Printing date 11.12.2019

vivadent:

Version number 4

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Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

· Product identifier

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

• **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 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. I-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 Eye Irrit. 2A H319 Causes serious eye irritation.

STOT SE 3 H336 May cause drowsiness or dizziness.

· Label elements

GHS label elements

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

· Hazard pictograms



Signal word Warning
Hazard statements

Causes serious eye irritation.
May cause drowsiness or dizziness.

Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.
Do not breathe spray.
Wear eye protection / face protection.

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Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

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• 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: 75-28-5 isobutan | e Flam. O | Gas 1, H220; Press. Gas C, H280 | 25-50% |
|---|-------------|---|--------|
| CAS: 67-63-0 propan-2 | -ol Flam. I | Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336 | 10-25% |
| • 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.
- In case of unconsciousness place patient stably in side position for transportation.
- 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. Then consult a doctor.
- After swallowing: Rinse out mouth and then drink plenty of water.
- 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:
- CO2, sand, extinguishing powder. Do not use water.
- Use fire extinguishing methods suitable to surrounding conditions.
- · For safety reasons unsuitable extinguishing agents: Water with full jet
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: Do not inhale explosion gases or combustion gases.
- · Additional information
- Cool endangered receptacles with water spray.
- See Section 14 for Hazchem Code.

6 Accidental Release Measures

- *Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation*
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.

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| · Methods and material for containment | nt and cleaning up: |
|---|--|
| Ensure adequate ventilation. | |
| Absorb liquid components with liquid- | binding material. |
| · Reference to other sections | 0 |
| See Section 7 for information on safe h | handling. |
| See Section 8 for information on perso | nal protection equipment. |
| See Section 13 for disposal information | n. – – – – – – – – – – – – – – – – – – – |

7 Handling and Storage

· Handling:

- **Precautions for safe handling** Only adequately trained personnel should handle this product. For use in dentistry only. Keep away from heat and direct sunlight. Open and handle receptacle with care. Use only in well ventilated areas.
- Information about fire and explosion protection: Keep ignition sources away - Do not smoke. Protect against electrostatic charges.

· Conditions for safe storage, including any incompatibilities

- · Storage:
- Requirements to be met by storerooms and receptacles: Store in a cool location.
 Store only in the original receptacle.
 Observe official regulations on storing packagings with pressurised containers.
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions: Keep container tightly sealed. Store in cool, dry conditions in well sealed receptacles. 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:

CAS: 67-63-0 propan-2-ol NES Short-term value: 1230 mg/m³, 500 ppm Long-term value: 983 mg/m³, 400 ppm WES Short-term value: 1230 mg/m³, 500 ppm

Long-term value: 983 mg/m³, 400 ppm

• *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.

Do not inhale gases / fumes / aerosols.

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Avoid contact with the eyes.

• Respiratory protection:

Not necessary if room is well-ventilated.

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:

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

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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· 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

| Information on basic physical and chemic General Information | ical properties |
|---|--|
| Appearance: | |
| Form: | Aerosol |
| Colour: | Whitish |
| Odour: | Characteristic |
| Odour threshold: | Not determined. |
| pH-value: | Not applicable. |
| Change in condition | |
| Melting point/freezing point: | Undetermined. |
| Initial boiling point and boiling range: | Not applicable, as aerosol. |
| Flash point: | Not applicable, as aerosol. |
| Flammability (solid, gas): | Not applicable. |
| Auto-ignition temperature: | Product is not selfigniting. |
| Explosive properties: | <i>Product is not explosive. However, formation of explosive air/vapour mixtures are possible.</i> |
| Explosion limits: | |
| Lower: | Not determined. |
| Upper: | Not determined. |
| Vapour pressure: | Not determined. |
| Density: | Not determined. |
| Relative density | Not determined. |
| Vapour density | Not determined. |
| Evaporation rate | Not applicable. |

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|---|--|-----------------|
| Solubility in / Miscibility with | | |
| water: | Not miscible or difficult to mix. | |
| 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 Danger of explosion.

- · Conditions to avoid Keep away from heat and direct sunlight.
- · 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
- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation Irritating effect.
- · Respiratory or skin sensitisation No sensitising effects known.
- Additional toxicological information: No further relevant information available.

12 Ecological Information

- 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:

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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[·] Toxicity

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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.

| UN-Number | |
|----------------------------------|---|
| ADG, IMDG, IATA | UN1950 |
| UN proper shipping name | |
| ADĜ | 1950 AEROSOLS |
| IMDG | AEROSOLS |
| IATA | AEROSOLS, flammable |
| Transport hazard class(es) | |
| ADG | |
| | |
| Class | 2 5F Gases. |
| Label | 2.1 |
| IMDG, IATA | |
| Class Label | 2.1 2.1 |
| | 2.1 |
| Packing group ADG, IMDG, IATA | Void |
| Environmental hazards: | |
| Marine pollutant: | No |
| Special precautions for user | Warning: Gases. |
| Danger code (Kemler): | |
| EMS Number: | F- D , S - U |
| Stowage Code | SWI Protected from sources of heat. |
| | SW22 For AEROSOLS with a maximum capacity of 1 |
| | litre: Category A. For AEROSOLS with a capacity |
| | above 1 litre: Category B. For WASTE AEROSOLS: |
| | Category C, Clear of living quarters. |
| Segregation Code | SG69 For AEROSOLS with a maximum capacity of 1 |
| | litre: Segregation as for class 9. Stow "separated from |
| | class 1 except for division 1.4. For AEROSOLS with a |
| | capacity above 1 litre: Segregation as for the |

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|--|--|
| | AEROSOLS: Segregation as for the appropriate subdivision of class 2. |
| Transport in bulk according to Annex II of | f Marpol |
| and the IBC Code | Not applicable. |
| Transport/Additional information: | |
| ADG | |
| Limited quantities (LQ) | 1L |
| Excepted quantities $(\widetilde{E}Q)$ | Code: E0 |
| · · · · · · · · · · · · · · · · · · · | Not permitted as Excepted Quantity |
| Transport category | 2 |
| Tunnel restriction code | D |
| IMDG | |
| Limited quantities (LQ) | 1L |
| Excepted quantities $(\widetilde{E}Q)$ | Code: E0 |
| | Not permitted as Excepted Quantity |
| UN ''Model Regulation'': | UN 1950 AEROSOLS, 2.1 |

15 Regulatory information

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

· Australian Inventory of Chemical Substances

CAS: 75-28-5 isobutane

CAS: 67-63-0 propan-2-ol

· 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*



Signal word Warning
Hazard statements
Causes serious eye irritation.
May cause drowsiness or dizziness.
Precautionary statements
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Do not spray on an open flame or other ignition source.
Do not pierce or burn, even after use.
Do not breathe spray.
Wear eye protection / face protection.
Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

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· National regulations:

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

H220 Extremely flammable gas. H225 Highly flammable liquid and vapour. H280 Contains gas under pressure; may explode if heated. H319 Causes serious eye irritation. H336 May cause drowsiness or dizziness. • 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 vPvB: very Persistent and very Bioaccumulative Flam. Gas 1: Flammable gases - Category 1 Press. Gas C: Gases under pressure - Compressed gas Flam. Liq. 2: Flammable liquids - Category 2 Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A STOT SE 3: Specific target organ toxicity (single exposure) - Category 3