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Version number 4

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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 Spray

• 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 prothesis
- \cdot 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 1272/2008Flam. Aerosol 1H222-H229Extremely flammable aerosol. Pressurised container: May burst if heated.Eye Irrit. 2H319Causes serious eye irritation.STOT SE 3H336May cause drowsiness or dizziness.

· 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



· Signal word Danger

- · Hazard-determining components of labelling:
- propan-2-ol
- · Hazard statements
- H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- · Precautionary statements
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- *P280* Wear eye protection / face protection.
- P251 Do not pierce or burn, even after use.
- P260 Do not breathe spray.
- *P211* Do not spray on an open flame or other ignition source.

P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

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- · 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 compone	ents:	
CAS: 75-28-5	isobutane	25-50%
EINECS: 200-857-2	Flam. Gas 1, H220; Press. Gas C, H280	
CAS: 67-63-0	propan-2-ol	10-<25%
EINECS: 200-661-7	Flam. Liq. 2, H225; Eye Irrit. 2, H319; STOT SE 3, H336	
· Additional informat	ion: For the wording of the listed risk phrases refer to section 16.	

SECTION 4: First aid measures

· 4.1 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.
- 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 fires with water spray or alcohol resistant foam.
- For safety reasons unsuitable extinguishing agents: Water with full jet
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- Protective equipment: Do not inhale explosion gases or combustion gases.
- $\cdot \textit{Additional information Cool endangered receptacles with water spray}.$

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. Ensure adequate ventilation
- \cdot 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Ensure adequate ventilation.

Absorb liquid components with liquid-binding material.

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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. 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.
- 7.2 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 in one common storage factor • Further information about storage conditions: Keep container tightly sealed. Store in cool, dry conditions in well sealed receptacles. 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:
- 67-63-0 propan-2-ol
- WEL Short-term value: 1250 mg/m³, 500 ppm Long-term value: 999 mg/m³, 400 ppm
- Additional information: The lists valid during the making were used as basis.

- · Personal protective equipment:
- General protective and hygienic measures:
- Usual hygienic measures for dental practice.
- Keep away from foodstuffs, beverages and feed.
- Wash hands before breaks and at the end of work.
- Do not inhale gases / fumes / aerosols.
- 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.

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^{· 8.2} Exposure controls

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• *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

SECTION 9: Physical and chemical properties

Appearance: Form:	Aerosol
Colour:	Whitish
Odour:	Characteristic
Odour threshold:	Not determined.
pH-value:	Not applicable.
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Not applicable, as aerosol.
Flash point:	Not applicable, as aerosol.
Flammability (solid, gaseous):	Not applicable.
Self-igniting:	Product is not selfigniting.
Danger of explosion:	<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.
Solubility in / Miscibility with	
water:	Not miscible or difficult to mix.

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· Viscosity:

Dynamic:

Kinematic: • 9.2 Other information

Not determined. Not determined. 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 Danger of explosion.
- 10.4 Conditions to avoid Keep away from heat and direct sunlight.
- 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:
- Primary irritant effect:
- on the skin: No irritant effect.
- on the eye: 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

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.

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

14.1 UN-Number	
ADR, IMDG, IATA	UN1950
14.2 UN proper shipping name	
ADR	1950 AEROSOLS
IMDG	AEROSOLS
IATA	AEROSOLS, flammable
14.3 Transport hazard class(es)	
ADR	
Class	2 5F Gases.
Label	2.1
IMDG, IATA	
2	
Class	2.1
Label	2.1
14.4 Packing group	
ADR, IMDG, IATA	Void
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Gases.
Danger code (Kemler):	-
EMS Number:	F-D,S-U
14.7 Transport in bulk according to Ann	
MARPOL73/78 and the IBC Code	Not applicable.
Transport/Additional information:	
ADR	
Limited quantities (LQ)	1L
Excepted quantities (EQ)	Code: E0
T	Not permitted as Excepted Quantity
Transport category	2
Tunnel restriction code	D
IMDG	11
Limited quantities (LQ)	1L Code: E0
Excepted quantities (EQ)	
	Not permitted as Excepted Quantity

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· UN "Model Regulation":

UN1950, AEROSOLS, 2.1

SECTION 15: Regulatory information

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

· 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

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 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) Flam. Gas 1: Flammable gases, Hazard Category 1 Flam. Aerosol 1: Flammable aerosols, Hazard Category 1 Press. Gas C: Gases under pressure: Compressed gas Flam. Liq. 2: Flammable liquids, Hazard Category 2 Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2 STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3 \cdot * Data compared to the previous version altered.

[·] National regulations: