

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

1.1 Product identifier

Trade name: **Silikon Pastenhärter**

Product type: hardener for dental impression material

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

Use of the substance or mixture: Paste hardener for silicone impression material.

Uses advised against: Restricted to professional users.

1.3 Details of the supplier of the safety data sheet

Company name: Pluradent AG & Co KG

Street/Mailbox: Kaiserleistr. 3

Place: D-63067 Offenbach a.M.

Contact for technical information: Pluradent Vertrieb

Phone / Telefax / E-Mail

+49 (0) 69-82983-0 / +49 (0) 69-82983-271 / regulatory.affairs@pluradent.de

1.4 Emergency telephone number

Germany: Giftnotruf Mainz - 24 Hour Service - Tel.: +49 (0) 6131/19240

2. * Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:



GHS08

STOT SE 2

H371 May cause damage to organs



GHS07

Skin Irrit. 2

H315 Causes skin irritation.

Skin Sens. 1

H317 May cause an allergic skin reaction.

Aquatic Chronic 3

H412 Harmful to aquatic life with long lasting effects.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008:

The product is classified and labelled according to the CLP regulation.

Hazard pictograms:



GHS08



GHS07

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according to Regulation (EC) No 1907/2006, article 31



Trade name: **Silikon Pastenhärter**

Signal word: Warning

Hazard-determining components of labelling:

Diethylzinnacetylacetonat (CAS 54068-28-9)
Aroma mixture

Hazard statements

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H371 May cause damage to organs.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.
P103 Read label before use.
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P280 Wear protective gloves.
P273 Avoid release to the environment.
P321 Specific treatment (see on this label).
P405 Store locked up.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations

Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3 Other hazards

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

3. * Composition/information on ingredients

3.2 Mixtures

Description: Mixture of substances listed below with non-hazardous additions.

Dangerous components:

Name	Identificator	Regulation (EC) No 1272/2008	%
Silane	CAS: 18765-38-3	Skin Irrit. 2 - H315	10 - 25 %
Diethylzinnindilaurat	CAS 3648-18-8 EINECS: 222-883-3 Reg.nr.: 01-2119979527-19-0000	STOT SE 2 - H371	2,5 - < 10 %
Diethylzinnacetylacetonat	CAS 54068-28-9	STOT SE 2 - H371 Skin Sens 1- H317	2,5 - < 10 %

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Name	Identificator	Regulation (EC) No 1272/2008	%
Aroma mixture		Flam. Liq. 3 - H226 Asp. Tox. 1- H304 Skin Irrit. 2- H315 Skin Sens. 1- H317 Aquatic Acute 1- H400 Aquatic Chronic 1 H410	0,25 - < 0,5 %

Additional information: For the wording of the listed risk phrases refer to section 16.

4. First aid measures



4.1 Description of first aid measures

After inhalation

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation..

After skin contact

Immediately wash with water and soap and rinse thoroughly.

After eye contact

Rinse opened eye for several minutes under running water.

After swallowing

If symptoms persist consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Carbon dioxide (CO₂), Powder or water spray.

Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

No further relevant information available.

5.3 Advice for firefighters

No special measures required.

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Trade name: **Silikon Pastenhärter**

6. * Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Not required.

6.2 Environmental precautions

Inform respective authorities in case of seepage into water course or sewage system.
Do not allow product to reach ground water, water course or sewage system.

6.3 Methods and material for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose contaminated material as waste according to item 13.

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7. * Handling and storage

7.1 Precautions for safe handling

No special precautions are necessary if used correctly.

Information about fire- and explosion-protection: No special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Storage: -

Requirements for storage rooms and vessels: No special requirements.

Advice on storage compatibility: Not required.

Further information about storage conditions: No further relevant information available.

7.3 Specific end use(s)

No further relevant information available.

8. * Exposure controls/personal protection

8.1 Control parameters

8.1.1 Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists valid during the making were used as basis.

8.1.2. DNEL/PNEC-values

No further relevant information available.

8.1.3. Control-Banding

No further relevant information available.

8.2 Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

8.2.1 Appropriate engineering controls

No further relevant information available.

8.2.2 Individual protection measures - Personal protective equipment

General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing.

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Avoid contact with the eyes and skin.

Respiratory protection:

Not required.

Protection of hands



Protective gloves

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves

We recommend protective gloves of Nitril (EN 374).

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material

Time of permeation (EN 374):

long-term use: < 480 min

short-term use: < 30 min

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection



Goggles recommended during refilling.

Skin protection

Not required.

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8.2.3 Environmental exposure controls:

General notes:

Do not allow product to reach ground water, water course or sewage system.

9. * Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: - Form :	Pasty
- Colour :	According to product specification
Odour :	characteristic
Odour threshold :	Not determined
pH-value at 20 °C :	Not determined
Change in condition	
Melting point/ freezing point :	Not determined
Boiling point/Boiling range :	Not determined
Flash point :	> 70°C
Flammability (solid, gaseous) :	Not applicable
Evaporation rate :	Not applicable
Ignition temperature :	Not determined
Auto-ignition temperature :	Product is not self igniting
- Solid :	Not applicable
- Gas :	Not applicable
Decomposition temperature :	Not determined
Oxidizing properties	Not determined
Danger of explosion :	Product does not present an explosion hazard.
Explosion limits	
- lower :	Not determined
- upper :	Not determined
Vapour pressure at 20°C :	0,1 hPa
Vapour density :	Not determined
Density at 23 °C :	0,95 g/cm ³
Relative density :	Not determined
Solubility in / Miscibility with water :	Not miscible or difficult to mix
Partition coefficient (n-octanol/water) :	Not determined
Viscosity	
Dynamic at 23°C :	Not determined
cinematic :	Not determined
Solvent content :	
Organic solvents :	0,0 %
VOC (EC) :	0,00 %
Solids content :	91,6 %

9.2 Other information

No further relevant information available.

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10. Stability and reactivity

10.1 Reactivity

No further relevant information available.

10.2 Chemical Stability

The product is stable under normal handling and storage conditions.

Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

No further relevant information available.

10.5 Incompatible materials

No further relevant information available.

10.6 Hazardous decomposition products

No dangerous decomposition products known.

11. * Toxicological information

11.1 Information on toxicological effects

Acute toxicity

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

LD/LC₅₀-values relevant for classification:		
Diethylzinnacetylacetonat (CAS 3648-18-8)		
Oral	LD ₅₀	6450 mg/kg (rat)
Diethylzinnacetylacetonat (CAS 54068-28-9)		
Oral	LD ₅₀	> 2500 mg/kg (rat)
Dermal	LD ₅₀	> 2000 mg/kg (rat)

Primary irritant effect:

On the skin: Causes skin irritation.

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

Sensitization: May cause an allergic skin reaction.

Germ cell mutagenicity

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

Carcinogenicity

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

Reproductive toxicity

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

Specific target organ toxicity - single exposure

May cause damage to organs

Specific target organ toxicity - repeated exposure

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

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Severe effects after repeated or prolonged exposure

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

Aspiration hazard

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

Additional toxicological information

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

12. Ecological information

12.1 Toxicity

Aquatic Toxicity

No further relevant information available.

12.2 Persistence and degradability

No further relevant information available.

12.3 Bioaccumulative potential

No further relevant information available.

12.4 Mobility in soil

No further relevant information available.

Ecotoxicological effects:

Remark: Harmful to fish

General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.
Harmful to aquatic organisms

12.5 Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects

No further relevant information available.

13. Disposal considerations

13.1 Waste treatment methods

Advise on disposal:

Recommendation: Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Contaminated packaging:

Recommendation: Disposal must be made according to official regulations.

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14. Transport information

14.1 UN-Number

ADR, ADN, IMDG, IATA No dangerous good in sense of this transport regulation.

14.2 UN proper shipping name

ADR/RID, ADN, IMDG, IATA 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

ADR/RID, ADN, IMDG, IATA No dangerous good in sense of this transport regulation.

14.5 Transport/Additional information:

No dangerous good in sense of this transport regulation.

14.6 Environmental hazards:

Marine Pollutant: yes / no

14.7 Special precautions for user

No dangerous good in sense of this transport regulation.

14.8 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

No dangerous good in sense of this transport regulation.

14.9 UN "Model Regulation"

No dangerous good in sense of this transport regulation.

15. * Regulatory information

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

EU regulations:

Seveso category: None.
Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006: Conditions of restriction: 3
Substances in Candidate List (Art. 59 REACH): None
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

National regulations:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

15.2 Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

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16. * Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. The receiver of our product is solely responsible for adhering to existing laws and regulations.

Changes compared to the previous version

- * Data compared to the previous version altered.

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)
RID	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR	Dangerous Goods Regulations 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
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 (division of the American Chemical Society)
GefStoffV	Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
LC ₅₀	Lethal concentration, 50 percent
LD ₅₀	Lethal dose, 50 percent
ErC ₅₀	EC ₅₀ in terms of reduction of growth rate.
EC ₅₀	The effective concentration of a substance that causes 50% of the maximum response.
NOEC	No Observed Effect Concentration
VOC	Volatile organic Compounds
PBT	Persistent bioaccumulative and toxic as REACH Regulation
vPvB	Very Persistent and very Bioaccumulative as for REACH Regulation

Relevant phrases

Acute Tox. 4	Acute toxicity, category 4
Skin Corr.	Skin corrosion / irritation
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
STOT RE	Specific target organ toxicity - repeated exposure

H226	Flammable liquid and vapour.
H304	May be fatal if swallowed and enters airways.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H371	May cause damage to organs
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Further information

Department issuing MSDS: Regulatory Affairs

The information contained in this security data sheet is based on our best knowledge and conscience on topically available information about the correct use of the product under normal conditions. The user is solely responsible for any other usage of this product in connection with other processes / procedures which is not described in this data sheet. This document does not show any explicit or implicit guarantee with regard to product quality or suitability for a certain purpose.