



Safety Data Sheet

acc. to OSHA HCS

Printing date 11/09/2017

Reviewed on 11/09/2017

1 Identification

- **Product identifier**
- **Trade name: Regofix opaque**
- **Application of the substance / the mixture** Bite registration material on vinyl polysiloxane basis
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Dreve Dentamid GmbH
Max-Planck-Straße 31
59423 Unna / Germany
Tel.: + 49 2303 / 8807-0
Fax.: +49 2303 / 8807-55
- **Information department:**
Department Research & Development
Fax.: +49 2303 8807-562
Email: sicherheitsdatenblatt@dreve.de
- **Emergency telephone number:**
+49 211 797-3350
Plant Fire Department Henkel

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



Health = 0
Fire = 1
Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



HEALTH 0 Health = 0
FIRE 1 Fire = 1
REACTIVITY 0 Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Additional-vulcanising 2-component silicone

- **Dangerous components:**

14464-46-1	cristobalite	50-100%
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- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **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.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture**
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid contact with eyes
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **Reference to other sections**
No dangerous substances are released.
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.
- **Protective Action Criteria for Chemicals**

- **PAC-1:**

14464-46-1	cristobalite	0.075 mg/m ³
	Vinylpolydimethylsiloxane	48 mg/m ³
	Methylhydrogenpolysiloxan	30 mg/m ³

- **PAC-2:**

14464-46-1	cristobalite	33 mg/m ³
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	Vinylpolydimethylsiloxane	530 mg/m ³
	Methylhydrogenpolysiloxan	330 mg/m ³
· PAC-3:		
14464-46-1	crystalite	200 mg/m ³
	Vinylpolydimethylsiloxane	3,200 mg/m ³
	Methylhydrogenpolysiloxan	2,000 mg/m ³

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** When using do not eat, drink or smoke.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Keep receptacle tightly sealed.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

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

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

14464-46-1 cristobalite

PEL	½ value from respirable dust formulae for Quartz
REL	Long-term value: 0.05* mg/m ³ *respirable dust; See Pocket Guide App. A
TLV	Long-term value: 0.025* mg/m ³ *as respirable fraction

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves** Not applicable
- **Penetration time of glove material** Not applicable
- **Eye protection:** Goggles recommended during refilling.
- **Body protection:** Protective work clothing

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9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

- Form: Viscous

- Color: Blue

- **Odor:** Characteristic

- **Odor threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

- Melting point/Melting range: Undetermined.

- Boiling point/Boiling range: 301 °C (573.8 °F)

- **Flash point:** 111 °C (231.8 °F)

- **Flammability (solid, gaseous):** Not applicable.

- **Ignition temperature:** >350 °C (>662 °F)

- **Decomposition temperature:** Not determined.

- **Auto igniting:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

- Lower: Not determined.

- Upper: Not determined.

- **Oxidizing properties** Not determined

- **Vapor pressure at 20 °C (68 °F):** 100 hPa (75 mm Hg)

- **Density at 20 °C (68 °F):** 1,6 g/cm³ (13.352 lbs/gal)

- **Relative density** Not determined.

- **Vapor density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

- Water: Not miscible or difficult to mix.

- **Partition coefficient (n-octanol/water):** Not determined.

- **Viscosity:**

- Dynamic: Not determined.

- Kinematic: Not determined.

- **Solvent content:**

- Organic solvents: 0,0 %

- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No dangerous reactions if used according to specifications

- **Chemical stability** Stable if used according to specifications

- **Thermal decomposition / conditions to be avoided:**

- No decomposition if used according to specifications.

- **Possibility of hazardous reactions** No dangerous reactions known.

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- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

11 Toxicological information

- **Information on toxicological effects**
- **Additional toxicological information:**
The product is not subject to classification according to internally approved calculation methods for preparations:
When used and handled according to specifications, the product does not have any harmful effects according to our experience and the information provided to us.

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

14464-46-1	cristobalite	1
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- **NTP (National Toxicology Program)**

14464-46-1	cristobalite	K
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- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:** Disposal must be made according to official regulations.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

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14 Transport information

· UN-Number	
· DOT, ADR, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, ADR, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, ADR, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	Void

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
· Sara
· Section 355 (extremely hazardous substances):
None of the ingredient is listed.
· Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.
· TSCA (Toxic Substances Control Act):
All ingredients are listed.
· TSCA new (21st Century Act) (Substances not listed)
· Proposition 65
· Chemicals known to cause cancer:
14464-46-1 cristobalite
· Chemicals known to cause reproductive toxicity for females:
None of the ingredients is listed.
· Chemicals known to cause reproductive toxicity for males:
None of the ingredients is listed.
· Chemicals known to cause developmental toxicity:
None of the ingredients is listed.
· Cancerogenity categories
· EPA (Environmental Protection Agency)
None of the ingredients is listed.

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· TLV (Threshold Limit Value established by ACGIH)		
14464-46-1	cristobalite	A2

· MAK (German Maximum Workplace Concentration)		
14464-46-1	cristobalite	1

· NIOSH-Ca (National Institute for Occupational Safety and Health)		
14464-46-1	cristobalite	

- **GHS label elements** Void

- **Hazard pictograms** Void

- **Signal word** Void

- **Hazard statements** Void

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

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.

- **Department issuing SDS:** Department Research & Development

- **Contact:** Dr. Thomas Veit, Lothar Sutor

- **Date of preparation / last revision** 11/09/2017 / 3

- **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit