

Printing date 12/11/2023 Version number 3 Reviewed on 12/11/2023

## 1 Identification

- · Product identifier
- · Trade name: NexxZr T, NexxZr T Multi
- · CAS Number:

66402-68-4

· EC number:

266-340-9

· 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

· 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 substance 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)



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· HMIS-ratings (scale 0 - 4)



- · 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: Substances
- · CAS No. Description

CAS: 66402-68-4 ceramic materials

- · Identification number(s) ---
- · EC number: 266-340-9

### 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.

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

- · Extinguishing media
- · Suitable extinguishing agents:

The product is not flammable.

Use fire fighting measures that suit the environment.

- · 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.

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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.

· Protective Action Criteria for Chemicals

· PAC-1:

Substance is not listed.

· PAC-2:

Substance is not listed.

· PAC-3:

Substance is not listed.

## 7 Handling and storage

- · Handling:
- · Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

- · 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: Not required.
- · 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.

· 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

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· 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.

· Eve 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: According to product specification · 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. · Ignition temperature: Not determined. Danger of explosion: Product does not present an explosion hazard. · Explosion limits: Lower: Not determined. Upper: Not determined. · Vapor pressure: Not applicable. · Density: Not determined. · Relative density Not determined. Not applicable. · Vapor density Not applicable. · Evaporation rate · Solubility in / Miscibility with Insoluble. Water: · Partition coefficient (n-octanol/water): Not determined.

## 10 Stability and reactivity

· Viscosity: Dynamic:

Kinematic:

· Other information

- · 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.

No further relevant information available.

Not applicable.

Not applicable.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.

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- · 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:
- · 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: No further relevant information available.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not 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.
- · 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

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· Transport hazard class(es)	
· DOT, ADR/RID/ADN, ADN, IMDG, IATA	A
· Class	Void
· Packing group	
· DOT, ADR/RID/ADN, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II o	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):

Substance is not listed.

Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not listed.

· Hazardous Air Pollutants

Substance is not listed.

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

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

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

Substance is not listed.

· TLV (Threshold Limit Value)

Substance is not listed.

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

Substance is not listed.

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- · 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 Regulation 2017/745 on Medical Devices (MDR). 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 12/11/2023
- · 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

DOT: US Department of Transportation

IATA: International Air Transport Association

EINECS: European Inventory of Existing Commercial 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

· \* Data compared to the previous version altered.

- US