

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 09.03.2022

Version number 1

Revision: 12.08.2021

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

- **1.1 Product identifier**
- **Trade name:** Silano Pen - Refill Cartridge
- **Article number:** 320 0047 0, 320 0047 1, 540 0083 0
- **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:** .
- **Application of the substance / the mixture:** Bonding system.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
bredent GmbH & Co.KG
Weißenhornher Straße 2
89250 Senden
Tel: +49 (0) 7309/872-0
Fax: +49 (0) 7309/872-24
- **Further information obtainable from:**
R & D
e-mail: R.D@bredent.com
- **1.4 Emergency telephone number:** (001) 352 323 3500

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Remark**
The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.
- **Classification according to Regulation (EC) No 1272/2008**



flame

Aerosol 1 H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms** GHS02
- **Signal word** Danger
- **Hazard statements**
H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211 Do not spray on an open flame or other ignition source.
P251 Do not pierce or burn, even after use.
P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description:

Active substance with propellant

Mixture of substances listed below with nonhazardous additions.

Dangerous components:

CAS: 106-97-8

butane, pure

EINECS: 203-448-7

 Flam. Gas 1, H220
Press. Gas (Comp.), H280

50-100%

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact:

In cases of frost bites, rinse with plenty of water. Do not remove clothing.

Cover wound with a sterile dressing.

If skin irritation continues, consult a doctor.

After eye contact: Rinse opened eye for several minutes under running water.

After swallowing: If symptoms persist consult 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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing agents: CO₂, sand, extinguishing powder. Do not use water.

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture Carbon monoxide (CO)

5.3 Advice for firefighters

Protective equipment: No special measures required.

Additional information Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions: No special measures required.

6.3 Methods and material for containment and cleaning up:

Ensure adequate ventilation.

Do not flush with water or aqueous cleansing agents

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

Handle with care. Avoid jolting, friction and impact.

Open and handle receptacle with care.

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- **Information about fire - and explosion protection:**
Do not spray onto a naked flame or any incandescent material.
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Pressurised container: protect from sunlight and do not expose to temperatures exceeding 50°C, i.e. electric lights. Do not pierce or burn, even after use.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store only in the original receptacle.
Store in a cool location.
Observe official regulations on storing packagings with pressurised containers.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Do not seal receptacle gas tight.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

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

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

106-97-8 butane, pure

WEL (Great Britain)	Short-term value: 1810 mg/m ³ , 750 ppm Long-term value: 1450 mg/m ³ , 600 ppm Carc (if more than 0.1% of buta-1.3-diene)
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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:**
The usual precautionary measures are to be adhered to when handling chemicals.
Wash hands before breaks and at the end of work.
- **Respiratory protection:**
Not necessary if room is well-ventilated.
Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:** Not required.
- **For the permanent contact gloves made of the following materials are suitable:** Leather gloves
- **Eye protection:**



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**
- Form: Compressed liquefied gas
- Colour: Colourless

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· Odour:	<i>Characteristic</i>
· Odour threshold:	<i>Not determined.</i>
· pH-value:	<i>Not determined.</i>
· Change in condition	
Melting point/freezing point:	<i>Undetermined.</i>
Initial boiling point and boiling range:	<i>-44 °C</i>
· Flash point:	<i>-97 °C</i>
· Flammability (solid, gas):	<i>Not applicable.</i>
· Ignition temperature:	<i>365 °C</i>
· Decomposition temperature:	<i>Not determined.</i>
· Auto-ignition temperature:	<i>Product is not selfigniting.</i>
· Explosive properties:	<i>Not determined.</i>
· Explosion limits:	
Lower:	<i>1.5 Vol %</i>
Upper:	<i>10.9 Vol %</i>
· Vapour pressure at 20 °C:	<i>8300 hPa</i>
· Density at 20 °C:	<i>0.80946 g/cm³</i>
· Relative density	<i>Not determined.</i>
· Vapour density	<i>Not determined.</i>
· Evaporation rate	<i>Not applicable.</i>
· Solubility in / Miscibility with water:	<i>Not miscible or difficult to mix.</i>
· Partition coefficient: n-octanol/water:	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not applicable.</i>
Kinematic:	<i>Not applicable.</i>
· Solvent content:	
Organic solvents:	<i>100.0 %</i>
· 9.2 Other information	<i>No further relevant information available.</i>

SECTION 10: Stability and reactivity

- **10.1 Reactivity** *No further relevant information available.*
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** *Stable at environment temperature.*
- **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.*
- **Primary irritant effect:**
- **Skin corrosion/irritation** *Based on available data, the classification criteria are not met.*
- **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*
- **Respiratory or skin sensitisation** *Based on available data, the classification criteria are not met.*

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- **Additional toxicological information:**
- **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** Based on available data, the classification criteria are not met.
- **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:** Not hazardous for water.
- **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 be specially treated adhering to official regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN1950
- **14.2 UN proper shipping name**
- **ADR** 1950 AEROSOLS
- **IMDG** AEROSOLS
- **IATA** AEROSOLS, flammable
- **14.3 Transport hazard class(es)**
- **ADR**
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- **Class** 2.1 5F Gases.

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· Label	2.1
· IMDG, IATA	
	
· Class	2.1 Gases.
· Label	2.1
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user · Hazard identification number (Kemler code): · EMS Number:	Not applicable. - F-D,S-U
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E0 Not permitted as Excepted Quantity
· Transport category · Tunnel restriction code	2 D
· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E0 Not permitted as Excepted Quantity
· UN "Model Regulation":	UN1950, AEROSOLS, 2.1

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms GHS02**
- **Signal word** Danger
- **Hazard statements**
H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.
- **Precautionary statements**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211 Do not spray on an open flame or other ignition source.
P251 Do not pierce or burn, even after use.
P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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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**

H220 Extremely flammable gas.

H280 Contains gas under pressure; may explode if heated.

· **Department issuing SDS: R & D**

· **Contact: R & D**

· **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 relatif au transport international 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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Gas 1: Flammable gases – Category 1

Aerosol 1: Aerosols – Category 1

Press. Gas (Comp.): Gases under pressure – Compressed gas

· *** Data compared to the previous version altered.**

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