ivoclar vivadent:

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 20.06.2017

Version number 2

Revision: 14.06.2017

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

· 1.1 Product identifier

Trade name: IPS e.max ZirCAD MT Colouring Liquid C1, C2, C3, C4, D4 / IPS e.max ZirCAD LT Colouring Liquid D2

• 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: Ivoclar Vivadent AG Bendererstrasse 2 FL-9494 Schaan PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 *Fax:* +423 235 33 60

 Further information obtainable from: Regulatory Affairs sds@ivoclarvivadent.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.

· 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



· 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/shower.

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.

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

Ox. Sol. 2, H272; Skin Irrit. 2, H315; Eye Irrit. 2, H319

1-<10%

• 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.
- 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).

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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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: 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:

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 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

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· 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 a	and chemical properties	
· General Information	I I I	
· Appearance:		
Form:	Fluid	
Colour:	Different according to colouring	
· Odour:	Characteristic	
• Odour threshold:	Not determined.	
• pH-value at 20 •C:	< 2	
· Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
· Flash point:	Undetermined.	
· Flammability (solid, gaseous):	Not applicable.	
· Self-igniting:	Product is not selfigniting.	
Danger of explosion:	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/wat	ter): 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.

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• 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 severe skin burns and 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.

 $\cdot \textit{STOT-repeated exposure Based on available data, the classification criteria are not met.}$

• 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.

SECTION 14: Transport information

· 14.1 UN-Number

· ADR,RID,ADN, IMDG, IATA

UN3264

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14.2 UN proper shipping name	
ADR/RID/ADN	3264 CORROSIVE LIQUID, ACIDIC, INORGANIC,
IMDC IATA	N.O.S. (inorganic nitrate salts) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S.
IMDG, IATA	(inorganic nitrate salts)
14.3 Transport hazard class(es)	
ADR/RID/ADN	
A CONTRACTOR OF	
Class	8 (C1) Corrosive substances.
Label	8
IMDG, IATA	
, ,	
and the second s	
V	
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.
Danger code (Kemler):	80
EMS Number:	F- A , S - B
Segregation groups	Acids
Stowage Category	В
Stowage Code	SW2 Clear of living quarters.
14.7 Transport in bulk according to Ann	nex 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
m	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	E
IMDG	
Limited quantities (LQ)	lL
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

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. · 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. 1B: Skin corrosion/irritation – Category 1B Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 • * Data compared to the previous version altered.