SECTION 1. Product identification/preparation/company undertaking

1.1. Product identifier:

Trade name: **BISICO Pastenhärter (various packaging sizes)**

Trade number: **00950, 00960, 09901**

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:

Hardening paste for condensation-curing dental silicone

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

BISICO Bielefelder Dentalsilicone GmbH & Co. KG
Johanneswerkstraße 3
D-33611 Bielefeld
Tel.: +49 521 8016800
Fax: +49 521 8016801
Email: info@Bisico.de
responsible for the Safety Data Sheet: Sebastian Zimmermann

1.4. Emergency telephone number:

BISICO Bielefelder Dentalsilicone GmbH & Co. KG

Tel.: +49 521 8016800 (08:00-16:00 PM)
Fax: +49 521 8016801
S. Zimmermann

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture:

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments:

Hazard Class	Hazard Category	Route	H Code
Reproductive toxicity	Category 2		H361d
Acute toxicity	Category 4	inhalation	H332
Serious eye damage/eye irritation	Category 2		H319
Flammable liquids	Category 3		H226
Specific target organ toxicity – repeated exposure	Category 1		H373
Specific target organ toxicity – single exposure	Category 3		H335

2.2 Label Elements:

Labeling according to Regulation (EC) No. 1272/2008:

Pictograms:

Signal word: Danger

H-Code	Hazard Statements
H226	Flammable liquid and vapour.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H361d	Suspected of damaging the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.

P-Code	Safety Instructions
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Do not smoke.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/ eye protection/ face protection.
P314	Get medical advice/ attention if you feel unwell.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P405	Store locked up.
P501	Dispose of contents/container.

Dangerous ingredients (labelling):
tetraethyl silicate
Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane

The following percentage of the mixture consists of ingredient(s) with unknown risk to the aquatic environment: 16.92%.

2.3 Other hazards:
No information available.

SECTION 3. Composition/Information of Ingredients

3.1 Substances

not applicable

3.2 Mixtures

3.2.1 Chemical characterization

Organo-tin compound + silicic acid ester + auxiliaries

3.2.2 Hazardous ingredients

Type	CAS no.	EC no. REACH no.	Substance	Content %	Classification according to Regulation (EC) No. 1272/2008*	Comment
INHA	78-10-4	201-083-8 01-2119496195-28	tetraethyl silicate	>=25 – <50	flam. Liq. 3; H226 Acute Tox. 4 inhalative; H332 eye irritation 2; H319 STOT SE 3; H335	[1],[2]
INHA	93925-43-0	300-346-5 01-2120753666-44	silicic acid (H4SiO4) tetraethyl ester, reaction products with Bis(acetyloxy)dioctylstannane	>=10-<20	Repr. 2; H361d Aquatic Chronic 4; H413 eye irritation 2; H319 Acute Tox. 4 orally; H302 Flam. liquor 3; H226 STOT RE 1; H372	[1]
INHA	68299-15-0	269-595-4	Bis(neodecanoyloxy)dioctylstannan	>=1 – <3	Aquatic Chronic 4; H413 STOT RE 2; H373	[1]

Type: INHA: ingredient

[1] = Substance hazardous to health or the environment; [2] = substance with a Community workplace exposure limit; [3] = PBT substance; [4] = vPvB substance

*The classification information is explained in Chapter 16.

This product does not contain any substances of very high concern (REACH Regulation (EC) No. 1907/2006, Article 57) above ≥ 0.1%.

SECTION 4. First-aid measures

4.1 Description of first aid measures

General:
Bring people to safety. Pay attention to the self-protection of the first aider. If pregnant women are exposed, seek medical advice.

After eye contact:
Rinse immediately with plenty of water for 10-15 minutes. Hold the eyelids wide open to rinse the entire surface of the eye, including the eyelids, with water. If irritation persists, seek medical advice.

After skin contact:
Remove contaminated or soaked clothing. Wash off immediately with plenty of water and soap. In the case of large quantities, immediately go under the emergency shower. In case of visible skin changes or complaints, seek medical advice (if possible show the label or SDS).

After inhalation:
Store quietly. If unconscious, position in a stable lateral position. Protect from cooling down. Consult a doctor and name the substance precisely.

After swallowing:
Have the person drink plenty of water in small portions, but only if the person is conscious. Do not induce vomiting. Consult a doctor and name the substance precisely.

4.2 Most important symptoms and effects, both acute and delayed

Relevant information can be found in other parts of this section.

4.3 Indications of immediate medical attention or special treatment

Further information on toxicology in Section 11 must be observed. Product can be toxic to reproduction (Damaging to fruit or impairment of female or male reproductive function). After exposure, specialist advice (e.g. gynaecology/obstetrics or, if necessary, toxicology/human genetics) is recommended.

SECTION 5. Fire fighting measures

5.1 Extinguishing media

Suitable extinguishing agents:
Water fog, dry powder, alcohol-resistant foam, carbon dioxide, sand.

Unsuitable extinguishing media for safety reasons:
water jet.

5.2 Special hazards arising from the substance or mixture

In case of fire hazardous combustion gases or vapors possible. Exposure to combustion products can be a health hazard! Dangerous fire products: toxic and very toxic fumes.

5.3 Advice for firefighters
Special protective equipment for firefighting:
Use self-contained breathing apparatus. Keep unprotected people away.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
secure area. Wear personal protective equipment (see Section 8). Keep unprotected people away. Avoid contact with eyes and skin. Do not inhale gases/vapours/aerosols. If material is released draw attention to slip hazard. Do not walk through spilled material.

6.2 Environmental Protection Measures
Do not discharge into the drains or waterways. Retain contaminated water/extinguishing water. Disposal in properly labeled containers.

6.3 Methods and material for containment and cleaning up
To avoid adhesion, dust the surface with sand or fuller's earth and pick up the material mechanically. Sweep up or scrape up spilled material and place in a chemical waste container. Remove any remaining slippery surface with detergent/soap solution or other biodegradable cleaner. Apply sand or other inert granular material to improve grip.

Additional information:
Eliminate sources of ignition.

6.4 Reference to Other Sections
Relevant information in other sections must be observed. This applies in particular to information on personal protective equipment (section 8) and disposal (section 13).

SECTION 7. Handling and storage

7.1 Precautions for safe handling
General:
Avoid exposure by technical measures or personal protective equipment.

Advice for safe handling:
Ensure good room and workplace ventilation. Extraction required on the object. Spilled substance increases the risk of slipping. Observe the information in section 8. Keep away from incompatible substances according to point 10.

Information about fire and explosion protection:
Take precautionary measures against electrostatic charging. Keep away from open flames, sources of heat and sparks. Cool endangered containers with water. Formation of explosive mixtures possible within partially emptied containers.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage rooms and containers:
Observe local official regulations.

Notes on storage together:
Observe local official regulations.

Further information on storage conditions:
Store dry and cool. Protect from moisture. Keep container in a well-ventilated place.

Storage class (TRGS 510): 3

7.3 Specific End Uses
No information available.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters:

Air limit values at the workplace (TRGS 900):

CAS no.	Substance	Type	mg/m3	ppm	dust fraction	fibres/ m3
78-10-4	tetraethyl silicate	AGW	12.0	1.4		
78 -10-4	tetraethyl silicate	EU	44.0	5.0		
	Tin compounds (organic)	AGW	0.009	0.0018		
64-17-5	ethanol	AGW	380.0	200.0		

Tetraethyl silicate (CAS # 78-10-4): excursion factor 1(I); Note AGS. (Status: May 2010)

n-butyltin compounds: excursion factor 1 (I); Notes H, 10, 11, AGS and Z (di- and tri-n-butyl-) and Y (mono- and tetra-n-butyl-), respectively.

