

## Safety data sheet according to UK REACH

Printing date 05.08.2025

Version number 2 (replaces version 1)

Revision: 05.08.2025

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

- **1.1 Product identifier**
- **Trade name:** NexxZr S (Disc)
- **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:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

### SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
The product 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

- **3.2 Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1314-23-4	zirconium oxide	50-100%
EINECS: 215-227-2	substance with a Community workplace exposure limit	
Reg.nr.: 05-2118470272-46-XXXX		

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· **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**
- **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.
- **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.
- **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.  
Do not allow to enter sewers/ surface or ground water.
- **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.  
Ensure good ventilation/exhaustion at the workplace.
- **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:**

CAS: 1314-23-4 zirconium oxide

WEL	Short-term value: 10 mg/m <sup>3</sup> Long-term value: 5 mg/m <sup>3</sup> as Zr
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- **Regulatory information** WEL: EH40/2011

- **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.

Avoid breathing sanding dust /swarf.

- **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 -**

- **Eyeface 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:** Whitish

- **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.

- **Flash point:** Not applicable.

- **pH** Not applicable.

- **Viscosity:**

- **Kinematic viscosity** Not applicable.

- **Dynamic:** Not applicable.

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· <b>Solubility</b>	
· <b>water:</b>	<i>Insoluble.</i>
· <b>Partition coefficient n-octanol/water (log value)</b>	<i>Not determined.</i>
· <b>Vapour pressure:</b>	<i>Not applicable.</i>
· <b>Density and/or relative density</b>	
· <b>Density at 20 °C:</b>	<i>3-3.5 g/cm<sup>3</sup></i>
· <b>Relative density</b>	<i>Not determined.</i>
· <b>Vapour density</b>	<i>Not applicable.</i>
· <b>9.2 Other information</b>	
· <b>Appearance:</b>	
· <b>Form:</b>	<i>Solid</i>
· <b>Important information on protection of health and environment, and on safety.</b>	
· <b>Ignition temperature:</b>	<i>Product is not selfigniting.</i>
· <b>Explosive properties:</b>	<i>Product does not present an explosion hazard.</i>
· <b>Change in condition</b>	
· <b>Evaporation rate</b>	<i>Not applicable.</i>
· <b>Information with regard to physical hazard classes</b>	
· <b>Explosives</b>	<i>Void</i>
· <b>Flammable gases</b>	<i>Void</i>
· <b>Aerosols</b>	<i>Void</i>
· <b>Oxidising gases</b>	<i>Void</i>
· <b>Gases under pressure</b>	<i>Void</i>
· <b>Flammable liquids</b>	<i>Void</i>
· <b>Flammable solids</b>	<i>Void</i>
· <b>Self-reactive substances and mixtures</b>	<i>Void</i>
· <b>Pyrophoric liquids</b>	<i>Void</i>
· <b>Pyrophoric solids</b>	<i>Void</i>
· <b>Self-heating substances and mixtures</b>	<i>Void</i>
· <b>Substances and mixtures, which emit flammable gases in contact with water</b>	<i>Void</i>
· <b>Oxidising liquids</b>	<i>Void</i>
· <b>Oxidising solids</b>	<i>Void</i>
· <b>Organic peroxides</b>	<i>Void</i>
· <b>Corrosive to metals</b>	<i>Void</i>
· <b>Desensitised explosives</b>	<i>Void</i>

### 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.*

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- **Specific symptoms in biological assay:**
- **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.
- **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.
- **11.2 Information on other hazards**

· <b>Endocrine disrupting properties</b>
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None of the ingredients is 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:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

### 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.

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### 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 |

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· <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>	Not applicable.
· <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** None of the ingredients is listed.
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
The product is a medical device according to the Directive 93/42/EEC.
- **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:

IMO: International Maritime Organization

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

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

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

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