

**C700100**  
**ELITE RELINING VARNISH**

## Information Sheet

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

**1.1. Product identifier**

Code: C700100  
Product name: ELITE RELINING VARNISH

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

Intended use: For professional use only. Addition silicone denture liner varnish.

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

Name: Zhermack S.p.a  
Full address: Via Bovazecchino 100  
District and Country: 45021 Badia Polesine (RO)  
Italy  
Tel. +39 0425-597611  
Fax +39 0425-597689

e-mail address of the competent person responsible for the Safety Data Sheet: msds@zhermack.com

**1.4. Emergency telephone number**

For urgent inquiries refer to: 0039 0425597611

### SECTION 2. Hazards identification

**2.1. Classification of the substance or mixture**

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication:

**2.2. Label elements**

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 5.1, letter d). Therefore the product is exempted from the CLP labeling requirements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

This product is not subject to hazard labeling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

**2.3. Other hazards**

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

**SECTION 3. Composition/information on ingredients****3.1. Substances**

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

**3.2. Mixtures**

Mixture of polydimethyl polymethyl vinyl siloxane, polydimethyl polymethyl hydrogen siloxane and silica.

**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

No episodes of damage to health ascribable to the product have been reported.

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

Information not available

**SECTION 5. Firefighting measures****5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

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UNSUITABLE EXTINGUISHING EQUIPMENT  
None in particular.

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

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE  
Do not breathe combustion products.

**5.3. Advice for firefighters****GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

**SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS**

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

**SECTION 6. Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

**6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

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

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

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Any information on personal protection and disposal is given in sections 8 and 13.

**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

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

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

**7.3. Specific end use(s)**

See section 1.2.

**SECTION 8. Exposure controls/personal protection****8.1. Control parameters**

Information not available

**8.2. Exposure controls**

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION  
None required.

SKIN PROTECTION  
None required.

EYE PROTECTION  
None required.

RESPIRATORY PROTECTION  
None required, unless indicated otherwise in the chemical risk assessment.

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## ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

**SECTION 9. Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Appearance	paste
Colour	transparent
Odour	odourless
Odour threshold	Not available
pH	neutral
Melting point / freezing point	Not applicable
Initial boiling point	Not applicable
Boiling range	Not applicable
Flash point	Not available
Evaporation Rate	Not available
Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Relative density	Not available
Solubility	insoluble in water
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not applicable
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

**9.2. Other information**

Information not available

**SECTION 10. Stability and reactivity****10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**C700100**  
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No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid**

None in particular. However the usual precautions used for chemical products should be respected.

**10.5. Incompatible materials**

Information not available

**10.6. Hazardous decomposition products**

Information not available

**SECTION 11. Toxicological information****11.1. Information on toxicological effects****Metabolism, toxicokinetics, mechanism of action and other information**

Information not available

**Information on likely routes of exposure**

Information not available

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

Information not available

**Interactive effects**

Information not available

**ACUTE TOXICITY**

Does not meet the classification criteria for this hazard class

**SKIN CORROSION / IRRITATION**

Does not meet the classification criteria for this hazard class

**SERIOUS EYE DAMAGE / IRRITATION**

Does not meet the classification criteria for this hazard class

**RESPIRATORY OR SKIN SENSITISATION**

Does not meet the classification criteria for this hazard class

**GERM CELL MUTAGENICITY**

Does not meet the classification criteria for this hazard class

**CARCINOGENICITY**

Does not meet the classification criteria for this hazard class

**C700100**  
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Does not meet the classification criteria for this hazard class

**STOT - SINGLE EXPOSURE**

Does not meet the classification criteria for this hazard class

**STOT - REPEATED EXPOSURE**

Does not meet the classification criteria for this hazard class

**ASPIRATION HAZARD**

Does not meet the classification criteria for this hazard class

**SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

**12.1. Toxicity**

Information not available

**12.2. Persistence and degradability**

Information not available

**12.3. Bioaccumulative potential**

Information not available

**12.4. Mobility in soil**

Information not available

**12.5. Results of PBT and vPvB assessment**

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

**12.6. Other adverse effects**

Information not available

**SECTION 13. Disposal considerations****13.1. Waste treatment methods**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

**CONTAMINATED PACKAGING**

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

**SECTION 14. Transport information**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

**14.1. UN number**

Not applicable

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

Not applicable

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Information not relevant

**SECTION 15. Regulatory information**



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Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

None

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

German regulation on the classification of substances hazardous to water (VwVwS 2005)

WGK 1: Low hazard to waters

**15.2. Chemical safety assessment**

No chemical safety assessment has been processed for the mixture and the substances it contains.

**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%

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- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

**GENERAL BIBLIOGRAPHY**

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
  2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
  3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
  4. Regulation (EU) 2015/830 of the European Parliament
  5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
  6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
  7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
  8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
  9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
  10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
  11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
  - Handling Chemical Safety
  - INRS - Fiche Toxicologique (toxicological sheet)
  - Patty - Industrial Hygiene and Toxicology
  - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
  - IFA GESTIS website
  - ECHA website
  - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) – Italy

**Note for users:**

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.

This safety data sheet has been created on a voluntary basis.

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

**Changes to previous review:**

The following sections were modified:

01 / 02 / 03 / 04 / 05 / 07 / 08 / 09 / 11 / 12 / 14 / 15 / 16.

## Safety Data Sheet ELITE SOFT RELINING - BASE

Revision nr. 5  
Dated 26/10/2023

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

#### 1.1. Product identifier

Mixture identification:

Product Name: ELITE SOFT RELINING - BASE

Code: C700100, C700130

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

For professional use only. Addition silicone for the preparation of soft relining.

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

Name

Zhermack S.p.a

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

#### 1.4. Emergency telephone number

+39 0425 597611 (office hours)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

None

#### 2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

#### 2.3. Other hazards

PBT, vPvB or endocrine disruptor substances present in concentration  $\geq 0.1\%$ :

$\geq 0,3\%$  -  $< 0,5\%$  octamethylcyclotetrasiloxane; [D4] - Index number: 014-018-00-1,

CAS: 556-67-2, EC: 209-136-7:

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PBT, vPvB  
≥ 0,3% - < 0,5% Decamethylcyclopentasiloxane - D5 - CAS: 541-02-6, EC:  
208-764-9:  
PBT, vPvB

Other Hazards:  
No other hazards

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

##### 3.1. Substances

Not Applicable

##### 3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
≥ 0,3% - < 0,5%	octamethylcyclotetrasiloxane; [D4]	Index 014-018-00-1 number: CAS: 556-67-2 EC: 209-136-7	Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10.
≥ 0,3% - < 0,5%	Decamethylcyclopentasiloxane - D5	CAS: 541-02-6 EC: 208-764-9	The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

SVHC, PBT, vPvB, endocrine disruptor substances:

≥ 0,3% - < 0,5% octamethylcyclotetrasiloxane; [D4]  
Index number: 014-018-00-1, CAS: 556-67-2, EC: 209-136-7  
PBT, vPvB, SVHC  
≥ 0,3% - < 0,5% Decamethylcyclopentasiloxane - D5  
CAS: 541-02-6, EC: 208-764-9  
PBT, vPvB, SVHC

#### SECTION 4: First aid measures

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

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

None

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

Treatment:

None

#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO<sub>2</sub>).

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### ELITE SOFT RELINING - BASE

Extinguishing media which must not be used for safety reasons:  
None in particular.

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

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

#### 5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

## SECTION 6: Accidental release measures

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

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

#### 6.2. Environmental precautions

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

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

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

Wash with plenty of water.

#### 6.4. Reference to other sections

See also section 8 and 13

## SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Do not eat or drink while working.

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

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

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

See section 1.2.

## SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

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octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

OEL Type	TWA		Duratio n	STEL		Duratio n	Notes	Country
No data available								

Decamethylcyclopentasiloxane - D5 - CAS: 541-02-6

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### ELITE SOFT RELINING - BASE

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

#### 8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

## SECTION 9: Physical and chemical properties

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

Properties	Value	Method:	Notes
Physical state:	Viscous fluid	--	--
Colour:	Pink	--	--
Odour:	Odourless	--	--
Melting point/freezing point:	Not Relevant	--	--
Boiling point or initial boiling point and boiling range:	Not Relevant	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	>100 ° C	EN ISO 3679	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--

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pH:	Not Relevant	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	1.0-1.2 g/cm <sup>3</sup>	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

**9.2. Other information**

No other relevant information

**SECTION 10: Stability and reactivity****10.1. Reactivity**

Stable under normal conditions

**10.2. Chemical stability**

Stable under normal conditions

**10.3. Possibility of hazardous reactions**

None

**10.4. Conditions to avoid**

Stable under normal conditions.

**10.5. Incompatible materials**

None in particular.

**10.6. Hazardous decomposition products**

None.

**SECTION 11: Toxicological information****11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Toxicological information of the product:

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a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

d) respiratory or skin sensitisation

Not classified

e) germ cell mutagenicity

Not classified

f) carcinogenicity

Not classified

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- g) reproductive toxicity  
Not classified
- h) STOT-single exposure  
Not classified
- i) STOT-repeated exposure  
Not classified
- j) aspiration hazard  
Not classified

Toxicological information of the main substances found in the product:

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Species: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier).

Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (similar to OECD 402, rat, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, ECHA dossier).

#### 11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

## SECTION 12: Ecological information

The product is not classified for chronic aquatic hazard: a test based on the bioavailability / release of D4 by the polymer silicone was performed with the OECD 29 method. It was found that the quantity of D4 released by 100mg of polymer is at least below the quantification limit of the method (i.e. 4.4 ppb), a value significantly lower than the limit that would result in the classification for chronic aquatic toxicity, i.e. NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for aquatic invertebrates. Therefore, the product is not classified for this hazard class..

#### 12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

ELITE SOFT RELINING - BASE

The product is classified: -

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae > 0.0022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

Long-term toxicity to aquatic invertebrates:

Endpoint: NOEC - Species: Daphnia = 7.9 µg/L - Duration h: 21d EPA OTS 797.1330, Daphnia magna, ECHA dossier

#### 12.2. Persistence and degradability

Decamethylcyclopentasiloxane - D5 - CAS: 541-02-6

Biodegradability: Non-readily biodegradable

#### 12.3. Bioaccumulative potential

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes: (Log Pow, ECHA dossier).

#### 12.4. Mobility in soil

Not available



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#### 12.5. Results of PBT and vPvB assessment

PBT Substances:

- >= 0,3% - < 0,5% octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2
- >= 0,3% - < 0,5% Decamethylcyclopentasiloxane - D5 - CAS: 541-02-6

vPvB Substances:

- >= 0,3% - < 0,5% octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2
- >= 0,3% - < 0,5% Decamethylcyclopentasiloxane - D5 - CAS: 541-02-6

#### 12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration >= 0.1%

#### 12.7. Other adverse effects

None

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

### SECTION 14: Transport information

#### 14.1. UN number or ID number

Not classified as dangerous in the meaning of transport regulations.

#### 14.2. UN proper shipping name

Not available

#### 14.3. Transport hazard class(es)

Not available

#### 14.4. Packing group

Not available

#### 14.5. Environmental hazards

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

#### 14.6. Special precautions for user

Not available

#### 14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

### SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

## Safety Data Sheet

### ELITE SOFT RELINING - BASE

Regulation (EU) n. 2019/521 (ATP 12 CLP)  
Regulation (EU) n. 2020/217 (ATP 14 CLP)  
Regulation (EU) n. 2020/1182 (ATP 15 CLP)  
Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

Restriction 70

SVHC Substances:

Substances in candidate list (Art. 59 Reg. 1907/2006, REACH):

octamethylcyclotetrasiloxane; [D4]

PBT, vPvB

Decamethylcyclopentasiloxane - D5

PBT, vPvB

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

Product belongs to category: E2

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)

WGK2 - Hazardous for water

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

California Proposition 65

Substance(s) listed under California Proposition 65:

None.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

None

#### SECTION 16: Other information

Full text of phrases referred to in Section 3:

H226 Flammable liquid and vapour.

H361f Suspected of damaging fertility.

H410 Very toxic to aquatic life with long lasting effects.

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Repr. 2	3.7/2	Reproductive toxicity, Category 2
Aquatic Chronic 1	4.1/C1	Chronic (long term) aquatic hazard, category 1
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

**Safety Data Sheet  
ELITE SOFT RELINING - BASE**

<b>Classification according to Regulation (EC) Nr. 1272/2008</b>	<b>Classification procedure</b>
Aquatic Chronic	According to Article 12 of the CLP Regulation, "Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification: [...] (b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable." Following a release study of D4 through the OECD 29 test on polymeric products representative for quantity of D4, the limit that would result in the classification for chronic aquatic toxicity (NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for invertebrates aquatic) is not reached.

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECHA – European Chemical Agency  
GESTIS - Information system on hazardous substances of the German Social Accident Insurance  
IARC – International Agency for Research on Cancer  
IPCS INCHEM – International Programme on Chemical Safety  
ISS – Istituto Superiore di Sanità  
PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.  
This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.  
ATE: Acute Toxicity Estimate  
ATEmix: Acute toxicity Estimate (Mixtures)  
CAS: Chemical Abstracts Service (division of the American Chemical Society).  
CLP: Classification, Labeling, Packaging.  
DNEL: Derived No Effect Level.  
EINECS: European Inventory of Existing Commercial Chemical Substances.  
GefStoffVO: Ordinance on Hazardous Substances, Germany.  
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.  
IATA: International Air Transport Association.  
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).  
ICAO: International Civil Aviation Organization.  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization"

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### **ELITE SOFT RELINING - BASE**

	(ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.

## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

Revision nr. 5  
Dated 26/10/2023

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

##### 1.1. Product identifier

Mixture identification:

Product Name: ELITE SOFT RELINING - CATALYST

Code: C700100, C700130

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

For professional use only. Addition silicone for the preparation of soft relining.

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

Name

Zhermack S.p.a

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

##### 1.4. Emergency telephone number

+39 0425 597611 (office hours)

#### SECTION 2: Hazards identification

##### 2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

##### 2.2. Label elements

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

The product is not classified as hazardous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

##### 2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration  $\geq 0.1\%$

Other Hazards:

No other hazards

## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

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

##### 3.1. Substances

Not Applicable

##### 3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
<0,09%	octamethylcyclotetrasiloxane; [D4]	Index 014-018-00-1 number: CAS: 556-67-2 EC: 209-136-7	Flam. Liq. 3 H226 Flammable liquid and vapour. Repr. 2 H361f Suspected of damaging fertility. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects. M=10.

SVHC, PBT, vPvB, endocrine disruptor substances:

<0,09% octamethylcyclotetrasiloxane; [D4]

Index number: 014-018-00-1, CAS: 556-67-2, EC: 209-136-7

PBT, vPvB, SVHC

#### SECTION 4: First aid measures

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

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

None

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

Treatment:

None

#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO2).

Extinguishing media which must not be used for safety reasons:

None in particular.

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

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

##### 5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

#### SECTION 6: Accidental release measures

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### ELITE SOFT RELINING - CATALYST

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

For non emergency personnel:  
Wear personal protection equipment.  
Remove persons to safety.  
See protective measures under point 7 and 8.  
For emergency responders:  
Wear personal protection equipment.

#### 6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.  
Retain contaminated washing water and dispose it.  
In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

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

Wash with plenty of water.

#### 6.4. Reference to other sections

See also section 8 and 13

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.  
See also section 8 for recommended protective equipment.  
Advice on general occupational hygiene:  
Do not eat or drink while working.

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

Keep away from food, drink and feed.  
Incompatible materials:  
See section 10.5.  
Instructions as regards storage premises:  
Adequately ventilated premises.

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

See section 1.2.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

ELITE SOFT RELINING - CATALYST  
octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
No data available								

DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

#### 8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

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### ELITE SOFT RELINING - CATALYST

The following should be considered when choosing work glove material (EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

## SECTION 9: Physical and chemical properties

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

Properties	Value	Method:	Notes
Physical state:	Viscous fluid	--	--
Colour:	White	--	--
Odour:	Odourless	--	--
Melting point/freezing point:	Not Relevant	--	--
Boiling point or initial boiling point and boiling range:	Not Relevant	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	>100 ° C	EN ISO 3679	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not Relevant	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	1.0-1.2 g/cm <sup>3</sup>	--	--
Relative vapour density:	Not available	--	--
Particle characteristics:			
Particle size:	Not available	--	--

### 9.2. Other information

No other relevant information



## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

#### SECTION 10: Stability and reactivity

**10.1. Reactivity**

Stable under normal conditions

**10.2. Chemical stability**

Stable under normal conditions

**10.3. Possibility of hazardous reactions**

None

**10.4. Conditions to avoid**

Stable under normal conditions.

**10.5. Incompatible materials**

None in particular.

**10.6. Hazardous decomposition products**

None.

#### SECTION 11: Toxicological information

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

Toxicological information of the product:

ELITE SOFT RELINING - CATALYST

a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

d) respiratory or skin sensitisation

Not classified

e) germ cell mutagenicity

Not classified

f) carcinogenicity

Not classified

g) reproductive toxicity

Not classified

h) STOT-single exposure

Not classified

i) STOT-repeated exposure

Not classified

j) aspiration hazard

Not classified

Toxicological information of the main substances found in the product:

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) acute toxicity:

Test: LC50 - Species: Rat 36 mg/l - Source: (OECD 403, GLP, rat, 4 h, ECHA dossier).

## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

Test: LD50 - Route: Skin - Species: Rat > 2000 mg/kg - Source: (similar to OECD 402, rat, ECHA dossier).

Test: LD50 - Route: Oral - Species: Rat 4800 mg/kg - Source: (similar to OECD 401, rat, ECHA dossier).

