

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 11.08.2020

Version number 1

Revision: 04.04.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** **NexxZr Effect Coloring Liquid Blue**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Manufacture of dental prothesis
- **1.3 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
- **Further information obtainable from:**
Quality Assurance / Regulatory Affairs
USA: support@sagemax.com
EU: info@sagemax.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Corr. 1 H314 Causes severe skin burns and eye damage.
Eye Dam. 1 H318 Causes serious eye damage.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

- **Hazard pictograms**



GHS05

- **Signal word** Danger
- **Hazard-determining components of labelling:**
inorganic nitrate salts
- **Hazard statements**
H314 Causes severe skin burns and eye damage.
- **Precautionary statements**
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

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P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*

P310 *Immediately call a POISON CENTER/doctor.*

P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 16454-60-7	neodymium(III) nitrate hexahydrate	2.5-<10%
Reg.nr.: 05-2114135952-48-XXXX	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- **4.1 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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to enter sewers/ surface or ground water.

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- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 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 container tightly sealed.
Protect from heat and direct sunlight.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**
· **Ingredients 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 valid during the making were used as basis.
- **8.2 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.
- **Respiratory protection:** Not required.
- **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

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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

SECTION 9: Physical and chemical properties

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

Form:	Fluid
Colour:	Blue
· Odour:	Characteristic
· Odour threshold:	Not determined.

· pH-value at 20 °C: <2

· Change in condition
Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: Undetermined.

· Flash point: Undetermined.

· Flammability (solid, gas): Not applicable.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Vapour pressure: Not determined.

· Density: Not determined.

· Relative density Not determined.

· Vapour density Not determined.

· Evaporation rate Not determined.

· Solubility in / Miscibility with water: Soluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:
Dynamic: Not determined.

Kinematic: Not determined.

· 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability Stable under normal handling and storage conditions.

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

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- **10.3 Possibility of hazardous reactions** Reacts with various metals.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** Corrosive action on metals.
- **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR/RID/ADN, IMDG, IATA** UN3264

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· **14.2 UN proper shipping name**

· ADR/RID/ADN

3264 CORROSIVE LIQUID, ACIDIC, INORGANIC,
N.O.S. (inorganic nitrate salts)

· IMDG, IATA

CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.
(inorganic nitrate salts)· **14.3 Transport hazard class(es)**

· ADR/RID/ADN



· Class

8 (C1) Corrosive substances.

· Label

8

· IMDG, IATA



· Class

8 Corrosive substances.

· Label

8

· **14.4 Packing group**

· ADR/RID/ADN, IMDG, IATA

II

· **14.5 Environmental hazards:**

Not applicable.

· **14.6 Special precautions for user**

Warning: Corrosive substances.

· Hazard identification number (Kemler code):

80

· EMS Number:

F-A,S-B

· Segregation groups

Acids

· Stowage Category

B

· Stowage Code

SW2 Clear of living quarters.

· **14.7 Transport in bulk according to Annex II of
Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· ADR/RID/ADN

· 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

· Transport category

2

· Tunnel restriction code

E

· 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

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· UN "Model Regulation":

UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC,
N.O.S. (INORGANIC NITRATE SALTS), 8, II

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

- **Relevant phrases**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

- **Abbreviations and acronyms:**

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

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Corr. 1: Skin corrosion/irritation – Category 1

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

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