

**Safety data sheet**  
**according to 1907/2006/EC, Article 31**

Printing date 11.12.2023

Version number 3 (replaces version 2)

Revision: 11.12.2023

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1 Product identifier****Trade name:** NexxZr T, NexxZr T Multi**CAS Number:**

66402-68-4

**EC number:**

266-340-9

**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**

Manufacture of dental prosthesis

Yttrium-stabilized zirconium oxide disc for the CAD/CAM technology

**1.3 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

**Further information obtainable from:**

Quality Assurance / Regulatory Affairs

USA: support@sagemax.com

EU: info@sagemax.com

**1.4 Emergency telephone number:** Tel. +423 239 4000 (DSSM AG)**SECTION 2: Hazards identification****2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

The substance is not classified, according to the GB CLP regulation.

**2.2 Label elements****Labelling according to Regulation (EC) No 1272/2008 Void****Hazard pictograms** Void**Signal word** Void**Hazard statements** Void**2.3 Other hazards** Avoid breathing sanding dust /swarf.**Results of PBT and vPvB assessment****PBT:** Not applicable.**vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****3.1 Substances****CAS No. Description**

CAS: 66402-68-4 ceramic materials

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- Identification number(s) ---
- EC number: 266-340-9

#### SECTION 4: First aid measures

- **4.1 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.
- **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:**  
The product is not flammable.  
Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

#### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **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**  
Only adequately trained personnel should handle this product.  
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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.

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- **7.3 Specific end use(s)** No further relevant information available.

#### SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Usual hygienic measures for dental practice and dental laboratories.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.
- **Respiratory protection:**  
Mechanical processing:  
Use respiratory protective device against the effects of dust.
- **Recommended filter device for short term use:** Filter P1
- **Hand protection**  
Protective gloves should always be worn during mechanical and thermal processing.  
After use of gloves apply skin-cleaning agents and skin cosmetics.
- **Material of gloves**  
Mechanical processing:  
Leather gloves  
Strong material gloves
- **Penetration time of glove material**  
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **Eye/face protection**  
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

#### SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Colour:** According to product specification
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** Undetermined.
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Product is not flammable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **pH** Not applicable.
- **Viscosity:**
- **Kinematic viscosity** Not applicable.
- **Dynamic:** Not applicable.
- **Solubility**
- **water:** Insoluble.

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|---|-----------------|
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure:                                  | Not applicable. |
| · Density and/or relative density                   |                 |
| · Density:  | Not determined. |
| · Relative density                                  | Not determined. |
| · Vapour density                                    | Not applicable. |
- 
- |   |   |
|---|---|
| · 9.2 Other information   |   |
| · Appearance:   |   |
| · Form:   | Solid   |
| · Important information on protection of health and environment, and on safety. |   |
| · Ignition temperature:   | Not determined.                               |
| · Explosive properties:   | Product does not present an explosion hazard. |
| · Change in condition   |   |
| · Evaporation rate  | Not applicable.                               |
- 
- |   |      |
|---|------|
| · Information with regard to physical hazard classes                        |      |
| · Explosives  | Void |
| · Flammable gases   | Void |
| · Aerosols  | Void |
| · Oxidising gases   | Void |
| · Gases under pressure  | Void |
| · Flammable liquids   | Void |
| · Flammable solids  | Void |
| · Self-reactive substances and mixtures                                     | Void |
| · Pyrophoric liquids  | Void |
| · Pyrophoric solids   | Void |
| · Self-heating substances and mixtures                                      | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids   | Void |
| · Oxidising solids  | Void |
| · Organic peroxides   | Void |
| · Corrosive to metals   | Void |
| · Desensitised explosives   | Void |

#### SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 10.2 Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 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: None under normal conditions of storage and use.

#### SECTION 11: Toxicological information

- 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- Acute toxicity Based on available data, the classification criteria are not met.
- 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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- **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.
- **Additional toxicological information:** No further relevant information available.
- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>
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Substance is not listed.
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### 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:** Not hazardous for water.

### SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**  
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |  |      |
|--|------|
| · <b>14.1 UN number or ID number</b>     |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>    | Void |
| · <b>14.2 UN proper shipping name</b>    |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>    | Void |
| · <b>14.3 Transport hazard class(es)</b> |      |
| · <b>ADR/RID/ADN, ADN, IMDG, IATA</b>    |      |
| · <b>Class</b>                           | Void |
| · <b>14.4 Packing group</b>              |      |
| · <b>ADR/RID/ADN, IMDG, IATA</b>         | Void |
| · <b>14.5 Environmental hazards:</b>     |      |
| · <b>Marine pollutant:</b>               | No   |

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· <b>14.6 Special precautions for user</b>	Not applicable.
· <b>14.7 Maritime transport in bulk according to IMO instruments</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

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### 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.*

- **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  
 CAS: Chemical Abstracts Service (division of the American Chemical Society)  
 PBT: Persistent, Bioaccumulative and Toxic  
 vPvB: very Persistent and very Bioaccumulative
- **\* Data compared to the previous version altered.**

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