

**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:

Safety Data Sheet

ELITE RELINING PRIMER

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

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

ELITE RELINING PRIMER

Safety Data Sheet

ELITE RELINING PRIMER

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

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

Safety Data Sheet

ELITE RELINING PRIMER

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

Safety Data Sheet

ELITE RELINING PRIMER

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 RELINING PRIMER

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).

Safety Data Sheet

ELITE RELINING PRIMER

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.

ELITE RELINING PRIMER

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

Safety Data Sheet

ELITE RELINING PRIMER

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

Safety Data Sheet
ELITE RELINING PRIMER**SECTION 16: Other information**

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.

Safety Data Sheet
ELITE RELINING PRIMER

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.