

**Safety Data Sheet**  
according to HPR, Schedule 1

Printing date 12/11/2023

Version number 3

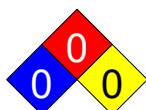
Reviewed on 12/11/2023

**1 Identification**

- **Product identifier**
- **Trade name:** **PressCeramic**
- **CAS Number:**  
66402-68-4
- **EC number:**  
266-340-9
- **Application of the substance / the mixture**  
Manufacture of dental prosthesis  
Lithium disilicate glass-ceramic ingot for the PRESS technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Manufacturer:  
Sagemax Bioceramics, Inc.  
34210 9th Avenue South, Suite 118  
Federal Way, WA 98003 USA  
Tel. +1 253-214-0389 / +1 877-386-0389  
Fax +1 888-856-2615  
  
EC Representative:  
DSSM AG  
Im alten Riet 9  
9494 Schaan/Liechtenstein  
Tel. +423 239 4000  
www.DSSM.group
- **Information department:**  
Quality Assurance / Regulatory Affairs  
USA: support@sagemax.com  
EU: info@sagemax.com
- **Emergency telephone number:**  
24 Hour Emergency Assistance:  
Emergency-Call USA - Infotrac: 1-800-535-5053  
Emergency-Call Canada - Canutec: 1-613-996-6666  
  
General SDS Assistance:  
US: 1-800-533-6825  
Canada: 1-800-263-8182

**2 Hazard identification**

- **Classification of the substance or mixture**  
The substance 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 = 0  
Reactivity = 0

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· **HMIS-ratings (scale 0 - 4)**

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

- **Other hazards** Avoid breathing sanding dust /swarf.

### 3 Composition/Information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**  
66402-68-4 ceramic materials
- **Identification number(s) ---**
- **EC number:** 266-340-9
- **Description:** Lithium disilicate glass-ceramic ingot

### 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**  
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Grinding dust: Rinse out mouth and then drink plenty of water.  
If symptoms persist consult doctor.
- **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:** The product is not flammable.
- **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** Not required.
- **Environmental precautions:**  
No special measures required.  
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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### 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **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:** Store only in the original receptacle.
- **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 section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:**  
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

### 9 Physical and chemical properties

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

Form:	Solid
Color:	According to product specification
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Product is not flammable.

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· <b>Ignition temperature:</b>	Not determined.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
Lower:	Not determined.
Upper:	Not determined.
· <b>Vapor pressure:</b>	Not applicable.
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not applicable.
· <b>Evaporation rate</b>	Not applicable.
· <b>Solubility in / Miscibility with Water:</b>	Insoluble.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· <b>Other information</b>	No further relevant information available.

### 10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** None under normal conditions of storage and use.

### 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Specific symptoms in biological assay:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

#### · **Carcinogenic categories**

#### · **NTP (National Toxicology Program)**

Substance is not listed.

### 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.

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- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
 Water hazard class 3 (Assessment by list): extremely hazardous for water  
 Do not allow product to reach ground water, water course or sewage system, even in small quantities.  
 Danger to drinking water if even extremely small quantities leak into the ground.
- **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:**  
 Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |                                                                                   |                                                                                |
|-----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>UN-Number</b>                                                                |                                                                                |
| · <b>DOT/TDG, ADR, ADN, IMDG, IATA</b>                                            | Void                                                                           |
| · <b>UN proper shipping name</b>                                                  |                                                                                |
| · <b>DOT/TDG, ADR, ADN, IMDG, IATA</b>                                            | Void                                                                           |
| · <b>Transport hazard class(es)</b>                                               |                                                                                |
| · <b>DOT, ADR, ADN, IMDG, IATA</b>                                                |                                                                                |
| · <b>Class</b>                                                                    | Void                                                                           |
| · <b>Packing group</b>                                                            |                                                                                |
| · <b>DOT/TDG, ADR, IMDG, IATA</b>                                                 | Void                                                                           |
| · <b>Environmental hazards:</b>                                                   |                                                                                |
| · <b>Marine pollutant:</b>                                                        | No                                                                             |
| · <b>Special precautions for user</b>                                             | Not applicable.                                                                |
| · <b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b> | Not applicable.                                                                |
| · <b>Transport/Additional information:</b>                                        | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>                                                   | Void                                                                           |

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### 15 Regulatory information

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

· **Sara**

· **Section 355 (extremely hazardous substances):**

Substance is not listed.

· **Section 313 (Specific toxic chemical listings):**

Substance is not listed.

· **TSCA (Toxic Substances Control Act):**

ACTIVE

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Contact:**

· **Date of the latest revision of the safety data sheet** 12/11/2023

· **Abbreviations and acronyms:**

ICAO: International Civil Aviation Organisation

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial 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

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

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