**Safety Data Sheet**
**ZETALABOR**
Version: 5. Revision date: 17/07/2026
Previous version: 4. Previous version date: 26/04/2023

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

### 1.1. Product identifier

Mixture identification:

Product Name: ZETALABOR

Code: C400790, C400791, C400798, C400804, C400811, C400812

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

Recommended use: For professional use only. Condensation silicone for the dental lab.

Uses advised against: All uses except those identified.

### 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
Responsable: N/A

### 1.4. Emergency telephone number

UK Emergency number: 999 (24 hours)
+39 0425 597611 (office hours)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

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

**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 >= 0.1%.

Other Hazards: No other hazards

There is no exposure to breathable free crystalline silica during normal use of this product. For more information see section 11.

The product is not classified for chronic aquatic toxicity, for more details see section 12.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

N.A.

### 3.2. Mixtures

Mixture identification: ZETALABOR

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

| Qty | Name | Ident. Numb. | Classification | Registration Number | Material Properties |
|---|---|---|---|---|---|
| 1-2.5 % | Cristobalite | CAS:14464-46-1<br>EC:238-455-4 | STOT RE 1, H372 | | |
| < 0.1% | octamethylcyclotetrasiloxane; [D4] | CAS:556-67-2<br>EC:209-136-7<br>Index:014-018-00-1 | Flam. Liq. 3, H226; Repr. 2, H361; Aquatic Chronic 1, H410, M-Chronic:10 | | PBT, vPvB |

## 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:

Wash immediately with water.

In case of Ingestion:

Do not induce vomiting, get medical attention showing the SDS and label hazardous.

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

N.A.

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

N.A.

## 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

### 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**

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

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, inhaltion 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**

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

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

None in particular

Industrial sector specific solutions:

None in particular

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters**

**Community Occupational Exposure Limits (OEL)**

Cristobalite

| | | |
|---|---|---|
| CAS: 14464-46-1 | ACGIH | Long Term: 0.025 mg/m3<br>Notes: (R), A2 - Pulm fibrosis, lung cancer |
| | | Long Term: 0.025 mg/m3<br>Notes: (R), A2 - Pulm fibrosis, lung cancer |
| | EU | Long Term: 0.1 mg/m3<br>Notes: Respirable |
| | TLV | Long Term: 0.1 mg/m3<br>Notes: Respirable |

octamethylcyclotetrasiloxane; [D4]

| | | |
|---|---|---|
| CAS: 556-67-2 | TWA | Long Term: 120 mg/m3 - 10 ppm |

**8.2. Exposure controls**

Eye protection:

No specific requirements during normal conditions of use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

Not needed for normal use.

Respiratory protection:

N.A.

Thermal Hazards:

N.A.

Environmental exposure controls:

N.A.

Hygienic and Technical measures

N.A.

Appropriate engineering controls:

N.A.

## SECTION 9: Physical and chemical properties

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

Physical state: Solid

| | |
|---|---|
| Colour: | grey |
| Appearance: | Viscous fluid |
| Odour: | odourless |
| pH: | N.A. |
| Kinematic viscosity: | N.A. |
| Melting point/freezing point: | N.A. |
| Boiling point or initial boiling point and boiling range: | N.A. |
| Flash point: | N.A. |
| Lower and upper explosion limit: | N.A. |
| Relative vapour density: | N.A. |
| Vapour pressure: | N.A. |
| Density and/or relative density: | N.A. |
| Solubility in water: | Insoluble |
| Solubility in oil: | N.A. |
| Partition coefficient n-octanol/water (log value): | N.A. |
| Auto-ignition temperature: | N.A. |
| Decomposition temperature: | N.A. |
| Flammability: | N.A. |
| Volatile Organic compounds - VOCs = | N.A. |
| **Particle characteristics:** | |
| Particle size: | N.A. |

**9.2. Other information**

No other relevant information

## SECTION 10: Stability and reactivity

**10.1. Reactivity**

Stable under normal conditions

**10.2. Chemical stability**

Data not available.

**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

'For the purpose of the classification of health hazards (Part 3), route of exposure, information on mechanisms and metabolism studies are useful in determining the significance of an effect on humans. If such information raises doubts as to its relevance to humans, no matter how well-founded and high-quality the data are, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant for humans, the substance or mixture shall not be classified' (Annex I, Section 1.1.1.5, Regulation EC 1272/2008). Monitoring of possible inhalation exposure conducted in-house according to industrial hygiene regulations for paste and fluid products revealed dust exposure levels below the quantification limit of the method, therefore exposure is not expected during the use indicated in section 1.2 for this specific product. However, the actual levels of dust present in the workplace must be obtained by monitoring as required by worker health and safety regulations.

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

**Toxicological Information of the Preparation**

| | |
|---|---|
| a) acute toxicity | Not classified |
| | Based on available data, the classification criteria are not met |
| b) skin corrosion/irritation | Not classified |
| | Based on available data, the classification criteria are not met |
| c) serious eye damage/irritation | Not classified |
| | Based on available data, the classification criteria are not met |
| d) respiratory or skin sensitisation | Not classified |
| | Based on available data, the classification criteria are not met |
| e) germ cell mutagenicity | Not classified |
| | Based on available data, the classification criteria are not met |
| f) carcinogenicity | Not classified |
| | Based on available data, the classification criteria are not met |
| g) reproductive toxicity | Not classified |
| | Based on available data, the classification criteria are not met |
| h) STOT-single exposure | Not classified |
| | Based on available data, the classification criteria are not met |
| i) STOT-repeated exposure | Not classified |
| | Based on available data, the classification criteria are not met |
| j) aspiration hazard | Not classified |
| | Based on available data, the classification criteria are not met |

**Toxicological information on main components of the mixture:**

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 g) reproductive toxicity No Observed Adverse Effect Level 3.64 mg/l

**11.2. Information on other hazards**

**Endocrine disrupting properties:**

No endocrine disruptor substances present in concentration >= 0.1%

## SECTION 12: Ecological information

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.

**12.1. Toxicity**

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

Eco-Toxicological Information:

**List of Eco-Toxicological properties of the product**

Not classified for environmental hazards.

No data available for the product

**List of Eco-Toxicological properties of the components**

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 a) Aquatic acute toxicity: Algae > 0.0022 mg/L 96h

a) Aquatic acute toxicity: ErC10 Algae > 0.0022 mg/L 96h

a) Aquatic acute toxicity: EC50 Fish > 10000 mg/L 3h

a) Aquatic acute toxicity: EC50 Daphnia > 0.015 mg/L 48h

b) Aquatic chronic toxicity: NOEC Fish > 0.0044 mg/L 93d

b) Aquatic chronic toxicity: NOEC Daphnia > 0.015 mg/L 21d

**12.2. Persistence and degradability**

Cristobalite

CAS: 14464-46-1 Non-readily biodegradable

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 Non-readily biodegradable Notes: MSDS supplier

**12.3. Bioaccumulative potential**

Cristobalite

CAS: 14464-46-1 Not bioaccumulative

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 Not bioaccumulative Test: BCF - Bioconcentrantion factor; Value: 14900
Notes: (Log Pow, ECHA dossier).

**12.4. Mobility in soil**

N.A.

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

**List of Eco-Toxicological properties of the components**

octamethylcyclotetrasiloxane; [D4]

CAS: 556-67-2 < 0.1% PBT - vPvB

**12.6 Endocrine disrupting properties**

No endocrine disruptor substances present in concentration >= 0.1%

**12.7 Other adverse effects**

N.A.

## 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

Not classified as dangerous in the meaning of transport regulations.

**14.1. UN number or ID number**

N.A.

**14.2. UN proper shipping name**

N.A.

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

ADR-Class: NA

IATA-Class: NA

IMDG-Class: NA

**14.4. Packing group**

N.A.

**14.5. Environmental hazards**

N.A.

**14.6. Special precautions for user**

N.A.

Road and Rail (ADR-RID):

N.A.

Air (IATA):

N.A.

Sea (IMDG):

N.A.

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

N.A.

