

**Product Name: egger flex S-Pro**

REF: 36985, 36986, 36990, 36991, 36994

Date of print: 15.01.2025

Date of last alteration: 15.01.2025

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

egger flex S-Pro (base + catalyst)

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

Silicone material for use in audiology.

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

Manufacturer/distributor: egger Otoplastik + Labortechnik GmbH  
Street/POB-No.: Aybühlweg 59  
Postal code/city/country: 87439 Kempten/Germany  
Telephone: +49 831 58113-60  
Telefax: +49 831 58113-14  
Internet: www.eggeronline.com  
E-mail: sales@eggeronline.com

**1.4. Emergency telephone number: +49 89 19240**

Emergency number: Munich, Germany, (toxicological dep. of the II. Med. Hospital)

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No. 1272/2008.

**2.2. Label elements****Regulation (EC) No. 1272/2008****Special labelling of certain mixtures**

EUH210 Safety data sheet available on request.

**Additional advice on labelling**

According to Regulation (EC) 1272/2008, art.1 No. 5 (d) this product as a medical product must not be labelled!

**2.3. Other hazards**

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:

Dodecamethylcyclhexasiloxane.

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Dodecamethylcyclhexasiloxane.

No information available.

**SECTION 3: Composition/information on ingredients****3.2. Mixtures****Chemical characterization**

Contains polydimethylsiloxane with functional groups + fillers and pigment.

Catalyst: additionally platinum complex compound.


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**Hazardous components**

| CAS No            | Chemical name   |          |                  | Quantity             |
|-------------------|---|----------|------------------|----------------------|
|                   | EG No   | Index No | REACH No         |                      |
|                   | Classification according to Regulation (EC) No. 1272/2008 [CLP] |          |                  |                      |
| <b>14464-46-1</b> | <b>crystalite flour</b>   |          |                  | <b>5 - &lt; 20 %</b> |
|                   | 238-455-4   |          |                  |                      |
|                   | STOT RE 1; H372   |          |                  |                      |
| <b>8042-47-5</b>  | <b>paraffin oil</b>   |          |                  | <b>5 - &lt; 20 %</b> |
|                   | 232-455-8   |          | 01-2119487078-27 |                      |
|                   | Asp. Tox. 1; H304   |          |                  |                      |
| <b>540-97-6</b>   | <b>Dodecaemthylcyclohexasiloxane</b>                            |          |                  | <b>0.1 &lt; 5 %</b>  |
|                   | 208-762-8   |          | 01-2119517435-42 |                      |

Full text of R-, H- and EUH-phrases: see section 16.

**Specific Conc. Limits, M-factors and ATE**

| CAS No           | EC No   | Chemical name                        | Quantity              |
|------------------|---|--------------------------------------|-----------------------|
|                  | Specific Conc. Limits, M-factors and ATE  |                                      |                       |
| <b>8042-47-5</b> | <b>232-455-8</b>  | <b>paraffin oil</b>                  | <b>5 - &lt; 20 %</b>  |
|                  | inhalation: LC50 = > 5 mg/l (vapours);<br>dermal: LD50 = >2000 mg/kg; oral: = >5000 mg/kg |                                      |                       |
| <b>540-97-6</b>  | <b>208-762-8</b>  | <b>Dodecamethylcyclohexasiloxane</b> | <b>0.1 - &lt; 5 %</b> |
|                  | dermal: LD50 = 2000 mg/kg; oral: LD50 = 2000 mg/kg  |                                      |                       |

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### General information

First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.

#### After inhalation

Provide fresh air.

#### After contact with skin

Remove product mechanically with cloth or paper. Wash with plenty of water and soap. In case of visible changes on the skin or complaints, seek medical advice (if possible have label or safety data sheet with you).

#### After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water.

#### After ingestion

Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips ( dilution effect).

Do not induce vomiting. If you feel unwell, seek medical advice.

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

No information available.

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

Treat symptomatically.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

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

Non-flammable. Vapours can form explosive mixtures with air.

**5.3. Advice for firefighters**

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

**Additional information**

Use water spray jet to protect personnel and to cool endangered containers. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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

Use personal protection equipment.

**6.2. Environmental precautions**

Do not allow to enter into surface water or drains.

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

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Treat the recovered material as prescribed in the section on waste disposal.

**6.4. Reference to other sections**

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

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

No special measures are necessary.

**Advice on protection against fire and explosion**

No special fire protection measures are necessary.

**Advice on general occupational hygiene**

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat or drink.



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

#### Requirements for storage rooms and vessels

Keep container tightly closed.

#### Hints on joint storage

Do not store with acids, lyes, alcohols, metallic powders and metallic oxides (release of hydrogen is favoured).

#### Further information on storage conditions

Keep only in the original container in a cool, dry and well-ventilated place, away from foodstuffs.

### 7.3. Specific end use(s)

Silicone material for use in audiology.

For use by trained specialist staff.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

### 8.2. Exposure controls

#### Individual protection measures, such as personal protective equipment

##### Eye/face protection

Wear eye/face protection.

##### Hand protection

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Suitable are gloves of the following material: NBR (Nitrile rubber).

##### Skin protection

Wear suitable protective clothing.

##### Respiratory protection

In case of inadequate ventilation wear respiratory protection.

## SECTION 9: Physical and chemical properties

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

Physical state: Paste

Colour: base: several, catalyst: white

Odour: characteristic

|   |                                  | Test method |
|---|----------------------------------|-------------|
| Melting point/freezing point:                             | not determined                   |             |
| Boiling point or initial boiling point and boiling range: | not determined                   |             |
| Flammability:   | not applicable<br>not applicable |             |


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|  |  |           |
|--|--|-----------|
| Lower explosion limits:                | not determined   |           |
| Upper explosion limits:                | not determined   |           |
| Flash point:                           | >100 °C  | DIN 51755 |
| Auto-ignition temperature:             | >400 °C  | DIN 51794 |
| Decomposition temperature:             | >180 °C  |           |
| pH-Value:                              | not determined   |           |
| Water solubility:                      | The study does not need to be conducted because the substance is known to be insoluble in water. |           |
| Solubility in other solvents           | not determined   |           |
| Partition coefficient n-octanol/water: | not determined   |           |
| Vapour pressure: (at 20 °C)            | <10 hPa  |           |
| Density (at 20 °C):                    | 0,97 g/cm <sup>3</sup>   | DIN 51757 |
| Relative vapour density:               | not determined   |           |

**9.2. Other information**
**Information with regard to physical hazard classes**

Self-ignition temperature

Solid: not applicable

Gas: not applicable

Oxidizing properties

Not oxidizing.

**Other safety characteristics**

Evaporation rate: not determined

Solid content: not determined

Viscosity / dynamic: 800000 mPa·s  
(at 23 °C)

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

No hazardous reaction when handled and stored according to provisions.

**10.2. Chemical stability**

The product is stable under storage at normal ambient temperatures.

**10.3. Possibility of hazardous reactions**

Reacts with: Acids, alkalis, alcohols, powdered metals or metal oxides with release of hydrogen.

**10.4. Conditions to avoid**

Temperatures &gt; 150 °C/ 302 °F.

**10.5. Incompatible materials**

No information available.



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### 10.6. Hazardous decomposition products

In case of thermic decomposition hydrogen is released. At a temperature of approx. 150 °C / 302 °F a small amount of formaldehyde can be released by oxidative degradation.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EG) Nr. 1272/2008

#### Acute toxicity

Based on available data, the classification criteria are not met.

For the product itself no toxicological data are available. In products with a comparable composition, a LD50 (orally, species rat) of > 5000 mg/kg has been found.

#### ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l;

ATE (inhalation dust/mist) > 5 mg/l

| CAS No           | Chemical name                        |                  |         |        |        |
|------------------|--------------------------------------|------------------|---------|--------|--------|
|                  | Exposure route                       | Dose             | Species | Source | Method |
| <b>8042-47-5</b> | <b>paraffin oil</b>                  |                  |         |        |        |
|                  | oral                                 | LD50 >5000 mg/kg | Rat     | OECD   |        |
|                  | dermal                               | LD50 >2000 mg/kg | Rabbit  | OECD   |        |
|                  | inhalation (4 h) vapour              | LC50 >5 mg/l     | Rat     | OECD   |        |
| <b>540-97-6</b>  | <b>Dodecaemthylcyclohexasiloxane</b> |                  |         |        |        |
|                  | oral                                 | LD50 2000 mg/kg  | Rat     |        |        |
|                  | dermal                               | LD50 2000 mg/kg  | Rat     |        |        |

#### Irritation and corrosivity

Based on available data, the classification criteria are not met.

#### Sensitising effects

Based on available data, the classification criteria are not met.

#### Carcinogenic/mutagenic/toxic effects for reproduction

Based on available data, the classification criteria are not met.

#### STOT-single exposure

Based on available data, the classification criteria are not met.

Due to physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible.

EC regulation 1272/2008 annex 1, section 1.1.1.5: „For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans.

If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified.“

#### STOT-repeated exposure

Based on available data, the classification criteria are not met.

#### Aspiration hazard

Based on available data, the classification criteria are not met.

#### Additional information on tests

This mixture is classified as not hazardous according to regulation (EC) 1272/2008 [CLP].



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## SECTION 12: Ecological information

### 12.1. Toxicity

The product is not: Ecotoxic.

| CAS No           | Chemical name            |      |            |         |                                 |        |
|------------------|--------------------------|------|------------|---------|---------------------------------|--------|
|                  | Aquatic toxicity         | Dose | [h]   [d]  | Species | Source                          | Method |
| <b>8042-47-5</b> | <b>paraffin oil</b>      |      |            |         |                                 |        |
|                  | Acute fish toxicity      | LC50 | >1000 mg/l | 96 h    | Leuciscus idus (golden orfe)    | OECD   |
|                  | Acute algae toxicity     | ErC5 | >100 mg/l  | 72 h    | Pseudokirchneriella subcapitata | OECD   |
|                  | Acute crustacea toxicity | EC50 | >100 mg/l  | 48 h    | Daphnia magna (Big water flea)  |        |

### 12.2. Persistence and degradability

The product has not been tested.

| CAS No           | Chemical name   |       |    |        |
|------------------|---|-------|----|--------|
|                  | Method  | Value | d  | Source |
|                  | Evaluation  |       |    |        |
| <b>8042-47-5</b> | <b>paraffin oil</b>                                     |       |    |        |
|                  | OECD 301F/ ISO 9408/ EEC 92/69/V, C.4-D                 | 31 %  | 28 |        |
|                  | Not readily biodegradable (according to OECD criteria). |       |    |        |

### 12.3. Bioaccumulative potential

The product has not been tested.

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

The mixture contains the following substances fulfilling the PBT criteria according to UK REACH:

Dodecamethylcyclohexasiloxane.

The mixture contains the following substances fulfilling the vPvB criteria according to UK REACH:

Dodecamethylcyclohexasiloxane.

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

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

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

**12.6. Endocrine disrupting properties**

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

**12.7. Other adverse effects**

No information available.

**Further information**

Avoid release to the environment.

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Advice on disposal**

Do not allow to enter into surface water or drains. Dispose of waste according to applicable legislation.

**Contaminated packaging**

Wash with plenty of water. Completely emptied packages can be recycled.

**SECTION 14: Transport information****Land transport (ADR/RID)**

- 14.1. UN number:** No dangerous good in sense of this transport regulation.  
**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.  
**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.  
**14.4. Packing group:** No dangerous good in sense of this transport regulation.

**Inland waterways transport (ADN)**

- 14.1. UN number:** No dangerous good in sense of this transport regulation.  
**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.  
**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.  
**14.4. Packing group:** No dangerous good in sense of this transport regulation.

**Marine transport (IMDG)**

- 14.1. UN number:** No dangerous good in sense of this transport regulation.  
**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.  
**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.  
**14.4. Packing group:** No dangerous good in sense of this transport regulation.

**Air transport (ICAO-TI/IATA-DGR)**

- 14.1. UN number:** No dangerous good in sense of this transport regulation.  
**14.2. UN proper shipping name:** No dangerous good in sense of this transport regulation.  
**14.3. Transport hazard class(es):** No dangerous good in sense of this transport regulation.  
**14.4. Packing group:** No dangerous good in sense of this transport regulation.

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**egger****14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

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

No dangerous good in sense of this transport regulation.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****EU regulatory information**

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

Dodecamethylcyclohexasiloxane

Restrictions on use (REACH, annex XVII):

Entry 75

**Additional information**

The mixture contains substances of very high concern (SVHC candidates):

Dodecamethylcyclohexasiloxane (D6), CAS no. 540-97-6

Decamethylcyclopentasiloxane (D5), CAS no. 541-02-6

Octamethylcyclotetrasiloxane (D4), CAS no. 556-67-2

**National regulatory information**

Water contaminating class (D): 1 - slightly hazardous to water

**15.2. Chemical safety assessment**

Chemical safety assessments for substances in this mixture were not carried out.

**SECTION 16: Other information****Abbreviations and acronyms**ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service

LC50: Lethal concentration, 50 %

LD50: Lethal dose, 50 %

Asp. Tox: Aspiration hazard

STOT RE: Specific target organ toxicity - repeated exposure

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

H304 May be fatal if swallowed and enters airways.

H372 Causes damage to organs (lung) through prolonged or repeated exposure if inhaled.

EUH210 Safety data sheet available on request.



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**Further Information**

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)