mg/m³ population oral long-term, systemic 5 mg/kg bw/day

PNEC Value

Substance:	CAS-No.:	PNEC
Octamethylcyclotetrasiloxane	556-67-2	air 0,44 µg/l aquatic, marine water 0,44 µg/l sediment, freshwater 590 µg/kg dw sediment, marine water 59 µg/kg dw soil 150 µg/kg dw sewage treatment plant 10000 µg/l secondary poisoning 41000 µg/kg food
Dodecamethylcyclohexasiloxane	540-97-6	sediment, freshwater 13500 µg/kg dw sediment, marine water 1350 µg/kg dw secondary poisoning 66700 µg/kg food
Decamethylcyclopentasiloxane	541-02-6	aquatic, freshwater 1,2 µg/l aquatic, marine water 0,12 µg/l sewage treatment plant 10000 µg/l sediment, freshwater 11000 µg/kg dw sediment, marine water 1100 µg/kg dw soil 2540 µg/kg dw secondary poisoning oral 16000 µg/kg food

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

9.2. Other information

none

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.

SECTION 11: Toxicological information

11.1. Information on toxicological effects
There are no data available on the preparation/mixture itself.

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

Acute toxicity

Substance:	CAS-No.:	Toxicological information
Decamethylcyclopentasiloxane	541-02-6	LD50 dermal (Rabbit) > 2000 mg/kg LC50 inhalation (rat, 4 h) 8,67 mg/L LD50 oral (rat) > 5000 mg/kg
Dodecamethylcyclohexasiloxane	540-97-6	LD50 oral (rat) > 2000 mg/kg LD50 dermal (rat) 2000 mg/kg
Octamethylcyclotetrasiloxane	556-67-2	LD50 dermal (rat) > 2375 mg/kg LC50 inhalation (rat, 4 h) 36 mg/L LD50 oral (rat) 4800 mg/kg

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.

SECTION 12: Ecological information

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

Ecotoxicity

Substance:	CAS-No.:	Ecotoxicity

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
Octamethylcyclotetrasiloxane (D4) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for PBT and vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D4 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D4 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D4 is decomposed by naturally occurring processes in the atmosphere. D4-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.
Decamethylcyclopentasiloxane (D5) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for vPvB substances and was included in the candidate list of SVHCs. According to our knowledge of the state of the art, however, D5 cannot be compared with known PBT and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D5 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D5 is decomposed by naturally occurring processes in the atmosphere. D5-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.
Dodecamethylcyclohexasiloxane (D6) fulfills the current criteria set forth under Annex XIII of the EU REACH Regulation for very persistent and very bioaccumulative substances (vPvB) and was included in the candidate list of substances of very high concern (SVHC). According to our knowledge of the state of the art, however, D6 cannot be compared with known persistent, bioaccumulative and toxic (PBT) and/or vPvB substances. The interpretation of the available data by the silicone industry reveals that scientific evidence obtained from field tests essentially points out that D6 does not lead to biomagnification in aquatic and terrestrial food chains. In air, D6 is decomposed by naturally occurring processes in the atmosphere. D6-residues which do not decompose in this way in the air are not expected to accumulate from the air in water, the soil or living organisms.

12.6 Endocrine disruptive effect
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7. Other adverse effects
There are no data available on the mixture itself.

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.: -

14.2. UN proper shipping name
Land transport (ADR/RID)
-
-

Sea transport (IMDG), Air transport (ICAO-TI / IATA-DGR)
-
--

14.3. Transport hazard class(es)
Hazard label(s) / Label: -

Classification code: / Classification Code: -

14.4. Packing group
Packing group/ Packing Group: -

14.5. Environmental hazards

	Yes	No
ADR/RID / IMDG / ICAO-TI / IATA-DGR:	☐	☒
Marine pollutant:	☐	☒

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 -

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
This mixture contains the following substances of very high concern (SVHC) which are included in the Candidate List according to Article 59 of REACH: Octamethylcyclotetrasiloxane, Decamethylcyclopentasiloxane, Dodecamethylcyclohexasiloxane.

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
-

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 merchandises 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: Zubereitungsrichtline / Richtline 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 Seeschifffahrts-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, bioakkumlierbar, 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)