Ethanol (CAS No. 64-17-5): excursion factor 4(II); Notes DFG and Y (= a risk of fetal damage needs at compliance with the occupational exposure limit and the biological limit (BGW) need not be feared). (Status: June 2018).

Derived No-Effect Level (DNEL):

tetraethyl silicate

Scope:	Value:
workers; dermal; systemic (acute)	12.1 mg/kg/day
workers; dermal; systemic (long term)	12.1 mg/kg/day
workers; inhalative; systemic (acute)	85 mg/m³
workers; inhalative; local (acute)	85 mg/m³
workers; inhalative; systemic (long-term)	85 mg/m³
workers; inhalative; local (long-term)	85 mg/m³
Consumer; dermal; systemic (acute)	8.4 mg/kg/day
Consumer; dermal; systemic (long term)	8.4 mg/kg/day
Consumer; inhalative; systemic (acute)	25 mg/m³
Consumer; inhalative; local (acute)	25 mg/m³
Consumer; inhalative; systemic (long-term)	25 mg/m³
Consumer; inhalative; local (long-term)	25 mg/m³

Predicted No Effect Concentration (PNEC):

tetraethyl silicate

Scope:	Value:
Fresh water	0.192 mg/l
The value was determined for the following hydrolysis product: ethanol	
sea water	0.0192 mg/l
The value was determined for the following hydrolysis product: ethanol	
Sediment (fresh water)	0.18 mg/kg wet weight
The value was determined for the following hydrolysis product: ethanol	
Sediment (sea water)	0.018 mg/kg wet weight
The value was determined for the following hydrolysis product: ethanol	
soil	0.05 mg/kg wet weight
The value was determined for the following hydrolysis product: ethanol	
Sewage treatment plant	4000 mg/l

The value was determined for the following hydrolysis product: ethanol
Intermittent induction 10 mg/l
The value was determined for the following hydrolysis product: ethanol

8.2 Exposure controls

8.2.1 Limitation and monitoring of exposure at the workplace
General protection and hygiene measures:
Avoid exposure - obtain special instructions before use. Strictly avoid exposure in pregnant women. Avoid contact with eyes and skin. Do not inhale gases/vapours/aerosols. Use with adequate ventilation. Preventive skin protection is recommended. Take off dirty, soaked clothes immediately. Clean work areas regularly. Wash hands at the end of work and before eating. Provide showers and eyewash stations. Store work clothing separately. Do not eat, drink or smoke at work. Keep away from food, drink and animal feedingstuffs.

Personal protective equipment:

respiratory protection
If inhalative exposure above the occupational exposure limit cannot be ruled out, suitable respiratory protective equipment must be used. Appropriate respirator: Full-face respirator conforming to recognized standards such as EN 136.

Recommended filter type: Gas filter ABEK (certain inorganic, organic and acidic gases and vapours; ammonia/amines), according to recognized standards such as EN 14387

In the event of prolonged or severe exposure, breathing apparatus must be used. Suitable breathing apparatus: Self-contained breathing apparatus conforming to recognized standards such as EN 137.

The wearing time limit for respiratory protection and the instructions of the device manufacturer must be observed.

eye protection
tight fitting goggles.

handguard
Protective gloves must be worn at all times when handling the product, in accordance with recognized standards such as EN374.

Recommended glove material: Protective gloves made of butyl rubber
Material thickness: > 0.3 mm
Breakthrough time: > 480 min
Please note the information from the glove supplier in relation to permeability and breakthrough times. Also consider the specific local conditions in which the product will be used, such as risk of cuts, abrasion and contact duration.

body protection
In the case of open handling: chemical protective clothing, liquid-tight full protection suit may be required. Please note the information provided by the supplier with regard to permeability.

8.2.2 Limitation and monitoring of environmental exposure
Do not allow to enter water bodies, waste water and soil. Local waste water regulations for organotin and tin compounds must be observed. Do not bring larger quantities into sewage treatment plants.

