## **SAFETY DATA SHEETS**

## This SDS packet was issued with item:

071286822

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071282987 071283001 071283530 071283571 071283605 071284157 071284215 071284231 071284249 071284256 071284801 071285477 071286277 071286285 071286301 071286319 071286343 071286350 071286384 071286442 071286624 071286665 071286871 071286897 071286905 071286913 071286939



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#### 1 Identification

- · Product identifier
- · Trade name: NexxZr + 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:

AB Ardent

Generatorgatan 8

SE-19560 Arlandastad / Sweden

Tel. +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

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

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.
- · 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.

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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 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.

· Eve protection:

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

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Physical and chemical proper	rties
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.
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	ter): 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.

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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.

· 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, ÂDR/RÎD/ADN, ADN, IMDG, IATA Void
- · Transport hazard class(es)
- · DOT, ADR/RID/ADN, ADN, IMDG, IATA
- · Class Void

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· 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 I.	I 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.

- · 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 established by ACGIH)

Substance is not listed.

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

Substance is not listed.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void

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· 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 preparation / last revision 08/07/2020 / -

· 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 européen sur le transport 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

ACGIH: American Conference of Governmental Industrial Hygienists 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

- US