

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 06.05.2019

Version number 4

Revision: 06.05.2019

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

- **1.1 Product identifier**
- **Trade name: Hardener paste**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Hardener paste for all condensation-vulcanising impression materials for ear impression taking
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dreve Otoplastik GmbH
Max-Planck-Straße 31
59423 Unna / Germany
Tel.: ++49 2303 / 8807-0
Fax.: ++49 2303 / 8807-29
- **Further information obtainable from:**
Department Research & Development
Fax: ++49 2303 / 8807-562
Email: sicherheitsdatenblatt@dreve.de
- **1.4 Emergency telephone number:**
Tel.: ++ 49 211 / 797-3350
Plant Fire Department Henkel

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS08 health hazard

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



GHS07

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **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**



GHS07 GHS08

- **Signal word** Warning
- **Hazard-determining components of labelling:**
Diocetylacetylacetonate
dioctyltin oxide

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- **Hazard statements**
 - H315 Causes skin irritation.
 - H317 May cause an allergic skin reaction.
 - H373 May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**
 - P260 Do not breathe dust/fume/gas/mist/vapours/spray.
 - P280 Wear protective gloves.
 - P308+P313 IF exposed or concerned: Get medical advice/attention.
 - P362 Take off contaminated clothing.
 - P363 Wash contaminated clothing before reuse.
 - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

- **Dangerous components:**

CAS: 8002-74-2 EINECS: 232-315-6	Paraffin waxes and Hydrocarbon waxes substance with a Community workplace exposure limit	25-50%
CAS: 18765-38-3 EINECS: 242-560-0	tetrakis (2-butoxyethoxy) silane ⚠ Skin Irrit. 2, H315	10-25%
CAS: 870-08-6 EINECS: 212-791-1	dioctyltin oxide ⚠ STOT RE 2, H373; Aquatic Chronic 4, H413	10-25%
CAS: 54068-28-9	Dioctyltinacetylacetonate ⚠ STOT SE 2, H371; ⚠ Skin Sens. 1, H317	2.5-10%
CAS: 2768-02-7 EINECS: 220-449-8	trimethoxyvinylsilane ⚠ Flam. Liq. 3, H226; ⚠ Acute Tox. 4, H332	2.5-10%

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** Immediately remove any clothing soiled by the product.
- **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.
 - If skin irritation continues, consult a doctor.
- **After eye contact:**
 - Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
 - Do not induce vomiting.
 - Call a doctor immediately.
- **4.2 Most important symptoms and effects, both acute and delayed**
 - No further relevant information available.

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- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **5.2 Special hazards arising from the substance or mixture**
During heating or in case of fire poisonous gases are produced.
- **5.3 Advice for firefighters**
- **Protective equipment:** Mount respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid contact with skin and eyes.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Avoid contact with skin and eyes.
Ensure good ventilation/exhaustion at the workplace.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Keep container tightly sealed.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**

- **Ingredients with limit values that require monitoring at the workplace:**

8002-74-2 Paraffin waxes and Hydrocarbon waxes

WEL	Short-term value: 6 mg/m ³ Long-term value: 2 mg/m ³
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870-08-6 dioctyltin oxide

WEL	Short-term value: 0.2 mg/m ³ Long-term value: 0.1 mg/m ³ as Sn; Sk
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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Store protective clothing separately.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

- **Material of gloves**
Butyl rubber, BR
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**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
The determined penetration times according to EN 374 part III are not performed under practical conditions. Therefore a maximum wearing time, which corresponds to 50% of the penetration time, is recommended.
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Solid
Colour:	Different according to colouring
- **Odour:** Characteristic
- **Odour threshold:** Not determined.

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· pH-value:	Not applicable.
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	160 °C
· Flash point:	Not applicable.
· Flammability (solid, gas):	„not highly flammable" according UN-Method N.1, EG-A10
· Ignition temperature:	400 °C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure at 20 °C:	1 hPa
· Density at 20 °C:	1.02 g/cm ³
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· 9.2 Other information	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No dangerous reactions if used according to specifications.
- **10.2 Chemical stability** Stable if used according to specifications.
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **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.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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· LD/LC50 values relevant for classification:		
· 870-08-6 dioctyltin oxide		
Oral	LD50	2500 mg/kg (rat)

- **Primary irritant effect:**

- **Skin corrosion/irritation**

- Causes skin irritation.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation**

- May cause an allergic skin reaction.

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**

- **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.

- **STOT-single exposure** Based on available data, the classification criteria are not met.

- **STOT-repeated exposure**

- May cause damage to organs through prolonged or repeated exposure.

- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 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.

- **Additional ecological information:**

- **General notes:**

- 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.

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

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

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

- Disposal must be made according to official regulations.

· European waste catalogue	
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity

- **Uncleaned packaging:**

- **Recommendation:** Disposal must be made according to official regulations.

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SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es) · ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Directive 2012/18/EU
- Named dangerous substances - ANNEX I None of the ingredients is listed.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 20

- Regulation (EU) No 649/2012

870-08-6	dioctyltin oxide	Annex I Part 1
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- National regulations:
- Technical instructions (air):

Class	Share in %
NK	≤ 2,5

- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 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.

- Relevant phrases

H226 Flammable liquid and vapour.
 H315 Causes skin irritation.
 H317 May cause an allergic skin reaction.
 H332 Harmful if inhaled.
 H371 May cause damage to the immune system. Route of exposure: Oral.
 H373 May cause damage to organs through prolonged or repeated exposure.
 H413 May cause long lasting harmful effects to aquatic life.

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- **Department issuing SDS:** Department Research & Development
- **Contact:** Dr. Thomas Veit, Lothar Sutor
- **Abbreviations and acronyms:**
 - RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
 - ICAO: International Civil Aviation Organisation
 - 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 Harmonised 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)
 - LC50: Lethal concentration, 50 percent
 - LD50: Lethal dose, 50 percent
 - PBT: Persistent, Bioaccumulative and Toxic
 - vPvB: very Persistent and very Bioaccumulative
 - Flam. Liq. 3: Flammable liquids – Category 3
 - Acute Tox. 4: Acute toxicity – Category 4
 - Skin Irrit. 2: Skin corrosion/irritation – Category 2
 - Skin Sens. 1: Skin sensitisation – Category 1
 - STOT SE 2: Specific target organ toxicity (single exposure) – Category 2
 - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2
 - Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4
- *** Data compared to the previous version altered.**

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