

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 Ceramic Separating Liquid
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:

Auxiliary for dental technology

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:-**

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.

2.2 GHS Label elements, including precautionary statements:-**Hazard Pictogram:**

GHS08

Signal word:

Warning

Hazard-determining components of labelling:

White mineral oil (petroleum)

Hazard statements:

H304 May be fatal if swallowed and enters airways.
 P301+P310 **IF SWALLOWED: Immediately call a POISON CENTER/ doctor.**

Precautionary statements:

P331 Do NOT induce vomiting.
 P405 Store locked up.

2.3 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.

Other hazards:-

Results of PBT and vPvB assessment;

| | |
|--------------|-----------------|
| PBT: | Not applicable. |
| vPvB: | Not applicable. |

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture of substances listed below with nonhazardous additions.

| Ingredient name | CAS No. | Classification | Concentration |
|-------------------------------|-----------|----------------|---------------|
| White mineral oil (petroleum) | 8042-47-5 | | |

For the full text of the H-Statements mentioned in this Section, refer to Section 16.

4. FIRST AID MEASURES

4.1 Description of necessary first aid measures:-

If inhaled:

Supply fresh air; consult doctor in case of complaints.

In case of skin contact:

Generally the product does not irritate the skin.
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.

4.2 Symptoms caused by exposure:-

No further relevant information available

4.3 Medical attention and special treatment:-

No further relevant information available.

5. FIRE FIGHTING MEASURES

5.1 Suitable extinguishing equipment:-

Suitable extinguishing media:

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

Unsuitable extinguishing media:

No further relevant information available.

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

No further relevant information available.

5.3 Special protective equipment and precautions for fire fighters:-

Special personal protective equipment:

No further relevant information available

Precautions:

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:-

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

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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure control measures:-

Occupational exposure limits:

| Component | CAS No. | Value | Parameters | Basis |
|-----------|---------|-------|------------|-------|
| 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.

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: 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

- Butyl rubber, BR
- Chloroprene rubber, CR
- Fluorocarbon rubber (Viton)
- PVC gloves

- 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:-

IPS Ceramic Separating Liquid

| | | |
|----|--|--|
| a) | Appearance/Form: | Fluid |
| b) | Colour: | Colourless |
| c) | Odour: | Odourless |
| d) | Odour threshold: | Not determined. |
| e) | pH value: | Not applicable. |
| f) | Melting point/melting range: | Not determined |
| g) | Boiling point/boiling range: | 300 °C |
| h) | Flash point: | 215 °C |
| 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: | Not applicable. |
| n) | Density at 25°C: | 0.88 g/cm ³ |
| o) | Relative density: | Not determined. |
| p) | Vapour density: | Not applicable. |
| q) | Evaporation rate: | Not applicable. |
| r) | Solubility in/miscibility with water: | Nearly insoluble. |
| s) | Partition coefficient: n- octanol/water: | Not determined. |
| t) | Viscosity: | Dynamic Not applicable. Kinematic Not applicable. |
| u) | Solids content: | Not determined. |

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:-

No dangerous reactions known.

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.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:-

Acute toxicity / Values relevant for classification:

No further relevant information available.

Skin corrosion/irritation:

No irritant effect

Serious eye damage/eye irritation:

Irritating effect.

Respiratory or skin sensitization:

No sensitising effects known.

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:-

No further relevant information available.

11.6 Interactive effects:-

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: | 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.

16. OTHER INFORMATION

Key to abbreviations/acronyms used in SDS:- | Void

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

Copyright statement:-

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.

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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