#### 11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

## SECTION 12: Ecological information

The product is not classified for chronic aquatic hazard: a test based on the bioavailability / release of D4 by the polymer silicone was performed with the OECD 29 method. It was found that the quantity of D4 released by 100mg of polymer is at least below the quantification limit of the method (i.e. 4.4 ppb), a value significantly lower than the limit that would result in the classification for chronic aquatic toxicity, i.e. NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for aquatic invertebrates. Therefore, the product is not classified for this hazard class..

#### 12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

ELITE SOFT RELINING - CATALYST

The product is classified: -

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

a) Aquatic acute toxicity:

Endpoint: IC50 - Species: Algae > 0.0022 mg/l - Duration h: 72h (EPA OTS 797.1050, Selenastrum capricornutum, freshwater, ECHA dossier).

Endpoint: LC50 - Species: Fish > 0.0022 mg/l (Oncorhynchus mykiss, GLP, ECHA dossier).

Endpoint: NOEC - Species: Fish > 0.0044 mg/l (publication, Oncorhynchus mykiss, GLP, ECHA dossier).

Long-term toxicity to aquatic invertebrates:

Endpoint: NOEC - Species: Daphnia = 7.9 µg/L - Duration h: 21d EPA OTS 797.1330, Daphnia magna, ECHA dossier

#### 12.2. Persistence and degradability

Not available

#### 12.3. Bioaccumulative potential

octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

Test: Kow - Partition coefficient 6.49 - Notes: (Log Pow, ECHA dossier).

#### 12.4. Mobility in soil

Not available

#### 12.5. Results of PBT and vPvB assessment

PBT Substances:

<0,1% octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

vPvB Substances:

<0,1% octamethylcyclotetrasiloxane; [D4] - CAS: 556-67-2

#### 12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

#### 12.7. Other adverse effects

None

## SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

## SECTION 14: Transport information

## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

**14.1. UN number or ID number**

Not classified as dangerous in the meaning of transport regulations.

**14.2. UN proper shipping name**

Not available

**14.3. Transport hazard class(es)**

Not available

**14.4. Packing group**

Not available

**14.5. Environmental hazards**

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

**14.6. Special precautions for user**

Not available

**14.7. Maritime transport in bulk according to IMO instruments**

Not Applicable

## SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) n. 2020/878

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Regulation (EU) n. 2016/918 (ATP 8 CLP)

Regulation (EU) n. 2016/1179 (ATP 9 CLP)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/669 (ATP 11 CLP)

Regulation (EU) n. 2018/1480 (ATP 13 CLP)

Regulation (EU) n. 2019/521 (ATP 12 CLP)

Regulation (EU) n. 2020/217 (ATP 14 CLP)

Regulation (EU) n. 2020/1182 (ATP 15 CLP)

Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

SVHC Substances:

Substances in candidate list (Art. 59 Reg. 1907/2006, REACH):

octamethylcyclotetrasiloxane; [D4]

PBT, vPvB

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)  
WGK1 - Slightly hazardous for water

Lagerklasse according to TRGS 510:  
LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:  
None.

California Proposition 65  
Substance(s) listed under California Proposition 65:  
None.

#### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture.  
Substances for which a Chemical Safety Assessment has been carried out:  
None

### SECTION 16: Other information

Full text of phrases referred to in Section 3:  
H226 Flammable liquid and vapour.  
H361f Suspected of damaging fertility.  
H410 Very toxic to aquatic life with long lasting effects.

Hazard class and hazard category	Code	Description
Flam. Liq. 3	2.6/3	Flammable liquid, Category 3
Repr. 2	3.7/2	Reproductive toxicity, Category 2
Aquatic Chronic 1	4.1/C1	Chronic (long term) aquatic hazard, category 1
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Aquatic Chronic	According to Article 12 of the CLP Regulation, "Where, as a result of the evaluation carried out pursuant to Article 9, the following properties or effects are identified, manufacturers, importers and downstream users shall take them into account for the purposes of classification: [...] (b) conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable." Following a release study of D4 through the OECD 29 test on polymeric products representative for quantity of D4, the limit that would result in the classification for chronic aquatic toxicity (NOEC of 0.0044 mg / L for fish and 0.0079 mg / L for invertebrates aquatic) is not reached.

This document was prepared by a competent person who has received appropriate training.

## Safety Data Sheet

### ELITE SOFT RELINING - CATALYST

#### Main bibliographic sources:

ECHA – European Chemical Agency  
GESTIS - Information system on hazardous substances of the German Social Accident Insurance  
IARC – International Agency for Research on Cancer  
IPCS INCHEM – International Programme on Chemical Safety  
ISS – Istituto Superiore di Sanità  
PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC. This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

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ATE:	Acute Toxicity Estimate
ATEmix:	Acute toxicity Estimate (Mixtures)
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.
LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.

**Safety Data Sheet  
ELITE RELINING PRIMER****Revision nr. 5  
Dated 08/11/2023****SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Mixture identification:

Product Name: ELITE RELINING PRIMER

Code: C700100, C700140

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

For professional use only. Primer for silicone implants.

Prohibited use: paint strippers (restriction no. 59, Annex XVII to Reg. 1907/2006/EC).

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

Name

Zhermack S.p.a

Via Bovazecchino 100

45021 Badia Polesine (RO)

Italy

tel. +39 0425-597611

fax +39 0425-597689

Competent person responsible for the safety data sheet:

msds@zhermack.com

**1.4. Emergency telephone number**

UK Emergency number: 999 (24 hours)

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture**

EC regulation criteria 1272/2008 (CLP)

Carc. 2, H351 Suspected of causing cancer.

Adverse physicochemical, human health and environmental effects:

No other hazards

**2.2. Label elements**

The Regulation EC 1272/2008, on classification, labelling and packaging of substances and mixtures (CLP), shall not apply to a medical device in the finished state used in direct physical contact with the human body according to art. 1.5, letter d). Therefore the product is exempted from the CLP labeling requirements.

Hazard pictograms:



Warning

Hazard statements:

H351 Suspected of causing cancer.

Precautionary statements:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

## Safety Data Sheet

### ELITE RELINING PRIMER

P501 Dispose of contents/container in accordance with applicable regulations.

Special Provisions:

None

Contains

dichloromethane; methylene chloride

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

#### 2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration  $\geq 0.1\%$

Other Hazards:

No other hazards

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not Applicable

#### 3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

Qty	Name	Ident. Number	Classification
$\geq 80\%$ - $< 90\%$	dichloromethane; methylene chloride	Index 602-004-00-3 number: CAS: 75-09-2 EC: 200-838-9	Carc. 2 H351 Suspected of causing cancer.

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

In case of skin contact:

Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.

Wash with plenty of water and soap.

Wash thoroughly the body (shower or bath).

Remove contaminated clothing immediately and dispose off safely.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

None

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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

Treatment:

None

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media:

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Water.

Carbon dioxide (CO<sub>2</sub>).

Extinguishing media which must not be used for safety reasons:

None in particular.

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

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

#### 5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

### SECTION 6: Accidental release measures

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

For non emergency personnel:

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

For emergency responders:

Wear personal protection equipment.

#### 6.2. Environmental precautions

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

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

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

Wash with plenty of water.

#### 6.4. Reference to other sections

See also section 8 and 13

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Exercise the greatest care when handling or opening the container.

Don't use empty container before they have been cleaned.

Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.

See also section 8 for recommended protective equipment.

Advice on general occupational hygiene:

Contaminated clothing should be changed before entering eating areas.

Do not eat or drink while working.

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

Keep away from food, drink and feed.

Incompatible materials:

See section 10.5.

Instructions as regards storage premises:

Adequately ventilated premises.

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

See section 1.2.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

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dichloromethane; methylene chloride - CAS: 75-09-2

