

Version number 1

Printing date 12/18/2020

Reviewed on 12/18/2020

1 Identification
· Product identifier
Trade name: <u>NexxZr T Multi</u>
· CAS Number:
66402-68-4 • EC number:
266-340-9
· Application of the substance / the mixture Manufacture of dental prothesis
<i>Yttrium-stabilized zirconium oxide disc for the CAD/CAM technology</i>
• Details of the supplier of the safety data sheet
· Manufacturer/Supplier: Manufacturer:
Manujacturer. 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:
AB Ardent
Generatorgatan 8 SE-19560 Arlandastad / Sweden
<i>Tel.</i> +46 8594 412 57
Fax +46 8591 161 83
· 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
Emergency-Cuit Cunada - Cunalec. 1-015-990-0000
General SDS Assistance: US: 1-800-533-6825
Canada: 1-800-263-8182
2 Hazard identification
· Classification of the substance or mixture

 $\begin{array}{l} \hline Classification of the substance or mixture \\ The substance is not classified, according to the Globally Harmonized System (GHS). \\ \hline Label elements \\ \hline GHS label elements Void \\ \hline Hazard pictograms Void \\ \hline Signal word Void \\ \hline Hazard statements Void \\ \hline Classification system: \\ \hline NFPA ratings (scale 0 - 4) \\ \hline Health = 0 \\ Fire = 0 \\ Reactivity = 0 \end{array}$

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FIRE

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· HMIS-ratings (scale 0 - 4)

HEALTH 0 Health = 00 Fire = 0**REACTIVITY O** Reactivity = 0

· Other hazards Avoid breathing sanding dust /swarf.

3 Composition/Information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description
- 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.
- · Reference to other sections
- See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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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 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 item 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
- · 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).

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Information on basic physical and	chemical properties
General Information	
Appearance:	a 1.1
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.
Auto igniting:	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.
Vapor density	Not applicable.
Evaporation rate	Not applicable.
Solubility in / Miscibility with	
Water:	Insoluble.
Partition coefficient (n-octanol/wat	er): Not determined.
Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.

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:

• 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.

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.

· 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, ADR, ADN, IMDG, IATA		
· Class	Void	
· Packing group		
DOT/TDG, ADR, IMDG, IATA	Void	

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· Environmental hazards:	
• Marine pollutant:	No
· Special precautions for user	Not applicable.
• Transport in bulk according to Annex A MARPOL73/78 and the IBC Code	II 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):

Substance is not listed.

• Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is not 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.

Date of the latest revision of the safety data sheet 12/18/2020 / Abbreviations and acronyms:
 ICAO: International Civil Aviation Organisation
 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 Substances)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative