



# Product Name: Hardener for egger C/I.2 and C/II

REF: 22100

Date of print: 25.04.2023 Date of last alteration: 25.04.2023

  
**egger**

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

### 1.1. Product identifier

Hardener for egger C/I.2 and C/II

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

#### Use of the substance/mixture

Impression 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

#### Hazard categories:

Acute toxicity: Acute Tox. 4  
Acute toxicity: Acute Tox. 4  
Serious eye damage/eye irritation: Eye Irrit. 2  
Respiratory or skin sensitisation: Skin Sens. 1  
Germ cell mutagenicity: Muta. 2  
Reproductive toxicity: Repr. 1A  
Specific target organ toxicity - repeated exposure: STOT RE 1  
Hazardous to the aquatic environment: Aquatic Chronic 3

#### Hazard Statements:

Harmful if swallowed.  
Harmful if inhaled.  
Causes serious eye irritation.  
May cause an allergic skin reaction.  
Suspected of causing genetic defects.  
May damage fertility.  
Causes damage to organs through prolonged or repeated exposure.  
Harmful to aquatic life with long lasting effects.

### 2.2. Label elements

#### Regulation (EC) No. 1272/2008

#### Hazard components for labelling

alkylstannonic siloxanes  
(R)-p-mentha-1,8-diene, d-limonene  
citral

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Signal word: Danger

Pictograms:

**Hazard statements**

H302+H332 Harmful if swallowed or if inhaled.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H341 Suspected of causing genetic defects.

H360F May damage fertility.

H372 Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.

H412 Harmful to aquatic life with long lasting effects.

**Precautionary statements**

P201 Obtain special instructions before use.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

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

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P310 Immediately call a POISON CENTER/doctor.

**Special labelling of certain mixtures**

Restricted to professional users.

**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**

No information available.

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

Silicon-tin-compound with auxilliary matters.

**Hazardous components**

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
<b>93925-42-9</b>	<b>alkylstannonic siloxanes</b>			<b>65 - &lt; 70 %</b>
	300-344-4		01-2119560586-30	
	Flam. Liq. 3, Muta. 2, Repr. 1A, Acute Tox. 4, Acute Tox. 4, Eye Dam. 1, STOT RE 1, Aquatic Chronic 3; H226 H341 H360F H332 H302 H318 H372 H412			



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<b>5989-27-5</b>	<b>(R)-p-mentha-1,8-diene, d-limonene</b>		<b>1 - &lt; 5 %</b>
	227-813-5	601-029-00-7	
	Flam. Liq. 3, Skin Irrit. 2, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1; H226 H315 H317 H400 H410		
<b>5392-40-5</b>	<b>citral</b>		<b>&lt; 1 %</b>
	226-394-6	605-019-00-3	
	Skin Irrit. 2, Skin Sens. 1; H315 H317		

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

## 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. If breathing is irregular or stopped, administer artificial respiration. Medical treatment necessary.

#### After contact with skin

After contact with skin, wash immediately with polyethylene glycol, followed by plenty of water. Take off immediately all contaminated clothing and wash it before reuse. Medical treatment necessary.

#### After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

#### After ingestion

Rinse mouth immediately and drink plenty of water. Let water be drunken in little sips (dilution effect). Seek immediately medical advice. Do not induce vomiting. In case of spontaneous vomiting take care of an unhindered flow out of the vomit (danger of suffocation).

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

No information available.

### 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

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.



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### Additional information

Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. 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

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. 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

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

### 6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Advice on safe handling

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

#### Advice on protection against fire and explosion

No special fire protection measures are necessary.

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

#### Requirements for storage rooms and vessels

Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.

#### Hints an joint storage

Do not store with strong oxidising materials.

#### 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)

Component A of a silicone based impression ear material material. For use by trained specialist staff.

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egger**SECTION 8: Exposure controls/personal protection****8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe gas/fumes/vapour/spray.

**Protective and hygiene measures**

Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

**Eye/face protection**

Suitable eye protection: goggles.

**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), Butyl caoutchouc (butyl rubber), FKM (fluoro rubber), CR (polychloroprene, chloroprene 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: blue

Odour: characteristic

		Test method
pH-Value:	not determined	
<b>Changes in the physical state</b>		
Melting point:	not determined	
Initial boiling point and boiling range:	>200 °C	DIN 51356
Flash point:	>100 °C	DIN 51755
<b>Flammability</b>		
Solid:	not applicable	
Gas:	not applicable	
Lower explosion limits:	not determined	
Upper explosion limits:	not determined	
Ignition temperature:	>300 °C	DIN 51794



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Auto-ignition temperature		
Solid:	not applicable	
Gas:	not applicable	
Decomposition temperature:	>250 °C	
Oxidizing properties		
	Not oxidizing.	
Vapour pressure (at 20 °C):	<1 hPa	
Density (at 20 °C):	1,0 g/cm <sup>3</sup>	DIN 51757
Water solubility:	insoluble	
Solubility in other solvents		
	not determined	
Partition coefficient:	not determined	
Viscosity / dynamic (at 23 °C):	>80000 mPa·s	BROOKFIELD
Vapour density:	not determined	
Evaporation rate:	not determined	

## 9.2. Other information

Solid content: not determined.

