

SAFETY DATA SHEET (GHS)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE/PRODUCT AND MANUFACTURER/IMPORTER

1.1 Product identifier:-

> Product name: IPS Empress Universal Glaze and Stain Liquid

Product number: 562496

1.2 Other means of identification:-

Not applicable.

1.3 Recommended use of the chemical and restrictions on use:-

Not applicable.

Identified uses: Auxiliary for manufacture of dental prothesis

Details of the manufacturer and importer:-1.4

Manufacturer: Ivoclar Vivadent AG

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PRINCIPALITY OF LIECHTENSTEIN

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1.5 0800 764 766 (National Poison Centre) **Emergency phone number:**

Poisons Hotline (24 hours / 7 days)

HAZARD(S) IDENTIFICATION 2.

2.1 GHS Classification:-

Importer:

Void

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram: Void Signal word: Void Hazard-determining components of Void

labelling:

Hazard statements: Void **Precautionary statements:** Void

Additional information: Void

2.3

Other hazards:-Avoid breathing sanding dust /swarf.

Results of PBT and vPvB assessment;

PBT: Not applicable. **vPvB:** Not applicable.

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COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions

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3	Ingredient name	CAS No.	Classification	Concentration			
	butane-1,3-diol	107-88-0	Void	Void			
	,	t of the H-Statements mentioned in this Section, refer to Section 16.					
	FIRST AID MEASURES						
4.	Description of necessary first aid measures:-						
4.1							
	If inhaled:		Grinding dust: Supply fresh air; consult doctor in case of complaints.				
	In case of skin contact:		Rinse with water.				
	iii case of skill contact.		Generally the product does not irritate the skin.				
	In case of eye contact:		Rinse opened eye for several minutes under running				
	in case of eye contact.		water. If symptoms persist, consult a doctor.				
	If swallowed:		Rinse out mouth and then drink plenty of water.				
			If symptoms persist consult doctor				
	Symptoms caused by ex	(posure:-	No further relevant information available.				
4.2	Medical attention and s						
4.3	·						
	FIRE FIGHTING MEASU	RES					
5.	Suitable extinguishing equipment:-						
5.1	Suitable extinguishing r						
	Unsuitable extinguishin		The product is not flammable.				
	Specific hazards arising		CO2, powder or water spray. Fight larger fires with water				
	substance/mixture/prod	uct:-	spray or alcohol resistant foam				
5.2	Special protective equir	Il protective equipment and No further relevan		nt information available			
0.2	precautions for fire figh		No further relevant information ava	ilable			
	_	·					
5.3							
	Special personal protec	tive equipment:	No further relevant information ava	ailable			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:-

Particular danger of slipping on leaked/spilled product.

6.2 Environmental precautions:-

Precautions:

Do not allow to enter sewers/ surface or ground water.

6.3 Methods and materials for containment and cleaning up:-

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

No further relevant information available

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling:-

Only adequately trained personnel should handle this product. For use in dentistry only.

7.2 Conditions for safe storage, including any incompatibilities:-

Store only in the original receptacle

This product is hygroscopic.

Keep container tightly sealed.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

Component	CAS No.	Value	Parameters	Basis
Void	Void	Void	Void	Void

Ingredients with biological limit values:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

8.2 Biological monitoring:-

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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:-

Void

8.5 Individual protection measures include PPE:-

Eye/face protection:

Safety glasses

Required

Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

Skin protection:

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 break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Respiratory protection:

Not Required

9. PHYSICAL/CHEMICAL PROPERTIES

- 9.1 Information on physical/chemical properties:-
- a) Appearance/Form:

Fluid

b) Colour:

Colourless

c) Odour:

Nearly odourless

f)

u)



d) Odour threshold:

e) pH value:

Not determined.

Not applicable.

Melting point/melting range: -50 °C

g) Boiling point/boiling range: Not determined.
h) Flash point: 109 °C

Flash point: 109 °C Ignition temperature: 375 °C

i) Ignition temperature:
 j) Self-igniting:
 k) Danger of explosion:
 375 °C
 Product is not self-igniting.
 Not determined.

Upper/lower flammability or explosive limits:Lower Lower Upper Not determined.

m) Vapour pressure 20°C: Not determined.

n) Density at 20°C: 1 g/cm³

o) Relative density:
p) Vapour density:
q) Evaporation rate:
Not applicable.
Not applicable.

r) Solubility in/miscibility with water: Fully miscible..
s) Partition coefficient: n- octanol/water: Not determined.

t) Viscosity:

Dynamic Not applicable.

Kinematic Not applicable.

Not applicable.

10. STABILITY AND REACTIVITY

10.1 Reactivity:
No further relevant information available.

10.2 Chemical stability:-

Solids content:

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.

10.4 Conditions to avoid:-

Protect from exposure to the light.

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.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

LD/LC50 values relevant for classification:

107-88-0 butane-1,3-diol Oral LD50 18610 mg/kg (rat)

Skin corrosion/irritation:
Serious eye damage/eye irritation:
No irritant effect.
No irritating effect.

Respiratory or skin sensitization:No sensitising effects known.

Germ cell mutagenicity:

Carcinogenicity:

No further relevant information available.

No further relevant information available.

Reproductive toxicity:

Specific target organ toxicity - single

No further relevant information available.

No further relevant information available.

exposure:

Specific target organ toxicity - repeated

No further relevant information available.

exposure:
Aspiration hazard:
Additional information:

No further relevant information available.
No further relevant information available.

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11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

Swallowed:

Eyes:

Skin:

Inhaled:

Inna Term (Chronic) Exposure:

No further relevant information available.

Long Term (Chronic) Exposure:

Swallowed:

Eyes:

No further relevant information available.

11.3 Early onset symptoms related to exposure:-

11.4 Delayed health effects from exposure: 11.5 Exposure levels and health effects: 11.6 Interactive effects: No further relevant information available.
 No further relevant information available.
 No further relevant information available.

11.7 Other:- No further relevant information available.

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity:-

No further relevant information available.

12.2 Persistence/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.

12.5 Other adverse effects:-

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

Additional ecological information / General notes:-

No further relevant information available.

12.6 Other adverse effects:-

No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods:-

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

UN number ADR / IMDG / IATA:- Void.
UN proper shipping name or technical name:ADR: Void.
IMDG, IATA: Void.
Transport hazard class(es): Void.
Label: Void.
Packaging group: Void.

Environmental hazards:Special precautions for user:
Not applicable.
Not applicable.



Danger code: Void. EMS Number: Void.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code:

Transport/Additional information: Product is not classified as a dangerous good for transport

(ADR, IMDG, IATA).

Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture/product:-

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.

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.

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:-

Key literature references/data sources used to compile SDS:-

Standard EN420:2003 General requirements for protective gloves: disposable gloves, e.g. nitrile rubber, material thickness 0.1 mm (Australian Standard 2161).

Long-term exposure (Level 6: < 480 min): protective gloves, e.g. nitrile rubber, material thickness 0.7 mm (Australian Standard 2161).

Personal eye protection - Eye and face protectors for occupational applications: safety glasses (Australian Standard AS 1336 and AS/NZS 1337.1:2010).

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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).

LC50: Lethal concentration, 50 percent.

LD50: Lethal dose, 50 percent.

Flam. Liq. 2: Flammable liquids, Hazard Category 2.

Flam. Liq. 3: Flammable liquids, Hazard Category 3.

Acute Tox. 4: Acute toxicity, Hazard Category 4.

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2.

Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2.

Repr. 2: Reproductive toxicity, Hazard Category 2.

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3.

STOT RE 2: Specific target organ toxicity - Repeated exposure, Hazard Category 2.

Asp. Tox. 1: Aspiration hazard, Hazard Category 1.

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Disclaimer:-

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Users should rely on their own knowledge and inquiries and make their own determination as to the applicability of this information in relation to their particular purposes and specific circumstances. Each user should read this SDS and consider the information in the context of how the product will be handled and used in the workplace and in conjunction with other substances or products.

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