OEL Type	TWA		Duration	STEL		Duration	Notes	Country
AGW	180 mg/m <sup>3</sup>	50 ppm	8h	360 mg/m <sup>3</sup>	100 ppm	15min		GERMANY
MAK	180 mg/m <sup>3</sup>	50 ppm	8h	353 mg/m <sup>3</sup>	100 ppm	15min		SWITZERLAND
AK	10 mg/m <sup>3</sup>		8h	10 mg/m <sup>3</sup>				HUNGARY
HTP	177 mg/m <sup>3</sup>	50 ppm	8h	353 mg/m <sup>3</sup>	100 ppm	15min		FINLAND
MAK	175 mg/m <sup>3</sup>	50 ppm	8h	700 mg/m <sup>3</sup>	200 ppm	15min		AUSTRIA
NDS/NDSch	88 mg/m <sup>3</sup>		8h					POLAND
EU	353 mg/m <sup>3</sup>	100 ppm	8h	706 mg/m <sup>3</sup>	200 ppm		Skin	
OELV	174 mg/m <sup>3</sup>	50 ppm	8h	550 mg/m <sup>3</sup>	150 ppm	15min		IRELAND
RV	120 mg/m <sup>3</sup>	34 ppm	8h	150 mg/m <sup>3</sup>	42 ppm	15min		LATVIA
TLV	122 mg/m <sup>3</sup>	35 ppm	8h	244 mg/m <sup>3</sup>	70 ppm	15min		DENMARK
VLEP	178 mg/m <sup>3</sup>	50 ppm	8h	356 mg/m <sup>3</sup>	100 ppm	15min		FRANCE
VLEP	177 mg/m <sup>3</sup>	50 ppm	8h	706 mg/m <sup>3</sup>	200 ppm	15min	Skin	BELGIUM
WEL	353 mg/m <sup>3</sup>	100 ppm	8h	706 mg/m <sup>3</sup>	200 ppm	15min		UNITED KINGDOM
TLV-ACGIH		50 ppm	8h				A3, BEI - COHb-emia, CNS impair	
TLV	353 mg/m <sup>3</sup>	100 ppm	8h	706 mg/m <sup>3</sup>	200 ppm	15min		ROMANIA
TLV	177 mg/m <sup>3</sup>	50 ppm	8h					SPAIN
TLV	120 mg/m <sup>3</sup>	35 ppm	8h	250 mg/m <sup>3</sup>	70 ppm	15min		SWEDEN
ACGIH		50 ppm	8h				A3, BEI - COHb-emia, CNS impair	

DNEL Exposure Limit Values

Not available

PNEC Exposure Limit Values

Not available

#### 8.2. Exposure controls

Precautionary measures:

Give adequate ventilation to the premises where the product is stored and/or handled.

Eye protection:

Wear airtight protective goggles (EN 166).

Protection for skin:

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Wear professional overalls and safety footwear (EN 14605).

Protection for hands:

Protect hands with work gloves (EN 374).

The following should be considered when choosing work glove material (EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

Respiratory protection:

Use respiratory protection where ventilation is insufficient or exposure is prolonged.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered (e.g. TLV-TWA).

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

## SECTION 9: Physical and chemical properties

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

Properties	Value	Method:	Notes
Physical state:	Liquid	--	--
Colour:	Light yellow	--	--
Odour:	Characteristic	--	--
Melting point/freezing point:	Not available	--	--
Boiling point or initial boiling point and boiling range:	Not available	--	--
Flammability:	Not available	--	--
Lower and upper explosion limit:	Not available	--	--
Flash point:	Not available	--	--
Auto-ignition temperature:	Not available	--	--
Decomposition temperature:	Not available	--	--
pH:	Not available	--	--
Kinematic viscosity:	Not available	--	--
Solubility in water:	Insoluble	--	--
Solubility in oil:	Not available	--	--
Partition coefficient n-octanol/water (log value):	Not available	--	--
Vapour pressure:	Not available	--	--
Density and/or relative density:	Not available	--	--
Relative vapour density:	Not available	--	--

Particle characteristics:

Particle size:	Not available	--	--
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### 9.2. Other information

No other relevant information

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#### SECTION 10: Stability and reactivity

##### 10.1. Reactivity

Stable under normal conditions

##### 10.2. Chemical stability

Stable under normal conditions

##### 10.3. Possibility of hazardous reactions

None

##### 10.4. Conditions to avoid

Stable under normal conditions.

##### 10.5. Incompatible materials

None in particular.

##### 10.6. Hazardous decomposition products

None.

#### SECTION 11: Toxicological information

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

Toxicological information of the product:

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a) acute toxicity

Not classified

b) skin corrosion/irritation

Not classified

c) serious eye damage/irritation

Not classified

d) respiratory or skin sensitisation

Not classified

e) germ cell mutagenicity

Not classified

f) carcinogenicity

The product is classified: Carc. 2 H351

g) reproductive toxicity

Not classified

h) STOT-single exposure

Not classified

i) STOT-repeated exposure

Not classified

j) aspiration hazard

Not classified

Toxicological information of the main substances found in the product:

dichloromethane; methylene chloride - CAS: 75-09-2

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat 1600 mg/kg - Source: (MSDS supplier).

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f) carcinogenicity:

Route: Inhalation Vapour - Species: Mouse - Notes: liver; lung - Positive - Source: (OECD 451, ECHA dossier).

#### 11.2. Information on other hazards

Endocrine disrupting properties:

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

## SECTION 12: Ecological information

#### 12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

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Not classified for environmental hazards

Based on available data, the classification criteria are not met  
dichloromethane; methylene chloride - CAS: 75-09-2

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia 27 mg/l - Duration h: 48h (Daphnia magna, ECHA dossier).

