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 violet / IPS e.max ZirCAD LT Colouring Liquid violet

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 prosthesis

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

Carc. 1B  H350i May cause cancer by inhalation.
Repr. 1B  H360F May damage fertility.
Aquatic Chronic 2  H411 Toxic to aquatic life with long lasting effects.

2.2 Label elements

The product is classified and labelled according to the CLP regulation.

Hazard pictograms

GHS08  GHS09

Signal word: Danger

Hazard-determining components of labelling:
cobalt dinitrate

Hazard statements

H350i  May cause cancer by inhalation.
H360F  May damage fertility.
H411   Toxic to aquatic life with long lasting effects.

Precautionary statements

P201  Obtain special instructions before use.
P273   Avoid release to the environment.
P308+P313 IF exposed or concerned: Get medical advice/attention.
P391   Collect spillage.
P405   Store locked up.

(Contd. on page 2)
Safety data sheet according to 1907/2006/EC, Article 31

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

- Additional information:
  - Contains cobalt dinitrate. May produce an allergic reaction.

- 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.

<table>
<thead>
<tr>
<th>Dangerous components:</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 10141-05-6</td>
</tr>
<tr>
<td>EINECS: 233-402-1</td>
</tr>
<tr>
<td>cobalt dinitrate</td>
</tr>
<tr>
<td>Resp. Sens. 1, H334; Muta. 2, H341; Carc. 1B, H350i; Repr. 1B, H360F; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Sens. 1, H317</td>
</tr>
</tbody>
</table>

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

- 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:
    - 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.

- 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.
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.
Open and handle receptacle with care.
Prevent formation of aerosols.

Information about fire - and explosion protection: Keep respiratory protective device available.

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:

<table>
<thead>
<tr>
<th>CAS</th>
<th>WEL Long-term value: 0.1 mg/m³ as Co: Carc, Sen</th>
</tr>
</thead>
<tbody>
<tr>
<td>10141-05-6</td>
<td>cobalt dinitrate</td>
</tr>
</tbody>
</table>

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.
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.
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

SECTION 9: Physical and chemical properties

9.1 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/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.
Trade name: IPS e.max ZirCAD MT Colouring Liquid violet / IPS e.max ZirCAD LT Colouring Liquid violet

43.0.9

- Solubility in / Miscibility with water: Soluble.
- Partition coefficient (n-octanol/water): 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.
- 10.3 Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 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: May cause cancer by inhalation.
  - Reproductive toxicity: May damage fertility.
  - 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.

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:
      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.
    - 12.5 Results of PBT and vPvB assessment
    - PBT: Not applicable.

(Contd. on page 6)
SECTION 13: Disposal considerations

13.1 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.

SECTION 14: Transport information

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 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 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

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.
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
REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 30

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

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
  - 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.
  - H350i May cause cancer by inhalation.
  - H360F May damage fertility.
  - H400 Very toxic to aquatic life.
  - H410 Very toxic to aquatic life with long lasting effects.

- 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
  - 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
  - Mut. 2: Germ cell mutagenicity – Category 2
  - Carc. 1B: Carcinogenicity – Category 1B
  - Repr. 1B: Reproductive toxicity – Category 1B
  - Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  - Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
  - Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

* Data compared to the previous version altered.