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 C1, C2, C3, C4, D4 / IPS e.max ZirCAD LT Colouring Liquid D2

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

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the 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.

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/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.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)
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:

<table>
<thead>
<tr>
<th>CAS</th>
<th>Iron(III) nitrate nonahydrate</th>
<th>Ox. Sol. 2, H272; Skin Irrit. 2, H315; Eye Irrit. 2, H319</th>
</tr>
</thead>
<tbody>
<tr>
<td>7782-61-8</td>
<td></td>
<td>1-&lt;10%</td>
</tr>
</tbody>
</table>

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).

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
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

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.

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
Avoid contact with the eyes and skin.
Respiratory protection: Not required.
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 breakthrough 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: Different according to colouring
Odour: Characteristic
Odour threshold: Not determined.

pH-value at 20 °C: < 2

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 self-igniting.

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.

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.

Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions
No dangerous reactions known.
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: Causes severe skin burns and eye damage.
  - Serious eye damage/irritation: Causes severe skin burns and 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.

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:
    - 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.
  - vPvB: Not applicable.
- 12.6 Other adverse effects: No further relevant information available.

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.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, RID, ADN, IMDG, IATA: UN3264
Trade name: IPS e.max ZirCAD MT Colouring Liquid C1, C2, C3, C4, D4 / IPS e.max ZirCAD LT Colouring Liquid D2

14.2 UN proper shipping name
- ADR/RID/ADN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)
- IMDG, IATA CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (inorganic nitrate salts)

14.3 Transport hazard class(es)
- ADR/RID/ADN
  - 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

14.5 Environmental hazards:
Not applicable.

14.6 Special precautions for user
- Warning: Corrosive substances.
- Danger code (Kemler): 80
- EMS Number: F-A,S-B
- Segregation groups Acids
- Stowage Category B
- Stowage Code SW2 Clear of living quarters.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
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 E
- 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
Trade name: IPS e.max ZirCAD MT Colouring Liquid C1, C2, C3, C4, D4 / IPS e.max ZirCAD LT Colouring Liquid D2

UN "Model Regulation": UN 3264 CORROSIVE LIQUID, ACIDIC, INORGANIC, 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.
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

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. Sol. 2: Oxidizing solids – Category 2
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
* Data compared to the previous version altered.