

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 Violet***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.

Carc. 1B H350i May cause cancer by inhalation.

Repr. 1B H360F May damage fertility.

Aquatic Chronic 2 H411 Toxic to aquatic life with long lasting effects.

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 GHS08 GHS09

Signal word Danger**Hazard-determining components of labelling:**

Erbium(III) nitrate pentahydrate

cobalt dinitrate

Hazard statements

H314 Causes severe skin burns and eye damage.

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H350i May cause cancer by inhalation.

H360F May damage fertility.

H411 Toxic to aquatic life with long lasting effects.

· Precautionary statements

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P308+P313 IF exposed or concerned: Get medical advice/attention.

P405 Store locked up.

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

· Additional information:

Contains cobalt dinitrate. May produce an allergic reaction.

Restricted to professional users.

· 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: 10031-51-3	Erbium(III) nitrate pentahydrate	1-<2.5%
	Ox. Sol. 2, H272; Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335	
CAS: 10141-05-6 EINECS: 233-402-1	cobalt dinitrate	0.3-<1%
	Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350i; Repr. 1B, H360F; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317	

· SVHC

CAS: 10141-05-6	cobalt dinitrate
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· 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. Then consult a doctor.

· 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.

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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:** Wear self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
Use respiratory protective device against the effects of fumes/dust/aerosol.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Ensure adequate ventilation.
- **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.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** Keep respiratory protective device available.
- **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:** Not required.
- **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:**

CAS: 10141-05-6 cobalt dinitrate

WEL	Long-term value: 0.1 mg/m ³ as Co; Carc, Sen
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- **Additional information:** The lists valid during the making were used as basis.

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· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

Usual hygienic measures for dental practice and dental laboratories.

· Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

· 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

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· 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: Red

· Odour: Characteristic

· Odour threshold: Not determined.

· pH-value at 20 °C: <2

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· 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.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **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**
May cause cancer by inhalation.
- **Reproductive toxicity**
May damage fertility.
- **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.

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- **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:**
 - Toxic for aquatic organisms
 - Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
 - Do not allow product 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**
 - Must not be disposed together with household garbage. Do not allow product to reach sewage system.
 - 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.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- | | |
|--|---|
| <ul style="list-style-type: none"> · 14.1 UN-Number · ADR/RID/ADN, IMDG, IATA | <p style="text-align: center;">UN3264</p> |
| <ul style="list-style-type: none"> · 14.2 UN proper shipping name · ADR/RID/ADN · IMDG, IATA | <p style="text-align: center;">3264 CORROSIVE LIQUID, ACIDIC, INORGANIC,
N.O.S. (inorganic nitrate salts)
CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.
(inorganic nitrate salts)</p> |
| <ul style="list-style-type: none"> · 14.3 Transport hazard class(es) · ADR/RID/ADN | <div style="text-align: center;">  </div> |
| <ul style="list-style-type: none"> · Class | <p style="text-align: center;">8 (C1) Corrosive substances.</p> |

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· 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
· UN "Model Regulation":	UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (INORGANIC NITRATE SALTS), 8, II, ENVIRONMENTALLY HAZARDOUS

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.
- **Seveso category E2** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 28, 30

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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.

· **Substances of very high concern (SVHC) according to REACH, Article 57**

CAS: 10141-05-6	cobalt dinitrate
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· **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**

H272 May intensify fire; oxidiser.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H341 Suspected of causing genetic defects.

H350i May cause cancer by inhalation.

H360F May damage fertility.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

· **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

SVHC: Substances of Very High Concern

vPvB: very Persistent and very Bioaccumulative

Ox. Sol. 2: Oxidizing solids – Category 2

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

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Muta. 2: Germ cell mutagenicity – Category 2

Carc. 1B: Carcinogenicity – Category 1B

Repr. 1B: Reproductive toxicity – Category 1B

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

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2