

Version number 2 Reviewed on 08/05/2025 Printing date 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(s) identification

· Classification of the substance or mixture

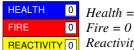
The product is not classified, according to the Globally Harmonized System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0Fire = 0

· HMIS-ratings (scale 0 - 4)



0 Health = 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	<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.

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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· Protective Action	Criteria for Chemicals	(Contd. of page 2
· PAC-1:	•	
CAS: 1314-23-4	zirconium oxide	14 mg/m3
CAS: 1314-36-9	yttrium oxide	3.8 mg/m3
CAS: 12055-23-1	hafnium dioxide	1.8 mg/m <sup>3</sup>
· PAC-2:		,
CAS: 1314-23-4	zirconium oxide	110 mg/m3
CAS: 1314-36-9	yttrium oxide	43 mg/m3
CAS: 12055-23-1	hafnium dioxide	19 mg/m3
· PAC-3:		,
CAS: 1314-23-4	zirconium oxide	680 mg/m3
CAS: 1314-36-9	yttrium oxide	260 mg/m <sup>3</sup>
CAS: 12055-23-1	hafnium dioxide	120 mg/m3

# 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.

	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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1 1	Long-term value: 1 mg/m³
	as Y
1 1	Long-term value: 1 mg/m³
	as Y
CAS:	12055-23-1 hafnium dioxide
PEL	Long-term value: 0.5 mg/m³
	as Hf
	Long-term value: 0.5 mg/m <sup>3</sup>
	as Hf
	Long-term value: 0.5 mg/m <sup>3</sup>
	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).

Information on basic physical and General Information	chemical properties	
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.	

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· Ignition temperature:	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/cm³ (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/w	ater): 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.
- $\cdot \textbf{Incompatible materials:} \ No \ further \ relevant \ information \ available.$
- · Hazardous decomposition products: None under normal conditions of storage and use.

## 11 Toxicological information

- · Information on toxicological effects
- · 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.

· 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.

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- · 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.

UN-Number DOT, ADR/RID/ADN, ADN, IMDG, IAT	TA Void
UN proper shipping name DOT, ADR/RID/ADN, ADN, IMDG, IAT	<b>TA</b> Void
Transport hazard class(es)	
DOT, ADR/RID/ADN, ADN, IMDG, IAT Class	<b>TA</b> 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 MARPOL73/78 and the IBC Code	of 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.

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· Section 313 (Spec	rific toxic chemical listings):
None of the ingred	lients is listed.
· TSCA (Toxic Sub	stances Control Act):
CAS: 1314-23-4	zirconium oxide
CAS: 1314-36-9	yttrium oxide
CAS: 12055-23-1	hafnium dioxide

#### · 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)

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.

- · Contact:
- · Date of preparation / last revision 08/05/2025 / 1
- · 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

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

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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

OSHA: Occupational Safety & Healt TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit

· \* Data compared to the previous version altered.

US