

Safety Data Sheet
according to HPR, Schedule 1

Printing date 08/05/2025

Version number 2

Reviewed on 08/05/2025

1 Identification

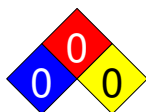
- **Product identifier**
- **Trade name:** **NexxZr S (Disc)**
- **Application of the substance / the mixture**
Manufacture of dental prothesis
Yttrium-stabilized zirconium oxide disc for the CAD/CAM technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Manufacturer:
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:
DSSM AG
Im alten Riet 9
9494 Schaan/Liechtenstein
Tel. +423 239 4000
www.DSSM.group
- **Information department:**
Quality Assurance / Regulatory Affairs
USA: support@sagemax.com
EU: info@sagemax.com
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA/Canada - Infotrac: 1-800-535-5053

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 | Health = 0 |
| FIRE | 0 | Fire = 0 |
| REACTIVITY | 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.

Do not allow to enter sewers/ surface or ground water.

· **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 section 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/m³
Long-term value: 5 mg/m³
as Zr

CAS: 1314-36-9 yttrium oxide

EL Long-term value: 1 mg/m³
as Y

CAS: 12055-23-1 hafnium dioxide

EL 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 -**

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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:** Product is not flammable.· **Ignition temperature:** 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/cm³· **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**
- **Acute toxicity:** Based on available data, the classification criteria are not met.
- **Specific symptoms in biological assay:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **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:**
Water hazard class 1 (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.
- **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.

14 Transport information

- | | |
|--|------|
| · UN-Number | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT/TDG, ADR, ADN, IMDG, IATA | |
| · Class | Void |

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| | |
|--|--|
| · Packing group | |
| · DOT/TDG, ADR, 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

· **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.

· **Contact:**

· **Date of the latest revision of the safety data sheet** 08/05/2025 / 1

· **Abbreviations and acronyms:**

IMO: International Maritime Organization

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)

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Trade name: NexxZr S (Disc)

PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative

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· * Data compared to the previous version altered.

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