

Date of issue: 05.08.2025 Version number 2 Revision: 05.08.2025

Not classified as hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Other means of identification
- · Trade name: NexxZr S (Disc)
- · 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 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

Importer:

Ivoclar Vivadent Pty. Ltd.

1-5 Overseas Drive

Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· Further information obtainable from:

Quality Assurance / Regulatory Affairs

USA: support@sagemax.com EU: info@sagemax.com

· Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· Classification of the substance or mixture

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

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Other hazards Avoid breathing sanding dust /swarf.
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.
- · Dangerous components:

CAS: 1314-23-4 zirconium oxide

50-100%

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CAS: 1314-36-9 | *yttrium oxide*

2.5-10%

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 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

- · Suitable extinguishing agents: The product is not flammable.
- · Special hazards arising from the substance or mixture No further relevant information available.
- · 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.

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 fire and explosion protection: No special measures required.
- · 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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· Specific end use(s) No further relevant information available.

8 Exposure controls and personal protection

· Appropriate engineering controls No further data; see section 7.

· Ingredients with limit values that require monitoring at the workplace:

CAS: 1314-23-4 zirconium oxide

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

CAS: 1314-36-9 yttrium oxide

WES Long-term value: 1 mg/m³ as Y

- · Additional information: The lists valid during the making were used as basis.
- · 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
- · 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 material 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

· General Information

· Appearance:

Form: Solid
Colour: Whitish
Odour: Odourless
Odour threshold: Not determined.
pH-value: Not applicable.

· Change in condition

Melting point/freezing point: Undetermined.
 Initial boiling point and boiling range: Undetermined.
 Flash point: Not applicable.

Flammability Product is not flammable.
Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

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Vapour pressure: Not applicable.
 Density at 20 °C: 3-3.5 g/cm³
 Relative density Not determined.
 Vapour 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.

· Particle characteristics Not determined.

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
- · Acute toxicity Based on available data, the classification criteria are not met.
- · 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.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour 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 (German Regulation) (Self-assessment): slightly hazardous for water

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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 packaging:
- · Recommendation: Disposal must be made according to official regulations.

Transport information	
UN-Number	
ADG, ADN, IMDG, IATA	Void
UN proper shipping name	
ADG, ADN, IMDG, IATA	Void
Transport hazard class(es)	
ADG, ADN, IMDG, IATA	
Class	Void
Packing group	
ADG, IMDG, IATA	Void
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of	^c Marpol
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
- · Australian Inventory of Industrial Chemicals

CAS: 1314-23-4 zirconium oxide CAS: 1314-36-9 yttrium oxide

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· GHS label elements Void

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- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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.

· 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:
- · 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

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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