ivoclar

Safety Data Sheet according to HPR, Schedule 1

Printing date 06/29/2023

Version number 3

Reviewed on 06/29/2023

1 Identification

· Product identifier

• Trade name: IPS e.max ZirCAD MT Colouring Liquid grey / IPS e.max ZirCAD LT Colouring Liquid grey

• Application of the substance / the mixture Manufacture of dental prothesis Colouring Liquid

Details of the supplier of the safety data sheet
Manufacturer/Supplier: Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228 USA Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada Phone: +1 905 670 8499 Fax: +1 905 670 3102

 Information department: Quality Assurance / Regulatory Affairs
 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 identification

· Classification of the substance or mixture

Skin Corrosion - Category 1B H314 Causes severe skin burns and eye damage. Serious Eye Damage - Category 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*

· Hazard statements

Causes severe skin burns and eye damage.

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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 [or 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.
Classification system:
NFPA ratings (scale 0 - 4)

 $\begin{array}{c} \textbf{Health} = 3\\ Fire = 0\\ Reactivity = 0 \end{array}$

· HMIS-ratings (scale 0 - 4)



3 Composition/Information on ingredients

· Chemical characterization: Mixtures

• Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 20694-39-7 Manganese(II) nitrate tetrahydrate

0.1-≤1% w/w *

* Actual concentration ranges are withheld as a trade secret.

4 First-aid measures

- · General information: Immediately remove any clothing soiled by the product.
- After inhalation: In case of unconsciousness place patient stably in side position for transportation.
- After skin contact:
- Immediately wash with water and soap and rinse thoroughly.
- Generally the product does not irritate the skin.
- After eye contact:
- Call a doctor immediately.
- 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.

Drink copious amounts of water and provide fresh air. Immediately call a doctor.

- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- · Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

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[·] Description of first aid measures

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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: No special measures required.
- Methods and material for containment and cleaning up:
- Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Use neutralizing agent.
- Dispose contaminated material as waste according to item 13.
- Ensure adequate ventilation.
- · 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.

7 Handling and storage

· Handling:

- · Precautions for safe handling
- Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.
- 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: Not required.
- Further information about storage conditions: Keep receptacle tightly sealed.
- Specific end use(s) No further relevant information available.

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.

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(Contd. of page 3) · 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. Avoid contact with the eyes and skin. Usual hygienic measures for dental practice and dental laboratories. • Breathing equipment: In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air. · Protection of hands: The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Protective gloves 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 9 Physical and chemical properties · Information on basic physical and chemical properties **General Information** Appearance: Form: Fluid Color: According to product specification · Odor: Characteristic · Odor threshold: Not determined. 2 · pH-value at 20 °C: · Change in condition Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined. · Flash point: Undetermined. (Contd. on page 5)

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Flammability (solid, gaseous):	Not applicable.	
Decomposition temperature:	Not determined.	
Auto igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapor pressure:	Not determined.	
Density:	Not determined.	
Relative density	Not determined.	
Vapor density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Not miscible or difficult to mix.	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
Solids content:	0.0 %	
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 No dangerous reactions known.
- Conditions to avoid No further relevant information available.
- *Incompatible materials:* No further relevant information available.
- · Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

- · Information on toxicological effects
- Acute toxicity:
- · Specific symptoms in biological assay:
- \cdot on the skin: Caustic effect on skin and mucous membranes.
- \cdot 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.

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· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

· Toxicity

- · 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.
- Additional ecological information:
- · General notes:
- Not hazardous for water.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- *PBT:* Not applicable.
- · vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods

· Recommendation:

Must not be disposed of 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 packagings:
- *Recommendation: Disposal must be made according to official regulations.*

UN-Number DOT/TDG, ADR, IMDG, IATA	UN3264
UN proper shipping name	
DOT/TDG	<i>Corrosive liquid, acidic, inorganic, n.o.s. (inorganic nitrate salts)</i>
ADR	3264 Corrosive liquid, acidic, inorganic, n.o.s. (inorganic nitrate salts)
IMDG, IATA	CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)

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Transport hazard class(es)	
DOT/TDG (Transport dangerous goods):	
8	
Class	8 Corrosive substances
Label	8
ADR	
<u>u</u>	
8	
	9 (C1) Company what was a start of the second secon
Class Label	8 (C1) Corrosive substances 8
	~
IMDG, IATA	
8	
Class	8 Corrosive substances
Label	8
Packing group	
DOT/TDG, ADR, IMDG, IATA	II
Environmental hazards:	Not applicable.
Special precautions for user	Warning: Corrosive substances
Hazard identification number (Kemler code):	
EMS Number:	F-A,S-B
Segregation groups Stowage Category	(SGG1) Acids
Stowage Cole	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 Excepted quantities (EQ)	Code: E2
Excepten quantines (EV)	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
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

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.

· Section 313 (Specific toxic chemical listings):

All ingredients are 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 [or 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 Regulation 2017/745 on Medical Devices (MDR). 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.

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.

· Contact:

• Date of the latest revision of the safety data sheet 06/29/2023

· Abbreviations and acronyms:

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation IATA: International Air Transport Association

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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 • * Data compared to the previous version altered.

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