8.3 Additional information on the design of technical systems
Observe the information in section 7. Observe national official regulations.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Property:	Value:	Method:
Physical state:	liquid	
Form:	paste	
Color:	red	
Odor		
Odor:	weak	
odor threshold		
Odor threshold:	no data available	
PH value		
pH value:	Not applicable. Insoluble in water.	
Melting Point/Freezing Point		
Melting point / melting range:	not applicable	
Initial boiling point and boiling range		
Boiling point / boiling range:	not determined	
flash point		
Flash point:	42 °C (not specified)	
evaporation rate		
Evaporation rate:	no data available	
Upper/lower flammability or explosive limits		
Lower explosion limit:	not applicable	
Upper explosion limit:	not applicable	
vapor pressure		
Vapor pressure:	not applicable	
solubility(ies)		
Water solubility / miscibility:	practically insoluble	
vapor density		
Gas/vapour relative density:	No data known.	
relativ density		
Relative density:	0.991 (water / 4°C = 1.00)	
Density:	0.991 g/cm³	
Partition coefficient: n-octanol/water		
Partition coefficient: n-octanol/water:	No data known.	
autoignition temperature		
Ignition temperature:	390 °C	(not specified)
decomposition temperature		
Thermal decomposition:	not applicable	

viscosity
Viscosity (dynamic): not applicable

molecular weight
Molecular mass: not applicable

9.2 Other information
Solubility in water: Hydrolytic decomposition will occur.
Hydrolysis products lower the flash point.

SECTION 10. Stability and reactivity

10.1 - 10.3 reactivity; chemical stability; Possibility of hazardous reactions
No dangerous reactions known if stored and handled appropriately.
Relevant information may be included in other parts of this section.

10.4 Conditions to avoid
Moisture, heat, open flames and other sources of ignition.

10.5 Incompatible Materials
Reacts with: water, basic substances and acids. The reaction takes place with the formation of alcohols.

10.6 Hazardous decomposition products
If stored and handled according to instructions: none known. Alcohols from humidity, water and protic agents.

SECTION 11. Toxicological information

11.1 Information on toxicological effects

11.1.1 General
Data determined with the entire product takes precedence over data on individual ingredients.

11.1.2 Acute toxicity
Judgement:
There are no toxicological test data for the entire product for this end point.

Acute toxicity estimate (ATE): ATEmix (Oral): > 2000 mg/kg

11.1.3 Skin corrosion/irritation
Product data:

Result/Effect Species/Test system Source
No skin irritation Rabbit Conclusion by analogy

11.1.4 Serious eye damage/eye irritation
Judgement:
There are no toxicological test data for the entire product for this end point.

11.1.5 Respiratory or skin sensitization
Judgement:
There are no toxicological test data for the entire product for this end point.

11.1.6 Germ cell mutagenicity
Judgement:
There are no toxicological test data for the entire product for this endpoint.

11.1.7 Carcinogenicity
Judgement:
There are no toxicological test data for the entire product for this end point.

11.1.8 Reproductive toxicity
Judgement:
There are no toxicological test data for the entire product for this end point.

11.1.9 Specific target organ toxicity (single exposure)
Judgement:
There are no toxicological test data for the entire product for this end point.

11.1.10 Specific target organ toxicity (repeated exposure)
Judgement:
There are no toxicological test data for the entire product for this end point.

11.1.11 Aspiration hazard
Judgement:
There are no toxicological test data for the entire product for this endpoint.

11.1.12 Additional toxicological information
Data on substances:
Hydrolysis product (ethanol):
Ethanol (64-17-5) is readily and rapidly absorbed from all exposure routes. Ethanol can irritate the eyes and mucous membranes as well as disorders of the central nervous system, nausea and dizziness. Chronic exposure to large amounts of ethanol can cause liver and central nervous system damage.

SECTION 12. Ecological information

12.1 Toxicity
Judgement:
No data known.

12.2 Persistence and Degradability
Judgement:
Reacts with water to form ethanol and silica.
Data on substances:
Hydrolysis product (ethanol):
Ethanol is easily biodegradable.

12.3 Bioaccumulative potential
Judgement:
Bioaccumulation cannot be ruled out.

12.4 Mobility in soil
Judgement:
Insoluble in water.

12.5 Results of PBT and vPvB assessment
There is no information.

12.6 Other adverse effects
not known

SECTION 13. Disposal consideration

13.1 Waste treatment methods

13.1.1 Product
Recommendation:
Material that cannot be reused, refurbished, or recycled should be disposed of at an approved facility in accordance with national, state, and local regulations. Depending on regulations, waste treatment methods may include, for example, landfilling or incineration.

13.1.2 Uncleaned packaging
Recommendation:
Packaging must be completely emptied (drip-free, trickle-free, spatula-clean). Packaging should preferably be reused or recycled, taking into account the applicable local/national regulations. Packaging that cannot be cleaned should be disposed of like the substance.

13.1.3 Waste key number (EG)
No waste key number according to the European Waste Catalog (AVV) can be specified for this product, as only the intended use by the consumer allows assignment. Within the EU, the waste key number must be determined in consultation with the disposal company.

SECTION 14. Transport information

14.1 – 14.4 UN number; UN proper shipping name; transport hazard classes; packing group
Street ADR:

Rating:	Dangerous Goods
14.1 UN No.:	1993
14.2 Designation:	Flammable liquid, n.o.s. (Contains tetraethyl silicate and ethanol)
14.3 Class:	3
14.4 Packing group:	III

Railway RID:

Rating:	Dangerous Goods
14.1 UN No.:	1993
14.2 Designation:	Flammable liquid, n.o.s. (Contains tetraethyl silicate and ethanol)
14.3 Class:	3
14.4 Packing group:	III

Sea transport IMDG code:

Rating:	Dangerous Goods
14.1 UN No.:	1993
14.2 Designation:	Flammable liquid, n.o.s. (Contains tetraethyl silicate and ethanol)
14.3 Class:	3
14.4 Packing group:	III

Air transport ICAO-TI/IATA-DGR:

Rating:	Dangerous Goods
14.1 UN No.:	1993
14.2 Designation:	Flammable liquid, n.o.s. (Contains tetraethyl silicate and ethanol)
14.3 Class:	3
14.4 Packing group:	III

14.5 Environmental Hazards

Dangerous for the environment:	no
Marine Pollutant (IMDG):	no

14.6 Special precautions for users
Relevant information in other sections must be observed.

14.7 Bulk transport according to Annex II of MARPOL and the IBC Code
No bulk carriage in tankers is intended.

SECTION 15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
National and local regulations must be observed.
Labeling information can be found in Chapter 2 of this document.

Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances (Seveso III):

Listing in guideline	Ser. No. in the list	Quantity threshold 1	Quantity threshold 2
FLAMMABLE LIQUIDS	P5c	5,000 t	50,000 t

Notes on employment restrictions:
Observe employment restrictions for young people in accordance with § 22 JArbSchG.
Observe employment restrictions for expectant and breastfeeding mothers in accordance with §§ 11 and 12 MuSchG.

Technical Instructions Air:

CAS no.	Substance	number	class
78-10-4	tetraethyl silicate	5.2.5	I
93925-43-0	Silicic acid (H4SiO4), tetraethyl ester, reaction products with bis(acetyloxy)dioctylstannane	5.2.5	
68299-15-0	Bis(neodecanoyloxy)dioctylstannane	5.2.5	

Water hazard class:
highly hazardous to water (classification according to AwSV, Appendix 1 (5.2))

Other regulations, restrictions and prohibitions:
Chemicals Prohibition Ordinance (ChemVerbotsV): This product is subject to the Chemicals Prohibition Ordinance when placed on the market in Germany.

REACh Annex XVII: This product contains more than 0.1% by weight of dioctyltin compounds. Annex XVII, entry 20 of Regulation 1907/2006 in the current version must be taken into account.

