

## 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 Incisal Enhancer**
- **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 Reg.nr.: 05-2114135952-48-XXXX	neodymium(III) nitrate hexahydrate Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	2.5-<10%
CAS: 10031-53-5 EINECS: 233-380-3	Europium(III)-nitrate-hexahydrate Ox. Sol. 2, H272; Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	0.1-<2.5%

- **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.

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· **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.*

· **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*

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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

### SECTION 9: Physical and chemical properties

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form:	Fluid
Colour:	Green
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.

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- **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** 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.

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**SECTION 14: Transport information**

· <b>14.1 UN-Number</b>	
· <b>ADR/RID/ADN, IMDG, IATA</b>	UN3264
· <b>14.2 UN proper shipping name</b>	
· <b>ADR/RID/ADN</b>	3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)
· <b>IMDG, IATA</b>	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)
· <b>14.3 Transport hazard class(es)</b>	
· <b>ADR/RID/ADN</b>	
	
· <b>Class</b>	8 (C1) Corrosive substances.
· <b>Label</b>	8
· <b>IMDG, IATA</b>	
	
· <b>Class</b>	8 Corrosive substances.
· <b>Label</b>	8
· <b>14.4 Packing group</b>	
· <b>ADR/RID/ADN, IMDG, IATA</b>	II
· <b>14.5 Environmental hazards:</b>	Not applicable.
· <b>14.6 Special precautions for user</b>	Warning: Corrosive substances.
· <b>Hazard identification number (Kemler code):</b>	80
· <b>EMS Number:</b>	F-A,S-B
· <b>Segregation groups</b>	Acids
· <b>Stowage Category</b>	B
· <b>Stowage Code</b>	SW2 Clear of living quarters.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR/RID/ADN</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>Transport category</b>	2
· <b>Tunnel restriction code</b>	E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L

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· <b>Excepted quantities (EQ)</b>	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· <b>UN "Model Regulation":</b>	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**  
H272 May intensify fire; oxidiser.  
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  
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  
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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