

Safety Data Sheet according to HPR, Schedule 1

Printing date 08/10/2020

Version number 1


Reviewed on 10/22/2019

1 Identification

- **Product identifier**
- **Trade name:** ***NexxZr+ Liquid B3, B4***
- **Application of the substance / the mixture** *Manufacture of dental prothesis*
- **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 identification

- **Classification of the substance or mixture**
Skin Corrosion - Category 1B H314 Causes severe skin burns and eye damage.
Serious Eye Damage - Category 1 H318 Causes serious eye damage.
- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**



GHS05
- **Signal word** *Danger*
- **Hazard-determining components of labeling:**
inorganic nitrate salts
- **Hazard statements**
Causes severe skin burns and eye damage.

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· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· Classification system:
· NFPA ratings (scale 0 - 4)


Health = 3

Fire = 0

Reactivity = 0

· HMIS-ratings (scale 0 - 4)


Health = *3

Fire = 0

Reactivity = 0

3 Composition/Information on ingredients

· Chemical characterization: Mixtures

· Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 10031-51-3	Erbium(III) nitrate pentahydrate	1-5% w/w *
CAS: 7782-61-8	Iron(III) nitrate nonahydrate	1-5% w/w *

* Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

· Description of first aid measures
· After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

· After skin contact: Immediately rinse with water.

· After eye contact:

Rinse opened eye for several minutes under running water.

Call a doctor immediately.

· After swallowing:

Rinse out mouth and then drink plenty of water.

Seek medical treatment.

· 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: Use fire fighting measures that suit the environment.

· Special hazards arising from the substance or mixture No further relevant information available.

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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 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:** Store away from metals.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Protect from heat and direct sunlight.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.
Immediately remove all soiled and contaminated clothing.
Avoid contact with the eyes and skin.
- **Breathing equipment:** Not required.

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· Protection of hands:


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
After use of gloves apply skin-cleaning agents and skin cosmetics.

· Material of gloves

Natural rubber, NR

Chloroprene rubber, CR

Nitrile rubber, NBR

Butyl rubber, BR

Fluorocarbon rubber (Viton)

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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:


Tightly sealed goggles

9 Physical and chemical properties

· Information on basic physical and chemical properties
· General Information
· Appearance:

Form:	Fluid
Color:	Yellowish
Odor:	Characteristic
Odor threshold:	Not determined.

· pH-value at 20 °C: < 2

· Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.

· Flash point: Undetermined.

· Flammability (solid, gaseous): Not applicable.

· Auto igniting: Product is not selfigniting.

· Danger of explosion: Product does not present an explosion hazard.

· Vapor pressure: Not determined.

· Density: Not determined.

· Relative density Not determined.

· Vapor density Not determined.

· Evaporation rate Not determined.

· Solubility in / Miscibility with

Water: Soluble.

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- **Partition coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **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** Reacts with various metals.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** Corrosive action on metals.
- **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.
- **on the skin:** Caustic effect on skin and mucous membranes.
- **on the eye:** Strong irritant with the danger of severe eye injury.
- **Additional toxicological information:**
Swallowing will lead to a strong caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.
- **Carcinogenic categories**
- **NTP (National Toxicology Program)**
- None of the ingredients is 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:**
Water hazard class 1 (Self-assessment): slightly hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- | | |
|---|--|
| · UN-Number | |
| · DOT/TDG, ADR, IMDG, IATA | UN3264 |
| · UN proper shipping name | |
| · DOT/TDG | Corrosive liquid, acidic, inorganic, n.o.s. (inorganic nitrate salts) |
| · ADR | 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts) |
| · IMDG, IATA | CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts) |
| · Transport hazard class(es) | |
| · DOT/TDG (Transport dangerous goods): | |
|  | |
| · Class | 8 Corrosive substances |
| · Label | 8 |
| · ADR | |
|  | |
| · Class | 8 (C1) Corrosive substances |
| · Label | 8 |
| · IMDG, IATA | |
|  | |
| · Class | 8 Corrosive substances |
| · Label | 8 |
| · Packing group | |
| · DOT/TDG, ADR, IMDG, IATA | II |
| · Environmental hazards: | |
| Not applicable. | |
| · Special precautions for user | |
| Warning: Corrosive substances | |
| · Hazard identification number (Kemler code): 80 | |
| · EMS Number: F-A,S-B | |

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· Segregation groups	Acids
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (INORGANIC NITRATE SALTS), 8, II

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture

· Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

CAS: 10031-51-3 Erbium(III) nitrate pentahydrate

CAS: 7782-61-8 Iron(III) nitrate nonahydrate

· TSCA (Toxic Substances Control Act):

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms



GHS05

· Signal word Danger

· Hazard-determining components of labeling:

inorganic nitrate salts

· Hazard statements

Causes severe skin burns and eye damage.

· Precautionary statements

Wear protective gloves/protective clothing/eye protection/face protection.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Immediately call a poison center/doctor.

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Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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** 08/10/2020 / -

· **Abbreviations and acronyms:**

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

ELINCS: European List of Notified 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

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