SAFETY DATA SHEETS

This SDS packet was issued with item: 071289925

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071286749 071286756 071289974 071290899 071321843



Printing date 08/07/2020

Version number 1

Reviewed on 04/04/2019

1 Identification

· Product identifier

Trade name: NexxZr T Coloring Liquid A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4

· 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(s) identification

• Classification of the substance or mixture Skin Corr. 1B H314 Causes severe skin burns and eye damage. Eye Dam. 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



· Signal word Danger

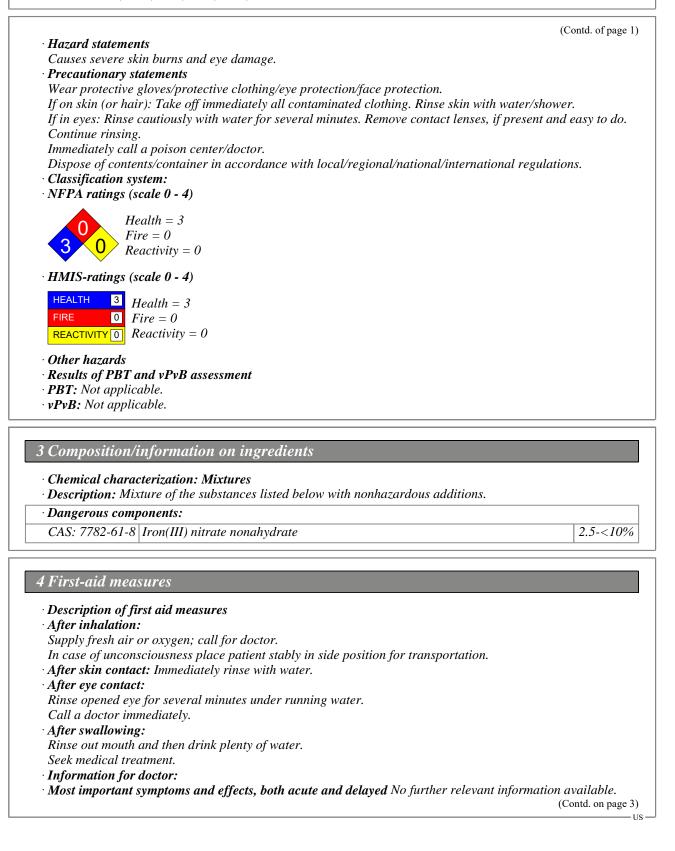
• Hazard-determining components of labeling: inorganic nitrate salts

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US

Printing date 08/07/2020

Trade name: NexxZr T Coloring Liquid A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4



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(Contd. of page 2)

• *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.
- · 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.
- · Protective Action Criteria for Chemicals

• PAC-1:

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

22 mg/m3

110 mg/m3

640 mg/m3

• PAC-2:

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

· PAC-3:

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

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.

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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.
- · 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.

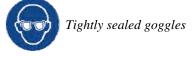
- Material of gloves
- Natural rubber, NR
- Chloroprene rubber, CR
- Nitrile rubber, NBR
- Butyl rubber, BR
- Fluorocarbon rubber (Viton)

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:



9 Physical and chemical properties

- · Information on basic physical and chemical properties
- General Information
- Appearance: Form: Color:

· Odor:

Fluid Yellowish Characteristic

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		(Contd. of page
· Odor threshold:	Not determined.	
• <i>pH-value at 20</i> • <i>C</i> (68 • <i>F</i>):	<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.	
· Partition coefficient (n-octanol/wa	ter): 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.

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 OSHA-Ca (Occupational Safety & Health Administration) None of the ingredients is listed. 12 Ecological information 	In Administration)
12 Ecological information	
12 Ecological information	
<i>h</i>	
 Toxicity Aquatic toxicity: No further relevant information available. 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. 	rmation available. r relevant information available. levant information available. mation available.
 Additional ecological information: General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large augmitities of it to reach eron. 	Additional ecological information: General notes: Water hazard class 1 (Self-assessment): slightly hazardous for water Do not allow undiluted product or large augnities of it to reach oround water water course or sewage
 System. System. Results of PBT and vPvB assessment PBT: Not applicable. vPvB: Not applicable. Other adverse effects No further relevant information available. 	quantues of a to reach Stoand watch, watch course of sowage t information available.
13 Disposal considerations	
 Waste treatment methods Recommendation: Take to an approved landfill or a waste 	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. 	de according to official regulations.
14 Transport information	
· UN-Number · DOT, ADR/RID/ADN, IMDG, IATA	UN3264
· UN proper shipping name · DOT	Corrosive liquid, acidic, inorganic, n.o.s. (inorganic nitrate
ADR/RID/ADN	saus) 3264 Corrosive liquid, acidic, inorganic, n.o.s. (inorganic
· IMDG, IATA	ntrate satts) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)
· Transport hazard class(es) · DOT	
The second secon	
· Class	O Comocine substances

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Label	8	
ADR/RID/ADN		
Class Label	8 (C1) Corrosive substances 8	
IMDG, IATA		
Class	8 Corrosive substances	
Label	8	
Packing group DOT, ADR/RID/ADN, IMDG, IATA	II	
Environmental hazards:	Not applicable.	
Special precautions for user Hazard identification number (Kemler code): EMS Number: Segregation groups Stowage Category Stowage Code	Warning: Corrosive substances 80 F-A,S-B Acids B 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/RID/ADN 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) Excepted quantities (EQ)	1L 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.

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• Section 313 (Specific toxic chemical listings):

All ingredients are listed.

• TSCA (Toxic Substances Control Act):

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

• TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

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

• Hazard pictograms



· 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/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.

· 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.

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- US

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· 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 preparation / last revision 08/07/2020 / -
- 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 DOT: US Department of Transportation IATA: International Air Transport Association ACGIH: American Conference of Governmental Industrial Hygienists 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 NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Skin Corr. 1B: Skin corrosion/irritation – Category 1B Eye Dam. 1: Serious eye damage/eye irritation - Category 1