

SAFETY DATA SHEETS

This SDS packet was issued with item:

071289974

N/A

Safety Data Sheet
acc. to OSHA HCS

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 prosthesis

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:

DSSM AG

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

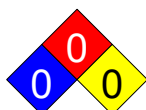
General SDS Assistance:

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)**

Health = 0

Fire = 0

Reactivity = 0

(Contd. on page 2)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/11/2023

Version number 3

Reviewed on 12/11/2023

Trade name: **NexxZr T, NexxZr T Multi**

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **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.

(Contd. on page 3)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/11/2023

Version number 3

Reviewed on 12/11/2023

Trade name: **NexxZr T, NexxZr T Multi**

(Contd. of page 2)

- **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

(Contd. on page 4)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/11/2023

Version number 3

Reviewed on 12/11/2023

Trade name: **NexxZr T, NexxZr T Multi**

(Contd. of page 3)

· **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

· **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.

· **Vapor 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.

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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/11/2023

Version number 3

Reviewed on 12/11/2023

Trade name: **NexxZr T, NexxZr T Multi**

(Contd. of page 4)

- **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

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/11/2023

Version number 3

Reviewed on 12/11/2023

Trade name: *NexxZr T, NexxZr T Multi*

(Contd. of page 5)

- | | |
|---|--|
| · Transport hazard class(es) | |
| · DOT, ADR/RID/ADN, ADN, IMDG, IATA | |
| · 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 of MARPOL 73/78 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.

(Contd. on page 7)

Safety Data Sheet

acc. to OSHA HCS

Printing date 12/11/2023

Version number 3

Reviewed on 12/11/2023

Trade name: **NexxZr T, NexxZr T Multi**

(Contd. of page 6)

- **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