## 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: strong oxidising agents.

### 10.4. Conditions to avoid

Higher temperatures advance the formation of flammable vapours, therefore don't expose the product to increased temperatures.

### 10.5. Incompatible materials

No information available.

### 10.6. Hazardous decomposition products

No known hazardous decomposition products.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute toxicity

Harmful if swallowed or if inhaled.

For the product itself no toxicological data are available. In products with a comparable composition a LD50 (orally, species rat) of &gt;2000 mg/kg has been found.



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## ATEmix calculated

ATE (oral) 758,5 mg/kg; ATE (inhalative vapour) 16,70 mg/l; ATE (inhalative aerosol) 2,277 mg/l

CAS No	Chemical name				
	Exposure routes	Dose	Species	Source	Method
<b>93925-42-9</b>	<b>alkylstannonic siloxanes</b>				
	oral	ATE 500 mg/kg			
	inhalative vapour	ATE 11 mg/l			
	inhalative aerosol	ATE 1,5 mg/l			
<b>5989-27-5</b>	<b>(R)-p-mentha-1,8-diene, d-limonene</b>				
	oral	LD50 >2000 mg/kg	Rat		
	dermal	LD50 >2000 mg/kg	Rabbit	UICLID	
<b>5392-40-5</b>	<b>citral</b>				
	oral	LD50 4960 mg/kg	Rat	GESTIS	
	dermal	LD50 2250 mg/kg	Rabbit	GESTIS	

## Irritation and corrosivity

Causes serious eye irritation.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Based on a Bovine Corneal Permeability Study conducted in accordance with OECD Guideline No. 437 (July 2013), H318 is not shown.

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.“

## Sensitising effects

May cause an allergic skin reaction. ((R)-p-mentha-1,8-diene, d-limonene; citral).

## Carcinogenic/mutagenic/toxic effects for reproduction

Suspected of causing genetic defects. (alkylstannonic siloxanes).

May damage fertility. (alkylstannonic siloxanes).

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

## STOT-single exposure

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

## STOT-repeated exposure

Causes damage to organs through prolonged or repeated exposure. (alkylstannonic siloxanes)

## Aspiration hazard

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

## Additional information on tests

This mixture is classified as hazardous according to regulation (EC) No. 1272/2008 [CLP].

Special hazards arising from the substance or mixture!



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## SECTION 12: Ecological information

### 12.1. Toxicity

Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h]   [d]	Species	Source	Method
5989-27-5	<b>(R)-p-mentha-1,8-diene, d-limonene</b>					
	Acute fish toxicity	LC50	0.7 mg/l	96 h	Pimephales promelas	
	Acute crustacea toxicity	EC50	0.42 mg/l	48 h	Daphnia magna	

### 12.2. Persistence and degradability

The product has not been tested.

### 12.3. Bioaccumulative potential

The product has not been tested.

### Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
5989-27-5	(R)-p-mentha-1,8-diene, d-limonene	4.23

### 12.4. Mobility in soil

The product has not been tested.

### 12.5. Results of PBT and vPvB assessment

Not identified as PBT /vPvB substances.

### 12.6. Other adverse effects

No information available.

### Further information

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

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Disposal recommendations

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

#### Contaminated packaging

This material and its container must be disposed of as hazardous waste. Handle contaminated packages in the same way as the substance itself.

## 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.



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**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.

**14.6. Special precautions for user**

No dangerous good in sense of this transport regulation.

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

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****National regulatory information**

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive 92/85/EEC) for expectant or nursing mothers.

Water contaminating class (D): 3 - strongly hazardous to water

Skin resorption/Sensitization: Causes allergic hypersensitivity reactions.

**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 %



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## Classification for mixtures and used evaluation method according to Regulation (EC) No. 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4; H302	Calculation method
Acute Tox. 4; H332	Calculation method
Eye Irrit. 2; H319	
Skin Sens. 1; H317	Calculation method
Muta. 2; H341	Calculation method
Repr. 1A; H360F	Calculation method
STOT RE 1; H372	Calculation method
Aquatic Chronic 3; H412	Calculation method

### Relevant H and EUH phrases (Number and full text)

H226 Flammable liquid and vapour.  
 H302 Harmful if swallowed.  
 H302+H332 Harmful if swallowed or if inhaled.  
 H315 Causes skin irritation.  
 H317 May cause an allergic skin reaction.  
 H318 Causes serious eye damage.  
 H319 Causes serious eye irritation.  
 H332 Harmful if inhaled.  
 H341 Suspected of causing genetic defects.  
 H360F May damage fertility.  
 H372 Causes damage to organs (Thymus) through prolonged or repeated exposure if swallowed.  
 H372 Causes damage to organs through prolonged or repeated exposure.  
 H400 Very toxic to aquatic life.  
 H410 Very toxic to aquatic life with long lasting effects.  
 H412 Harmful to aquatic life with long lasting effects.

### 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.)