Endpoint: LC50 - Species: Fish 97 mg/l - Duration h: 96h (Pimephales promelas, ECHA dossier).

#### 12.2. Persistence and degradability

Not available

#### 12.3. Bioaccumulative potential

Not available

#### 12.4. Mobility in soil

Not available

#### 12.5. Results of PBT and vPvB assessment

vPvB Substances: None - PBT Substances: None

#### 12.6. Endocrine disrupting properties

No endocrine disruptor substances present in concentration  $\geq 0.1\%$

#### 12.7. Other adverse effects

None

## SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

## SECTION 14: Transport information

#### 14.1. UN number or ID number

Not classified as dangerous in the meaning of transport regulations.

#### 14.2. UN proper shipping name

Not available

#### 14.3. Transport hazard class(es)

Not available

#### 14.4. Packing group

Not available

#### 14.5. Environmental hazards

ADR-Environmental Pollutant: No

IMDG-Marine pollutant: No

#### 14.6. Special precautions for user

Not available

#### 14.7. Maritime transport in bulk according to IMO instruments

Not Applicable

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#### SECTION 15: Regulatory information

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

Dir. 98/24/EC (Risks related to chemical agents at work)  
Dir. 2000/39/EC (Occupational exposure limit values)  
Regulation (EC) n. 1907/2006 (REACH)  
Regulation (EC) n. 1272/2008 (CLP)  
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013  
Regulation (EU) n. 2020/878  
Regulation (EU) n. 286/2011 (ATP 2 CLP)  
Regulation (EU) n. 618/2012 (ATP 3 CLP)  
Regulation (EU) n. 487/2013 (ATP 4 CLP)  
Regulation (EU) n. 944/2013 (ATP 5 CLP)  
Regulation (EU) n. 605/2014 (ATP 6 CLP)  
Regulation (EU) n. 2015/1221 (ATP 7 CLP)  
Regulation (EU) n. 2016/918 (ATP 8 CLP)  
Regulation (EU) n. 2016/1179 (ATP 9 CLP)  
Regulation (EU) n. 2017/776 (ATP 10 CLP)  
Regulation (EU) n. 2018/669 (ATP 11 CLP)  
Regulation (EU) n. 2018/1480 (ATP 13 CLP)  
Regulation (EU) n. 2019/521 (ATP 12 CLP)  
Regulation (EU) n. 2020/217 (ATP 14 CLP)  
Regulation (EU) n. 2020/1182 (ATP 15 CLP)  
Regulation (EU) n. 2021/643 (ATP 16 CLP)

Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

Restriction 3

Restrictions related to the substances contained:

Restriction 59

Restriction 75

Provisions related to directive EU 2012/18 (Seveso III):

Seveso III category according to Annex 1, part 1

None

WGK Classification (Water hazard class - Verwaltungsvorschrift wassergefährdende Stoffe)

Lagerklasse according to TRGS 510:

LGK 10: Combustible liquids

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

California Proposition 65

Substance(s) listed under California Proposition 65:

None.

##### 15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

None

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Hazard class and hazard category	Code	Description
Carc. 2	3.6/2	Carcinogenicity, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Classification according to Regulation (EC) Nr. 1272/2008	Classification procedure
Carc. 2, H351	Calculation method

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECHA – European Chemical Agency  
GESTIS - Information system on hazardous substances of the German Social Accident Insurance  
IARC – International Agency for Research on Cancer  
IPCS INCHEM – International Programme on Chemical Safety  
ISS – Istituto Superiore di Sanità  
PubChem - open chemistry database at the National Institutes of Health (NIH)

A safety data sheet is not required for this product under article 31 of Regulation 1907/2006/EC.  
This safety data sheet has been created on a voluntary basis.

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.  
ATE: Acute Toxicity Estimate  
ATEmix: Acute toxicity Estimate (Mixtures)  
CAS: Chemical Abstracts Service (division of the American Chemical Society).  
CLP: Classification, Labeling, Packaging.  
DNEL: Derived No Effect Level.  
EINECS: European Inventory of Existing Commercial Chemical Substances.  
GefStoffVO: Ordinance on Hazardous Substances, Germany.  
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.  
IATA: International Air Transport Association.  
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).  
ICAO: International Civil Aviation Organization.  
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO).  
IMDG: International Maritime Code for Dangerous Goods.  
INCI: International Nomenclature of Cosmetic Ingredients.  
KSt: Explosion coefficient.  
LC50: Lethal concentration, for 50 percent of test population.  
LD50: Lethal dose, for 50 percent of test population.

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PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.