Version number 1

# 1 Identification

- · Product identifier
- Trade name: Dental Lithium Disilicate Glass-Ceramic
- · CAS Number:

66402-68-4

· EC number:

266-340-9

· Application of the substance / the mixture

Manufacture of dental prothesis

Lithium disilicate glass-ceramic ingotfor the CAD/CAM technology

- Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Fuzhou Rick Brown Biomaterials Co., Ltd.

Jiecheng Industrial Park, No.36 Houshan Zhaishan, Nanyu Town, High-Tech District, Fuzhou, Fujian

Tel. +86-0591-23507151 Fax +86-0591-23507152

· Information department: Quality Assurance / Regulatory Affairs

# 2 Hazard(s) 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
- · Hazardpictograms Void · Signal word Void
- · Hazard statements Void
- Classification system:
- · NFPA ratings (scale 0 4)



 $Heal_{th} = 0$ Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH 0

Health = 0

**FIRE** 0

Fire = 0

REACTIVITY 0

Reactivity = 0

- · Other hazards Avoid breathing sanding dust/swarf. · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.

#### 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

# Safety Data Sheet acc. to OSHA HCS

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# Trade name: Dental Lithium Disilicate Glass-Ceramic

# 4 First-aid measures

- Description offirst aid measures
- · General information: No special measures required.
- · After inhalation: Grinding dust: Supplyfresh 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 Nofurther 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 notflammable.
- · Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for fire fighters
- · 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.
- · Methods and material for containment and cleaning up: Pick up mechanically.
- · Reference to other sections

See Section 7for information on safe handling.

See Section 8for information on personal protection equipment.

See Section 13 for disposal information.

# 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.

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# 8 Exposure controls/personal protection

- · Additional information about design of technical systems: No further data; see item 7.
- · Controlparameters
- · 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 According to product specification Color: · Odor: **Odorless** · Odor threshold: Not determined. ·pH-value: Not applicable. · Change in condition Undetermined. Melting point/Melting range: Boiling point/Boiling range: Undetermined. · Flashpoint: Not applicable. Flammability (solid, gaseous): Product is notflammable. · Auto igniting: Not determined. Danger of explosion: Product does not present an explosion hazard. · Explosion limits: Lower: Not determined. Not determined. Upper: · Vapor pressure: Not applicable. · Density: Not determined. Not determined. · Relative density · Vapor density Not applicable. · Evaporation rate Not applicable. · Solubility in / Miscibility with Insoluble. Water: · Partition coefficient (n-octanol/water): Not determined. · Viscosity: Dynamic: Not applicable. Kinematic: Not applicable. Other information No further relevant information available.

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# 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:
- · 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.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not 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: Generally not hazardous for water · 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.

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UN-Number DOT, ADR, RID, ADN, ADN, IMDG, IA	<b>T</b> A Void
UNproper shipping name DOT, ADR,RID,ADN, ADN,IMDG,IAT	<b>T</b> A Void
Transport hazard class(es)	
DOT, ADR,RID,ADN, ADN,IMDG, IA Class	TA Void
Packing group DOT, ADR,RID,ADN,IMDG, IATA	Void
Environmental hazards: Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	Product is not classified as a dangerous goodfor transport (ADR,IMDG, IATA).
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):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not listed.

- · Proposition 65
- · Chemicals known to cause cancer:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

Substance is not listed.

· TLV (Threshold Limit Value established by ACGIH)

Substance is not listed.

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# Trade name: Dental Lithium Disilicate Glass-Ceramic

# 15 Regulatory information

· NIOSH-Ca (National Institute for Occupational Safety and Health)

Substance is not listed.

- · GHS label elements Void
- · Hazardpictograms Void
- · Signal word Void
- · Hazard statements Void
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

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.

- · Date of preparation / last revision 20/12/2022
- · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereusespar chemin defer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord européen sur le transport des marchandises dangereusespar Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Codefor 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

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