

## Safety Data Sheet according to HPR, Schedule 1

Printing date 08/07/2020

Version number 1

Reviewed on 04/04/2019

### 1 Identification

· **Product identifier**

· **Trade name:** **NexxZr T/ + / S (Disc)**

· **Application of the substance / the mixture**

Manufacture of dental prothesis

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

AB Ardent

Generatorgatan 8

SE-19560 Arlandastad / Sweden

Tel. +46 8594 412 57

Fax +46 8591 161 83

· **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 product is not classified, according to the Globally Harmonized System (GHS).

· **Label elements**

· **GHS label elements** Void

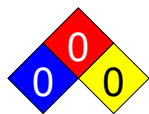
· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

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

### 3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**· **Description:** Mixture of the substances listed below with nonhazardous additions.· **Dangerous components:**

CAS: 1314-23-4	zirconium oxide	60-100% w/w *
CAS: 1314-36-9	yttrium oxide	1-5% w/w *
CAS: 12055-23-1	hafnium dioxide	1-5% w/w *

\* Actual concentration ranges are withheld as a trade secret.

### 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.

· **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.· **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.

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.  
Ensure good ventilation/exhaustion at the workplace.
- **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 item 7.
- **Control parameters**

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

CAS: 1314-23-4 zirconium oxide

EL	Short-term value: 10 mg/m <sup>3</sup> Long-term value: 5 mg/m <sup>3</sup> as Zr
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CAS: 1314-36-9 yttrium oxide

EL	Long-term value: 1 mg/m <sup>3</sup> as Y
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CAS: 12055-23-1 hafnium dioxide

EL	Long-term value: 0.5 mg/m <sup>3</sup> as Hf
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- **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.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Avoid breathing sanding dust /swarf.
- **Breathing equipment:**  
Mechanical processing:  
Use respiratory protective device against the effects of dust.
- **Recommended filter device for short term use:** Filter P1
- **Protection of hands:**  
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 gloves
- **Penetration time of glove material -**

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· **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:	Whitish
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.· **Auto igniting:** Product is not selfigniting.· **Danger of explosion:** Product does not present an explosion hazard.· **Vapor pressure:** Not applicable.

Density at 20 °C:	3-3.5 g/cm <sup>3</sup>
Relative density	Not determined.
Vapor density	Not applicable.
Evaporation rate	Not applicable.

· **Solubility in / Miscibility with Water:**

Insoluble.

· **Partition coefficient (n-octanol/water):** Not determined.· **Viscosity:**

Dynamic:	Not applicable.
Kinematic:	Not applicable.

· **Other information** 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.

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### 11 Toxicological information

- **Information on toxicological effects**
- **Additional toxicological information:**
- **Carcinogenic categories**
- **NTP (National Toxicology Program)**

None of the ingredients is 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:** 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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

- |  |                 |
|--|-----------------|
| · <b>UN-Number</b>                     | Void            |
| · <b>DOT/TDG, ADR, ADN, IMDG, IATA</b> | Void            |
| · <b>UN proper shipping name</b>       | Void            |
| · <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>        | Not applicable. |
| · <b>Special precautions for user</b>  | Not applicable. |

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- |  |  |
|--|--|
| <b>· Transport in bulk according to Annex II of MARPOL73/78 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   |

### 15 Regulatory information

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

- **Sara**

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

None of the ingredients is listed.

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

None of the ingredients is listed.

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

CAS: 1314-23-4    zirconium oxide

CAS: 1314-36-9    yttrium oxide

CAS: 12055-23-1    hafnium dioxide

- **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 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 the latest revision of the safety data sheet** 08/07/2020 / -

- **Abbreviations and acronyms:**

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

ELINCS: European List of Notified 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