

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 Direct Color
Product number: Void

1.2 Other means of identification:-

Not applicable.

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

Not applicable.

Identified uses:

Light-curing characterization material

1.4 Details of the manufacturer and importer:-

Manufacturer:

Ivoclar Vivadent AG
 Bendererstrasse 2
 FL-9494 Schaan
 PRINCIPALITY OF LIECHTENSTEIN
 Tel: +423 235 35 35
 Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Pty Ltd
 1- 5 Overseas Drive Noble Park North VIC 3174
 Tel: + 61 3 9795 9599 Fax: + 61 3 9795 9645
 Email: info@ivoclarvivadent.com

1.5 Emergency phone number:

13 11 26
 Poisons Hotline (24 hours / 7 days)

2. HAZARD(S) IDENTIFICATION

2.1 GHS Classification:-

Skin Irrit. 2 H315 Causes skin irritation.
 Eye Irrit. 2 H319 Causes serious eye irritation.
 Skin Sens. 1 H317 May cause an allergic skin reaction.
 Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects.

2.2 GHS Label elements, including precautionary statements:-

Hazard Pictogram:



GHS07

Signal word:

Warning

Hazard-determining components of labelling:

Bis-GMA
 urethane dimethacrylate
 triethylene glycol dimethacrylate

Hazard statements:

H315 Causes skin irritation.
 H319 Causes serious eye irritation.
 H317 May cause an allergic skin reaction.
 H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P280 Wear protective gloves/protective clothing/eye protection/face protection.
 P363 Wash contaminated clothing before reuse.
 P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
 P337+P313 If eye irritation persists: Get medical advice/attention

Additional information:

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

2.3

Other hazards:-

Results of PBT and vPvB assessment;

PBT: Not applicable.
vPvB: Not applicable.

COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

3

Ingredient name	CAS No.	Classification	Concentration
Bis-GMA	1565-94-2	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	25-50%
urethane dimethacrylate	72869-86-4	Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412	25-50%
hylene glycol dimethacrylate	109-16-0	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	10-<25%

For the full text 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:

Supply fresh air and to be sure call for a doctor.
 In case of unconsciousness place patient stably in side position for transportation.

In case of skin contact:

Rinse with water.

In case of eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

If swallowed:

If symptoms persist consult doctor.

Symptoms caused by exposure:-

No further relevant information available.

4.2

Medical attention and special treatment:-

No further relevant information available.

4.3

FIRE FIGHTING MEASURES

5.

Suitable extinguishing equipment:-

5.1

Suitable extinguishing media:

Unsuitable extinguishing media:

The product is not flammable.

Specific hazards arising from the substance/mixture/product:-

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam

5.2 Special protective equipment and precautions for fire fighters:- | No further relevant information available

5.3 Special personal protective equipment: Precautions: | No further relevant information available
| No further relevant information available

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:-

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

6.3 Methods and materials for containment and cleaning up:-

Pick up mechanically.

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

Protect from exposure to the light.

Protect from heat and direct sunlight.

Keep container tightly sealed

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.

Avoid contact with the eyes and skin.

Keep away from foodstuffs, beverages and feed.

8.3 Control banding:-

Use good industrial hygiene practice and general ventilation.

8.4 Engineering controls:-

In case of intensive contact, wear protective gloves (EN 374).

Before use, the protective gloves should be tested in any case for its specific work-station suitability (i.e. mechanical resistance, product compatibility and antistatic properties).

Adhere to the manufacturer's instructions and information relating to the use, storage, care and replacement of protective gloves.

Protective gloves shall be replaced immediately when physically damaged or worn.

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). Use tightly fitting safety glasses as per Australian Standard AS 1336 and AS/NZS 1337

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. As the product is a preparation of several substances, the resistance of the glove material cannot 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.

Respiratory protection:

Not Required

9. PHYSICAL/CHEMICAL PROPERTIES

9.1 Information on physical/chemical properties:-

a)	Appearance/Form:	Pastry
b)	Colour:	According to product specification
c)	Odour:	Characteristic
d)	Odour threshold:	Not determined.
e)	pH value:	Not applicable.
f)	Melting point/melting range:	Not determined.
g)	Boiling point/boiling range:	Not determined.
h)	Flash point:	Not determined.
i)	Ignition temperature:	Not determined.
j)	Self-igniting:	Product is not self-igniting.
k)	Danger of explosion:	Not determined.
l)	Upper/lower flammability or explosive limits:	Lower Not determined. Upper Not determined.
m)	Vapour pressure 20°C:	Not determined.
n)	Density at 20°C:	1.18 g/cm ³
o)	Relative density:	Not determined.
p)	Vapour density:	Not applicable.
q)	Evaporation rate:	Not applicable.
r)	Solubility in/miscibility with water:	Insoluble.
s)	Partition coefficient: n- octanol/water:	Not determined.

- | | | | |
|----|------------------------|-----------------|-----------------|
| t) | Viscosity: | Dynamic | Not applicable. |
| | | Kinematic | Not applicable. |
| u) | Solids content: | Not applicable. | |

10. STABILITY AND REACTIVITY

10.1 Reactivity:-

No further relevant information available.

10.2 Chemical stability:-

Stable under normal handling and storage conditions.

Photoreactive (Danger of polymerization).

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:

No further relevant information available.

Skin corrosion/irritation:

Irritant to skin and mucous membranes.

Serious eye damage/eye irritation:

Irritating effect.

Respiratory or skin sensitization:

Sensitisation possible through skin contact

Germ cell mutagenicity:

No further relevant information available.

Carcinogenicity:

No further relevant information available.

Reproductive toxicity:

No further relevant information available.

Specific target organ toxicity - single exposure:

No further relevant information available.

Specific target organ toxicity - repeated exposure:

No further relevant information available.

Aspiration hazard:

No further relevant information available.

Additional information:

No further relevant information available.

11.2 Information on possible routes of exposure:-

Short Term (Acute) Exposure:

No further relevant information available.

Swallowed:

No further relevant information available.

Eyes:

No further relevant information available.

Skin:

No further relevant information available.

Inhaled:

No further relevant information available.

Long Term (Chronic) Exposure:

No further relevant information available.

Swallowed:

No further relevant information available.

Eyes:

No further relevant information available.

Skin:

No further relevant information available.

Inhaled:

No further relevant information available.

11.3 Early onset symptoms related to exposure:-

No further relevant information available.

11.4 Delayed health effects from exposure:-

No further relevant information available.

- 11.5 **Exposure levels and health effects:-**
- 11.6 **Interactive effects:-**
- 11.7 **Other:-**

No further relevant information available.
No further relevant information available.
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:-**

Generally not hazardous for water

Additional ecological information / General notes:-

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

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:

Not applicable.

Special precautions for user:

Not applicable.

Danger code:

Void.

EMS Number:

Void.

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

Not applicable.

Transport/Additional information:

Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).

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:-

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H412 Harmful to aquatic life with long lasting effects.

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.

*** Data compared to the previous version altered**

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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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