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

1.1 Product identifier

Trade name: NexxZr Effect Coloring Liquid Grey

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, FL-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. 1B 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

(Contd. on page 2)
Safety data sheet
generated by 1907/2006/EC, Article 31

Printing date 19.11.2018
Revision: 19.11.2018
Version number 1

Trade name: NexxZr Effect Coloring Liquid Grey

- **Hazard statements**
  - H314 Causes severe skin burns and eye damage.
  - 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:**

<table>
<thead>
<tr>
<th>CAS: 10031-51-3</th>
<th>Erbium(III) nitrate pentahydrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ox. Sol. 2, H272; Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335</td>
<td></td>
</tr>
<tr>
<td>1.0-&lt;2.5%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CAS: 10141-05-6</th>
<th>cobalt dinitrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS: 233-402-1</td>
<td>Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H330i; Repr. 1B, H360F; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317</td>
</tr>
<tr>
<td>0.3-&lt;1%</td>
<td></td>
</tr>
</tbody>
</table>

- **SVHC**
  - CAS: 10141-05-6 | cobalt dinitrate |

- **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.
    - 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.

(Contd. on page 3)
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 storroooms and receptacles: Store only in the original receptacle.

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:

<table>
<thead>
<tr>
<th>CAS: 10141-05-6 cobalt dinitrate</th>
</tr>
</thead>
<tbody>
<tr>
<td>WEL</td>
</tr>
</tbody>
</table>

Additional information: The lists valid during the making were used as basis.

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

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: Dark grey
Odour: Characteristic
Trade name: NexxZr Effect Coloring Liquid Grey

- 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.
- 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.
Trade name: NexxZr Effect Coloring Liquid Grey

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:
Toxic for aquatic organisms
Water hazard class 1 (German Regulation) (Self-assessment): slightly 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.

SECTION 14: Transport information

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

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

\[ \text{Class} \ 8 \ (C1) \ Corrosive \ substances. \]
### Trade name: NexxZr Effect Coloring Liquid Grey

<table>
<thead>
<tr>
<th>14.4 Packing group</th>
<th>14.5 Environmental hazards:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR/RID/ADN, IMDG, IATA</td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td><strong>Class</strong> 8 Corrosive substances.</td>
</tr>
<tr>
<td><strong>IMDG, IATA</strong></td>
<td><strong>Label</strong> 8</td>
</tr>
<tr>
<td><strong>Class</strong></td>
<td>8</td>
</tr>
<tr>
<td><strong>Label</strong></td>
<td><strong>14.6 Special precautions for user</strong> Warning: Corrosive substances.</td>
</tr>
<tr>
<td><strong>14.4 Packing group</strong></td>
<td><strong>Danger code (Kemler):</strong> 80</td>
</tr>
<tr>
<td><strong>ADR/RID/ADN, IMDG, IATA</strong></td>
<td><strong>EMS Number:</strong> F-A,S-B</td>
</tr>
<tr>
<td><strong>Segregation groups</strong></td>
<td><strong>Acids</strong></td>
</tr>
<tr>
<td><strong>Stowage Category</strong></td>
<td><strong>B</strong></td>
</tr>
<tr>
<td><strong>Stowage Code</strong></td>
<td><strong>SW2 Clear of living quarters.</strong></td>
</tr>
<tr>
<td><strong>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</strong></td>
<td><strong>Transport/Additional information:</strong></td>
</tr>
<tr>
<td><strong>ADR/RID/ADN</strong></td>
<td><strong>Limited quantities (LQ) 1L</strong></td>
</tr>
<tr>
<td><strong>Excepted quantities (EQ)</strong></td>
<td><strong>Code:</strong> E2</td>
</tr>
<tr>
<td><strong>Maximum net quantity per inner packaging:</strong> 30 ml</td>
<td><strong>Maximum net quantity per outer packaging:</strong> 500 ml</td>
</tr>
<tr>
<td><strong>Transport category</strong></td>
<td><strong>Tunnel restriction code</strong> E</td>
</tr>
<tr>
<td><strong>IMDG</strong></td>
<td><strong>Limited quantities (LQ) 1L</strong></td>
</tr>
<tr>
<td><strong>Excepted quantities (EQ)</strong></td>
<td><strong>Code:</strong> E2</td>
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</tr>
<tr>
<td><strong>UN &quot;Model Regulation&quot;:</strong></td>
<td><strong>UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (INORGANIC NITRATE SALTS), 8, II, ENVIRONMENTALLY HAZARDOUS</strong></td>
</tr>
</tbody>
</table>

### 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 |
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

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 allergy or asthma symptoms or breathing difficulties if inhaled.
- 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. 1B: Skin corrosion/irritation – Category 1B
- 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