

SAFETY DATA SHEETS

This SDS packet was issued with item:

071284751

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071286715 071288307 071289891

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071285303 071289537 071289784

Safety Data Sheet
acc. to OSHA HCS

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

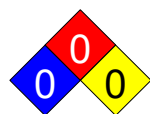
General SDS Assistance:

US: 1-800-533-6825

Canada: 1-800-263-8182

2 Hazard(s) 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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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	50-100%
CAS: 1314-36-9	yttrium oxide	2.5-<10%
CAS: 12055-23-1	hafnium dioxide	0.1-<2.5%

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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· Protective Action Criteria for Chemicals

· PAC-1:

CAS: 1314-23-4	zirconium oxide	14 mg/m ³
CAS: 1314-36-9	yttrium oxide	3.8 mg/m ³
CAS: 12055-23-1	hafnium dioxide	1.8 mg/m ³

· PAC-2:

CAS: 1314-23-4	zirconium oxide	110 mg/m ³
CAS: 1314-36-9	yttrium oxide	43 mg/m ³
CAS: 12055-23-1	hafnium dioxide	19 mg/m ³

· PAC-3:

CAS: 1314-23-4	zirconium oxide	680 mg/m ³
CAS: 1314-36-9	yttrium oxide	260 mg/m ³
CAS: 12055-23-1	hafnium dioxide	120 mg/m ³

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

PEL Long-term value: 5 mg/m³
as Zr

REL Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

TLV Short-term value: 10 mg/m³
Long-term value: 5 mg/m³
as Zr

CAS: 1314-36-9 yttrium oxide

PEL Long-term value: 1 mg/m³
as Y

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REL Long-term value: 1 mg/m³
as YTLV Long-term value: 1 mg/m³
as Y**CAS: 12055-23-1 hafnium dioxide**PEL Long-term value: 0.5 mg/m³
as HfREL Long-term value: 0.5 mg/m³
as HfTLV Long-term value: 0.5 mg/m³
as Hf

· **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 -**

· **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.

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· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Vapor pressure:	Not applicable.
· Density at 20 °C (68 °F):	3-3.5 g/cm ³ (25.035-29.208 lbs/gal)
· 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.

11 Toxicological information

- **Information on toxicological effects**
- **Additional toxicological information:**
- **Carcinogenic categories**

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

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.

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- **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

- | | |
|--|--|
| · UN-Number | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void | |
| · UN proper shipping name | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA Void | |
| · Transport hazard class(es) | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT, ADR/RID/ADN, IMDG, IATA Void | |
| · Environmental hazards: | Not applicable. |
| · Special precautions for user | Not applicable. |
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | |
| Not applicable. | |
| · Transport/Additional information: | Product is not classified as a dangerous good for 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):**

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

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

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

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

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

CAS: 1314-23-4 | zirconium oxide

A4

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

None of the ingredients is listed.

· **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 preparation / last revision** 08/07/2020 / -· **Abbreviations and acronyms:**

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

IMDG: International Maritime Code for 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

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit