ivoclar

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

Printing date 29.06.2023

Version number 3 (replaces version 2)

Revision: 29.06.2023

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 D2 / IPS e.max ZirCAD LT Colouring Liquid A1, A2 D3

- 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 Colouring Liquid
- 1.3 Details of the supplier of the safety data sheet • Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2

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, 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 GB 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 [or 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.

(Contd. on page 2)

GB -

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P501

(Contd. of page 1) 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 Mixtures

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

Dangerous components:

3 1				
		1.5-<10%		
	Ox. Sol. 2, H272; Skin Irrit. 2, H315; Eye Irrit. 2, H319			
CAS: 10031-51-3	Erbium(III) nitrate pentahydrate	0.1-2.5%		
	Ox. Sol. 2, H272; Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335			
• 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).

(Contd. on page 3)

Printing date 29.06.2023

Version number 3 (replaces version 2)

Trade name: IPS e.max ZirCAD MT Colouring Liquid D2 / IPS e.max ZirCAD LT Colouring Liquid A1, A2 D3

(Contd. of page 2)

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: 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

· 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

· Appropriate engineering controls No further data; see item 7.

· Individual protection measures, such as 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.
- · Hand protection



Protective gloves (EN 374)

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)

(Contd. on page 4)

⁻ GB -

Printing date 29.06.2023

Revision: 29.06.2023

Trade name: IPS e.max ZirCAD MT Colouring Liquid D2 / IPS e.max ZirCAD LT Colouring Liquid A1, A2 D3

(Contd. of page 3)

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/face protection

Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical prop	leriies
0.1 Information on basic physical and chemical p	properties
General Information	
Physical state	Fluid
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	Undetermined.
Boiling point or initial boiling point and boiling	
range	Undetermined.
Flammability	Not applicable.
Flash point:	Undetermined.
pH at 20 °C	< 2
Viscosity:	
Kinematic viscosity	Not determined.
Dynamic:	Not determined.
Solubility	
water:	Soluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not determined.
Density and/or relative density	
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
9.2 Other information	
Appearance:	
Form:	Fluid
Important information on protection of health an	
environment, and on safety.	
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Change in condition	
Evaporation rate	Not determined.
Information with regard to physical hazard classe	25
Explosives	Void
Flammable gases	Void
Aerosols	Void
Oxidising gases	Void
Gases under pressure	Void
	(Contd. on pag

Printing date 29.06.2023

Version number 3 (replaces version 2)

Revision: 29.06.2023

Trade name: IPS e.max ZirCAD MT Colouring Liquid D2 / IPS e.max ZirCAD LT Colouring Liquid A1, A2 D3

		(Contd. of page 4
· Flammable liquids	Void	
· Flammable solids	Void	
· Self-reactive substances and mixtures	Void	
· Pyrophoric liquids	Void	
· Pyrophoric solids	Void	
· Self-heating substances and mixtures	Void	
· Substances and mixtures, which emit flamm	able	
gases in contact with water	Void	
· Oxidising liquids	Void	
• Oxidising solids	Void	
· Organic peroxides	Void	
· Corrosive to metals	Void	
· Desensitised explosives	Void	

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 hazard classes as defined in Regulation (EC) No 1272/2008

· 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.

• 11.2 Information on other hazards

• Endocrine disrupting properties

None of the ingredients is listed.

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.

(Contd. on page 6)

Printing date 29.06.2023

Trade name: IPS e.max ZirCAD MT Colouring Liquid D2 / IPS e.max ZirCAD LT Colouring Liquid A1, A2 D3

(Contd. of page 5)

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- 12.6 Endocrine disrupting properties
- The product does not contain substances with endocrine disrupting properties.
- · 12.7 Other adverse effects
- · 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.

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.*

14.1 UN number or ID number ADR/RID/ADN, IMDG, IATA	UN3264	
14.2 UN proper shipping name ADR/RID/ADN IMDG, IATA	3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)	
14.3 Transport hazard class(es)		
Class	8 (C1) Corrosive substances.	
Label	8	
IMDG, IATA		
- Class	8 Corrosive substances.	
- Label	8	
· 14.4 Packing group · ADR/RID/ADN, IMDG, IATA	II	

Printing date 29.06.2023

Revision: 29.06.2023

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	(Contd. of page
14.5 Environmental hazards:	Not applicable.
14.6 Special precautions for user	Warning: Corrosive substances.
Hazard identification number (Kemler code):	80
EMS Number:	F-A,S-B
Segregation groups	Acids
Stowage Category	В
Stowage Code	SW2 Clear of living quarters.
14.7 Maritime transport in bulk according to IM	10
instruments	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
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	Ε
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
UN "Model Regulation":	UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANI
6	N.O.S. (INORGANIC NITRATE SALTS), 8, 11

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.

· National regulations:

- Other regulations, limitations and prohibitive regulations
- The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- 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.

H318 Causes serious eye damage.

H319 Causes serious eye irritation. H335 May cause respiratory irritation.

(Contd. on page 8)

GB

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Trade name: IPS e.max ZirCAD MT Colouring Liquid D2 / IPS e.max ZirCAD LT Colouring Liquid A1, A2 D3

	(Contd. of page
Classification according to Regulation (EC) No 1272/2008	
The classification of the mixture is generally based on the calculation method using substan to Regulation (EC) No 1272/2008.	ce data accordir
Abbreviations and acronyms:	
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Cor International Carriage of Dangerous Goods by Road)	cerning the
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	
* Data compared to the previous version altered.	