Safety Data Sheet
according to WHS Regulations

Printing date 06.12.2019 *Version number 2* *Revision: 06.12.2019*

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· **Product identifier**

· **Trade name:** ***IPS e.max ZirCAD MT Colouring Liquid violet / IPS e.max ZirCAD LT Colouring Liquid violet***

· **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*

· **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

Importer:
Ivoclar Vivadent Pty. Ltd.
1- 5 Overseas Drive
Noble Park North VIC 3174
Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· **Further information obtainable from:**
Regulatory Affairs
sds@ivoclarvivadent.com

· **Emergency telephone number:** *131 126 (Poisons Information Centre - 24 hours / 7 days)*

2 Hazard(s) Identification

· **Classification of the substance or mixture**
Carc. 1B H350 May cause cancer.
Repr. 1B H360 May damage fertility or the unborn child.

· **Label elements**

· **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**

GHS08

· **Signal word** *Danger*

· **Hazard-determining components of labelling:**
cobalt dinitrate

· **Hazard statements**
May cause cancer.
May damage fertility or the unborn child.

· **Precautionary statements**
Obtain special instructions before use.

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Avoid release to the environment.
IF exposed or concerned: Get medical advice/attention.
Collect spillage.
Store locked up.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** *Not applicable.*
· **vPvB:** *Not applicable.*

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**
· **Description:** *Mixture of substances listed below with nonhazardous additions.*

· **Dangerous components:**		
CAS: 10141-05-6	cobalt dinitrate Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350; Repr. 1B, H360; Skin Sens. 1, H317	<2.5%

· **SVHC**	
CAS: 10141-05-6	cobalt dinitrate

· **Additional information:** *For the wording of the listed hazard phrases refer to section 16.*

4 First Aid Measures

· **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:** *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.
Seek medical treatment.
· **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.

5 Fire Fighting Measures

· **Extinguishing media**
· **Suitable extinguishing agents:** *Use fire extinguishing methods suitable to surrounding conditions.*
· **Special hazards arising from the substance or mixture** *No further relevant information available.*
· **Advice for firefighters**
· **Protective equipment:** *Wear self-contained respiratory protective device.*

6 Accidental Release Measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.

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Use respiratory protective device against the effects of fumes/dust/aerosol.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
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**
Only adequately trained personnel should handle this product.
For use in dentistry only.
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
· **Information about fire - and explosion protection:** Keep respiratory protective device available.

· **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.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **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.

· **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
Do not inhale gases / fumes / aerosols.
Store protective clothing separately.
· **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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· **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

· **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
Colour:	Violet
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value at 20 °C:**	2.3
· **Change in condition**	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	Undetermined.
· **Flash point:**	Undetermined.
· **Flammability (solid, gas):**	Not applicable.
· **Auto-ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	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.

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· **Solubility in / Miscibility with water:**	Soluble.
· **Partition coefficient: n-octanol/water:**	Not determined.
· **Viscosity:**	
Dynamic:	Not determined.
Kinematic:	Not determined.
· **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**
· **Respiratory or skin sensitisation** Sensitisation possible through skin contact.
· **Additional toxicological information:** Carcinogenic if inhaled.
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
Carc. 1B, Repr. 1B

12 Ecological Information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** No further relevant information available.
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Toxic for aquatic organisms
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.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

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13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed 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 packaging:**
· **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

· **UN-Number** · **ADG, ADN, IMDG, IATA**	Void
· **UN proper shipping name** · **ADG, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)** · **ADG, ADN, IMDG, IATA** · **Class**	Void
· **Packing group** · **ADG, IMDG, IATA**	Void
· **Environmental hazards:**	Not applicable.
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· **UN "Model Regulation":**	Void

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Chemical Substances**
All ingredients are listed.

· **Standard for the Uniform Scheduling of Medicines and Poisons**
None of the ingredients is listed.

· **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
· **Hazard pictograms**

GHS08

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· **Signal word** Danger

· **Hazard-determining components of labelling:**
cobalt dinitrate
· **Hazard statements**
May cause cancer.
May damage fertility or the unborn child.
· **Precautionary statements**
Obtain special instructions before use.
Avoid release to the environment.
IF exposed or concerned: Get medical advice/attention.
Collect spillage.
Store locked up.

· **Directive 2012/18/EU**
· **Named dangerous substances - ANNEX I** None of the ingredients is listed.
· **Seveso category** E2 Hazardous to the Aquatic Environment
· **Qualifying quantity (tonnes) for the application of lower-tier requirements** 200 t
· **Qualifying quantity (tonnes) for the application of upper-tier requirements** 500 t

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.

· **Substances of very high concern (SVHC) according to REACH, Article 57**	
CAS: 10141-05-6	cobalt dinitrate

· **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.

· **Relevant phrases**
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341 Suspected of causing genetic defects.
H350 May cause cancer.
H360 May damage fertility or the unborn child.
· **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
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
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Resp. Sens. 1: Respiratory sensitisation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
Muta. 2: Germ cell mutagenicity – Category 2
Carc. 1B: Carcinogenicity – Category 1B
Repr. 1B: Reproductive toxicity – Category 1B