

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 orange / IPS e.max ZirCAD LT Colouring Liquid orange
- · 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.

STOT SE 3 H335 May cause respiratory irritation.

- · 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





GHS05

· **Signal word** Danger

- · Hazard-determining components of labelling:
- inorganic nitrate salts
- · Hazard statements

H314 Causes severe skin burns and eye damage.

H335 May cause respiratory irritation.

· Precautionary statements

P280 Wear protective gloves / 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.

(Contd. on page 2)

Printing date 29.06.2023 Version number 3 (replaces version 2) Revision: 29.06.2023

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

(Contd. of page 1)

P310 Immediately call a POISON CENTER/doctor.

P501 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:			
CAS: 10031-51-3	Erbium(III) nitrate pentahydrate	25-50%	
	Ox. Sol. 2, H272; Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335		
	- 1 /	2.5-<10%	
	Ox. Sol. 2, H272; Skin Irrit. 2, H315; Eye Irrit. 2, H319		

[·] 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: 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.

(Contd. on page 3)

Printing date 29.06.2023

Version number 3 (replaces version 2)

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

(Contd. of page 2)

Revision: 29.06.2023

· 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.

Prevent formation of aerosols.

- · 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.

Do not inhale gases / fumes / aerosols.

- Respiratory protection: Use suitable respiratory protective device in case of insufficient ventilation.
- · 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.

(Contd. on page 4)

Printing date 29.06.2023 Version number 3 (replaces version 2) Revision: 29.06.2023

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

(Contd. of page 3)

· 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/face protection



Tightly sealed goggles (EN 166)

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

Physical state
Colour:
Odour:
Odour threshold:
Melting point/freezing point:
Fluid
Orange
Characteristic
Not determined.
Undetermined.

· Boiling point or initial boiling point and boiling

range Undetermined.

Flammability Not applicable.

Flash point: Undetermined.

 \cdot 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 and 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.

(Contd. on page 5)

Printing date 29.06.2023

Version number 3 (replaces version 2)

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

(Contd. of page 4)

Revision: 29.06.2023

· Information with regard to physical hazard c	lasses	
· Explosives	Void	
· Flammable gases	Void	
· Aerosols	Void	
· Oxidising gases	Void	
· Gases under pressure	Void	
· 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 flamma	ıble	
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

May cause respiratory irritation.

- · 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.

(Contd. on page 6)

Printing date 29.06.2023

Version number 3 (replaces version 2)

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

(Contd. of page 5)

Revision: 29.06.2023

- · 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.
- 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 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	3264 CORROSIVE LIQUID, ACIDIC, INORGANIC,
IMDG, IATA	N.O.S. (inorganic nitrate salts) CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S (inorganic nitrate salts)



Class 8 (C1) Corrosive substances.

(Contd. on page 7)

Printing date 29.06.2023 Version number 3 (replaces version 2) Revision: 29.06.2023

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

	(Contd. of page
Label	8
IMDG, IATA	
Class Label	8 Corrosive substances.
14.4 Packing group ADR/RID/ADN, IMDG, IATA	II
14.5 Environmental hazards:	Not applicable.
14.6 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.
14.7 Maritime transport in bulk according to IM instruments	10 Not applicable.
Transport/Additional information:	
ADR/RID/ADN Limited quantities (LQ) Excepted quantities (EQ) Transport category	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml 2
Tunnel restriction code	E
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, INORGANI 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.
- · 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.

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Version number 3 (replaces version 2)

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

(Contd. of page 7)

Revision: 29.06.2023

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.

· Classification according to Regulation (EC) No 1272/2008

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

· Abbreviations and acronyms:

ADR: Accord relatif au transport international 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. 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.

GB