Regulation (EC) No. 649/2012 of the European Parliament and of the Council on exports and imports dangerous chemicals:
Prohibited and/or Restricted

Regulation (EU) No. 2019/1148 concerning the marketing and use of explosives precursors - APPENDIX I. RESTRICTED EXPLOSIVES PRECURSORS:
Not applicable

Regulation (EU) No. 2019/1148 on the marketing and use of explosives precursors - APPENDIX II. REPORTABLE EXPLOSIVES PRECURSORS:
Not applicable

15.2 Chemical Safety Assessment
No Chemical Safety Assessment according to Regulation (EC) 1907/2006 (REACH) has been carried out for this product.

15.3 International Registration Status Information
If relevant information on individual substance inventories is available, this is listed below.

Japan:
ENCS (Handbook of Existing and New Chemical Substances):
This product is listed or in line with the substance inventory.

Australia:
AICS (Australian Inventory of Chemical Substances):
This product is listed or in line with the substance inventory.

Canada:
DSL (Domestic Substance List):
This product is not listed or not in accordance with the substance inventory.

Philippines:
PICCS (Philippine Inventory of Chemicals and Chemical Substances):
This product is not listed or not in accordance with the substance inventory.

Taiwan:
TCSI (Taiwan Chemical Substance Inventory):
This product is listed or in line with the substance inventory. more general
Note: Chemical legislation in Taiwan requires a Phase 1 registration for TCSI listed or TCSI compliant substances when imported into or manufactured in Taiwan above the 100 kg/year threshold (for mixtures this is possible for each ingredient to calculate). The responsibility for this lies with the importer or manufacturer.

European Economic Area (EEA):
REACH (Regulation (EC) No. 1907/2006):
General note: Registration obligations resulting from manufacture in the EEA or import into the EEA by the supplier named in section 1 are fulfilled by the supplier. Registration obligations that arise when importing into the EEA by customers or other downstream users are to be observed by them.

South Korea (Republic of Korea:
AREC (Chemicals Registration and Evaluation Act; "K-REACH"): Please contact your regular contact for more information.

SECTION 16. Other information:

Changes compared with the previous version: 1.1 Complete revision

The information is based on the current state of knowledge and experience. the
Specifications in the safety data sheet do not have the meaning of property assurances.

16.2 Additional Notes:
Explanation of GHS classification information:
Flam. liquor 3; H226: Flammable liquids category 3; Flammable liquid and vapour.
Acute Tox. 4; H332: Acute Toxicity Category 4; Harmful if inhaled.
eye irritation 2; H319: Serious eye damage/eye irritation Category 2; Causes serious eye irritation.
STOT SE 3; H335: Specific target organ toxicity - single exposure Category 3; May cause respiratory irritation.
Rep. 2; H361d: reproductive toxicity Category 2; Suspected of damaging the unborn child.
Aquatic Chronic 4; H413Long-term (chronic) aquatic hazard Category 4; May be harmful to aquatic life: with long lasting effects.
eye irritation 2; H319: Serious eye damage/eye irritation Category 2; Causes serious eye irritation.
Acute Tox. 4; H302: Acute Toxicity Category 4; Harmful if swallowed.
Flam. liquor 3; H226: Flammable liquids category 3; Flammable liquid and vapour.
STOT RE 1; H372: Specific target organ toxicity - repeated exposure Category 1; Causes damage to organs through prolonged or repeated exposure.
Aquatic Chronic 4; H413Long-term (chronic) aquatic hazard Category 4; May be harmful to aquatic life : with long lasting effects.
STOT RE 2; H373: Specific target organ toxicity - repeated exposure Category 2; May cause damage to organs through prolonged or repeated exposure.

Classification	Reason:
Reproductive toxicity, Category 2	Calculation method
Acute toxicity, Category 4, inhalative	Calculation method
Serious eye damage/irritation, category 2	Calculation method
Flammable Liquids, Category 3	Based on test data.
Specific target organ toxicity - repeated exposure, category 1	Calculation method
Specific target organ toxicity - single exposure, category 3	Calculation method

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