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

Printing date 24.07.2018

vivadent:

Version number 1

Revision: 13.03.2017

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

· 1.1 Product identifier

Trade name: IPS e.max ZirCAD Colouring Liquid Diluter

• 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 The product is not classified according to the CLP regulation.

· 2.2 Label elements

· Labelling according to Regulation (EC) No 1272/2008 Void

· Hazard pictograms Void

• Signal word Void

• Hazard statements Void

· 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: 7697-37-2 nitric acid EINECS: 231-714-2

Ox. Liq. 2, H272; Skin Corr. 1A, H314

<0.1%

• 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

· General information: No special measures required.

• After inhalation:

Supply fresh air or oxygen; call for doctor.

In case of unconsciousness place patient stably in side position for transportation.

GB

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

Printing date 24.07.2018

Version number 1

Revision: 13.03.2017

Trade name: IPS e.max ZirCAD Colouring Liquid Diluter

(Contd. of page 1)

- · After skin contact: Rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing: Rinse out mouth and then drink plenty of water.
- 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:
- The product is not flammable.

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 clothing.
- · 6.2 Environmental precautions: Dilute with plenty of 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. 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: None.
- 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.

(Contd. on page 3)

GB

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

Printing date 24.07.2018

Version number 1

Revision: 13.03.2017

Trade name: IPS e.max ZirCAD Colouring Liquid Diluter

(Contd. of page 2)

8.2 Exposur	re controls
Personal pr	otective equipment:
General pro	stective and hygienic measures:
Usual hygie	nic measures for dental practice and dental laboratories.
	from foodstuffs, beverages and feed.
Wash hands	before breaks and at the end of work.
Respiratory	protection: Not required.
Protection of	of hands:
Impervious	gloves
After use of	gloves apply skin-cleaning agents and skin cosmetics.
Material of	gloves
Natural rub	ber, NR
Chloropren	e rubber, CR
Nitrile rubb	er, NBR
Butyl rubber	r, BR
Fluorocarbo	on rubber (Viton)
Penetration	time of glove material
The exact brobserved.	reak through time has to be found out by the manufacturer of the protective gloves and has to be
Eye protecti	ion: Safety glasses

9.1 Information on basic physical and c	hemical properties	
General Information		
Appearance:	$\Gamma_1 \cdot I$	
Form:	Fluid	
Colour:	Colourless	
Odour:	Odourless Net let a let	
Odour threshold:	Not determined.	
pH-value at 20 °C:	2.1	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range	: 100 °C	
Flash point:	Not applicable.	
Flammability (solid, gas):	Not applicable.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Vapour pressure at 20 °C:	23 hPa	
Density at 20 °C:	l g/cm ³	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
water:	Fully miscible.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not determined.	

GB

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

Printing date 24.07.2018

Version number 1

Revision: 13.03.2017

Trade name: IPS e.max ZirCAD Colouring Liquid Diluter

(Contd. of page 3)

Kinematic: 9.2 *Other information*

Not determined. 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.

• 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 Based on available data, the classification criteria are not met.

• Serious eye damage/irritation Based on available data, the classification criteria are not met.

• 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.

 \cdot **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 **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: Generally not hazardous for water

· 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 Disposal must be made according to official regulations.*

• Recommendation: Disposal must be made according to official regulations.

(Contd. on page 5)

[•] Uncleaned packaging:

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

Version number 1

Revision: 13.03.2017

Trade name: IPS e.max ZirCAD Colouring Liquid Diluter

(Contd. of page 4)

SECTION 14: Transport information	on		
· 14.1 UN-Number · ADR/RID/ADN, ADN, IMDG, IATA	Void		
· 14.2 UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA	Void		
· 14.3 Transport hazard class(es)			
· ADR/RID/ADN, ADN, IMDG, IATA · Class	Void		
· 14.4 Packing group · ADR/RID/ADN, IMDG, IATA	Void		
· 14.5 Environmental hazards:	Not applicable.		
· 14.6 Special precautions for user	Not applicable.		
· 14.7 Transport in bulk according to Annex Marpol and the IBC Code	c II of Not applicable.		
· Transport/Additional information:	Product is not classified as a dangerous good for transpor (ADR, IMDG, IATA).		
· UN ''Model Regulation'':	Void		

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 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. H314 Causes severe skin burns and eye damage. 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. Liq. 2: Oxidizing liquids Category 2

Skin Corr. 1A: Skin corrosion/irritation - Category 1A