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

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

1.1 Product identifier

Trade name: IPS e.max CAD Crystall./Glaze Liquid

CAS Number: 107-88-0
EC number: 203-529-7

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: Auxiliary for 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
The substance 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

3.1 Chemical characterisation: Substances

CAS No. Description
107-88-0 butane-1,3-diol

Identification number(s)
EC number: 203-529-7

SECTION 4: First aid measures

4.1 Description of first aid measures

General information: No special measures required.
After inhalation: Supply fresh air; consult doctor in case of complaints.
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· After skin contact:
  Rinse with water.
  Generally the product does not irritate the skin.
· After eye contact:
  Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· After swallowing:
  Rinse out mouth and then drink plenty of water.
  If symptoms persist consult doctor.

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: CO2, powder or water spray. Fight larger fire with alcohol resistant foam.
· 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
  Not required.
· 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.
  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:
  · This product is hygroscopic.
    · Keep container tightly sealed.
· 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: Not required.
Additional information: The lists valid during the making were used as basis.

8.2 Exposure controls

General protective and hygienic measures:
Usual hygienic measures for dental practice.
Wash hands before breaks and at the end of work.
Keep away from foodstuffs, beverages and feed.

Respiratory protection: Not required.

Protection of hands:
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.
Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

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: Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance:
Form: Fluid
Colour: Colourless
Odour: Odourless
Odour threshold: Not determined.

pH-value: Not determined.

Change in condition
Melting point/Melting range: -50 °C
Boiling point/Boiling range: 207 °C

Flash point: 109 °C

Flammability (solid, gaseous): Not applicable.

Ignition temperature: 375 °C

Self-igniting: Not determined.

Danger of explosion: Product does not present an explosion hazard.

Explosion limits:
Lower: Not determined.
Upper: Not determined.

Vapour pressure: Not determined.

Density at 20 °C: 1 g/cm³
Relative density Not determined.
Vapour density Not determined.
Evaporation rate Not determined.
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- Solubility in / Miscibility with water: Fully miscible.
- 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:
  - LD/LC50 values relevant for classification:
    - 107-88-0 butane-1,3-diol
      - Oral LD50 18610 mg/kg (rat)
  - Primary irritant effect:
    - on the skin: No irritant effect.
    - on the eye: No irritating effect.
  - Sensitisation: No sensitising effects known.
  - Additional toxicological information: No further relevant information available.

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.

- European waste catalogue
  
  18 01 07 chemicals other than those mentioned in 18 01 06

- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information

- 14.1 UN-Number
  - ADR, ADN, IMDG, IATA  Void

- 14.2 UN proper shipping name
  - ADR, ADN, IMDG, IATA  Void

- 14.3 Transport hazard class(es)
  - ADR, ADN, IMDG, IATA  Void
  - Class  Void

- 14.4 Packing group
  - ADR, IMDG, IATA  Void

- 14.5 Environmental hazards:
  - Marine pollutant:  No

- 14.6 Special precautions for user
  - Not applicable.

- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 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":  -

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
  - 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.

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
Trade name: IPS e.max CAD Crystall./Glaze Liquid

IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent

* Data compared to the previous version altered.