## 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 (EU) n. 2020/878

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

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

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)
Regulation (EU) n. 2021/849 (ATP 17 CLP)
Regulation (EU) n. 2022/692 (ATP 18 CLP)
Regulation (EU) n. 2023/707
Regulation (EU) n. 2023/1434 (ATP 19 CLP)
Regulation (EU) n. 2023/1435 (ATP 20 CLP)
Regulation (EU) n. 2024/197 (ATP 21 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: None.

Restrictions related to the substances contained: 40, 70, 75

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

None

Regulation (EU) No 649/2012 (PIC regulation)

No substances listed

SVHC Substances:

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

| Component | Ident. Numb. | Quantity | Material Properties |
|---|---|---|---|
| octamethylcyclotetrasiloxane; [D4] | CAS: 556-67-2<br>EINECS: 209-136-7<br>Index: 014-018-00-1 | < 0.1% | SVHC - PBT - vPvB |

### 15.2. Chemical safety assessment

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

## SECTION 16: Other information

| Code | Description |
|---|---|
| H226 | Flammable liquid and vapour. |
| H361 | Suspected of damaging fertility or the unborn child. |
| H372 | Causes damage to organs (lungs) through prolonged or repeated exposure if inhaled. |
| H410 | Very toxic to aquatic life with long lasting effects. |

| Code | Hazard class and hazard category | Description |
|---|---|---|
| 2.6/3 | Flam. Liq. 3 | Flammable liquid, Category 3 |
| 3.7/2 | Repr. 2 | Reproductive toxicity, Category 2 |
| 3.9/1 | STOT RE 1 | Specific target organ toxicity — repeated exposure, Category 1 |
| 4.1/C1 | Aquatic Chronic 1 | Chronic (long term) aquatic hazard, category 1 |

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

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

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.

Legend to abbreviations and acronyms used in the safety data sheet:

ACGIH: American Conference of Governmental Industrial Hygienists

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

AND: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ATE: Acute Toxicity Estimate

ATEmix: Acute toxicity Estimate (Mixtures)

BCF: Biological Concentration Factor

BEI: Biological Exposure Index

BOD: Biochemical Oxygen Demand

CAS: Chemical Abstracts Service (division of the American Chemical Society).

CAV: Poison Center

CE: European Community
CLP: Classification, Labeling, Packaging.
CMR: Carcinogenic, Mutagenic and Reprotoxic
COD: Chemical Oxygen Demand
COV: Volatile Organic Compound
CSA: Chemical Safety Assessment
CSR: Chemical Safety Report
DMEL: Derived Minimal Effect Level
DNEL: Derived No Effect Level.
DPD: Dangerous Preparations Directive
DSD: Dangerous Substances Directive
EC50: Half Maximal Effective Concentration
ECHA: European Chemicals Agency
EINECS: European Inventory of Existing Commercial Chemical Substances.
ES: Exposure Scenario
GefStoffVO: Ordinance on Hazardous Substances, Germany.
GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
IARC: International Agency for Research on Cancer
IATA: International Air Transport Association.
IATA-DGR: Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
IC50: half maximal inhibitory concentration
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.
IRCCS: Scientific Institute for Research, Hospitalization and Health Care
KAFH: Keep Away From Heat
KSt: Explosion coefficient.
LC50: Lethal concentration, for 50 percent of test population.
LD50: Lethal dose, for 50 percent of test population.
LDLo: Leathal Dose Low
N.A.: Not Applicable
N/A: Not Applicable
N/D: Not defined/ Not available
NA: Not available
NIOSH: National Institute for Occupational Safety and Health
NOAEL: No Observed Adverse Effect Level
OSHA: Occupational Safety and Health Administration
PBT: Persistent, Bioaccumulative and Toxic
PGK: Packaging Instruction
PNEC: Predicted No Effect Concentration.
PSG: Passengers
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.
TWATLV: Threshold Limit Value for the Time Weighted Average 8 hour day. (ACGIH Standard).
vPvB: Very Persistent, Very Bioaccumulative.
WGK: German Water Hazard Class.

**Paragraphs modified from the previous revision:**

- SECTION 9: Physical and chemical properties