

Printing date 11.12.2023 Version number 3 Revision: 11.12.2023

1 Identification of the substance or mixture and of the supplier

· Product identifier

· Trade name: NexxZr T, NexxZr T Multi

· CAS Number:

66402-68-4

· EC number:

266-340-9

· 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

EC Representative:

DSSMAG

Im alten Riet 9

9494 Schaan/Liechtenstein

Tel. +423 239 4000

www.DSSM.group

· Further information obtainable from:

Quality Assurance / Regulatory Affairs

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

· Emergency telephone number: 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

· Classification of the substance or mixture

The substance 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/Information on ingredients

- · Chemical characterisation: Substances
- · CAS No. Description

CAS: 66402-68-4 ceramic materials

· Identification number(s) ---

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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.

Mechanical effects only.

· 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.

Use fire extinguishing methods suitable to surrounding conditions.

- · 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.
- · 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.

- · 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.
- · Specific end use(s) No further relevant information available.

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8 Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see section 7.
- Ingredients with limit values that require monitoring at the workplace: Not required.
- · 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.

· 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

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· 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: According to product specification

Odour:
Odour threshold:
pH-value:
Odourless
Not determined.
Not applicable.

· Change in condition

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

· Flammability (solid, gas): Product is not flammable.

· **Ignition temperature:** Not determined.

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

· Explosion limits:

Lower: Not determined.
Upper: Not determined.
Vapour pressure: Not applicable.
Density: Not determined.
Relative density Not determined.
Vapour density Not applicable.
Evaporation rate Not applicable.

· Solubility in / Miscibility with

· water: Insoluble.

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· 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
- · Acute toxicity Based on available data, the classification criteria are not met.
- · 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.
- · Additional toxicological information: No further relevant information available.

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: Not hazardous for water.
- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

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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 NZS/RID/ADN, ADN, IMDG, IATA	Void
UN proper shipping name NZS/RID/ADN, ADN, IMDG, IATA	Void
Transport hazard class(es)	
NZS/RID/ADN, ADN, IMDG, IATA Class	Void
Packing group NZS/RID/ADN, IMDG, IATA	Void
Environmental hazards: Marine pollutant:	No
Special precautions for user	Not applicable.
Transport in bulk according to Annex II of and the IBC Code	Marpol 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
- · New Zealand Inventory of Chemicals

Substance is listed.

· HSNO Approval numbers

Substance is not listed.

- · **GHS label elements** Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I Substance is not listed.
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

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· 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:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

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

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