Safety Data Sheet
in accordance with HSNO

Printing date 16.09.2024 *Version number 1* *Revision: 16.09.2024*

1 Identification of the substance or mixture and of the supplier

· **Product identifier**

· **Trade name:** **IPS Empress Direct (opal shade)**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

· **Application of the substance / the mixture** Polymer-based dental restorative material (intraoral light-curing)

· **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 Ltd.
12 Omega St, Rosedale, Auckland
New Zealand
Tel: + 64 9 914 9999 / Fax: + 64 9 914 9990

· **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com

· **Emergency telephone number:** 0800 764 766 (National Poison Centre - 24 hours / 7 days)

2 Hazards identification

· **Classification of the substance or mixture**

Skin sensitisation Category 1	H317 May cause an allergic skin reaction.
Reproductive toxicity Category 1	H360 May damage fertility or the unborn child.
Hazardous to the aquatic environment chronic Category 3	H412 Harmful to aquatic life with long lasting effects.

· **Label elements**

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

· **Hazard pictograms**

GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**
aromatic aliphatic urethane dimethacrylate
ethyl p-dimethylaminobenzoate
1,10-decandiol dimethacrylate
tricyclodecane dimethanol dimethacrylate
urethane dimethacrylate

· **Hazard statements**
May cause an allergic skin reaction.
May damage fertility or the unborn child.
Harmful to aquatic life with long lasting effects.

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· **Precautionary statements**
Obtain special instructions before use.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves / eye protection / face protection.
IF ON SKIN: Wash with plenty of water.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.
· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

3 Composition/Information on ingredients

· **Chemical characterisation: Mixtures**
· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 1219495-43-8 EC number: 943-136-4	aromatic aliphatic urethane dimethacrylate Skin sensitisation Category 1, H317	2.5-10%
CAS: 6701-13-9 EINECS: 229-745-1	1,10-decandiol dimethacrylate Eye irritation Category 2, H319; Skin sensitisation Category 1, H317	2.5-10%
CAS: 43048-08-4 EINECS: 256-062-6	tricyclodecane dimethanol dimethacrylate Hazardous to the aquatic environment chronic Category 2, H411; Skin sensitisation Sub-category 1B, H317	<2.5%
CAS: 72869-86-4 EINECS: 276-957-5	urethane dimethacrylate Hazardous to the aquatic environment chronic Category 2, H411; Eye irritation Category 2, H319; Skin sensitisation Category 1, H317	<2.5%
CAS: 10287-53-3 EINECS: 233-634-3	ethyl p-dimethylaminobenzoate Reproductive toxicity Category 1, H360; Hazardous to the aquatic environment chronic Category 2, H411	<2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:** If symptoms persist consult doctor.
· **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

· **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
· **Special hazards arising from the substance or mixture** No further relevant information available.

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· **Protective equipment:** No special measures required.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:** Pick up mechanically.
· **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.

7 Handling and storage

· **Handling:**
· **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
· **Information about fire - and explosion protection:** No special measures required.
· **Storage:**
· **Requirements to be met by storerooms and receptacles:** Store only in the original receptacle.
· **Information about storage in one common storage facility:** Not required.
· **Further information about storage conditions:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
Keep container tightly sealed.
· **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see section 7.
· **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
· **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 and dental laboratories.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
· **Respiratory protection:** Not required.
· **Protection of hands:**

Protective gloves

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.

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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 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.

· **Not suitable are gloves made of the following materials:**
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· **Eye protection:** Safety glasses

9 Physical and chemical properties

· **General Information**	
· **Appearance:**	
· **Form:**	Pasty
· **Colour:**	According to product specification
· **Odour:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
· **Melting point/freezing point:**	Undetermined.
· **Initial boiling point and boiling range:**	Undetermined.
· **Flash point:**	Not applicable.
· **Ignition temperature:**	Product is not selfigniting.
· **Explosive properties:**	Product does not present an explosion hazard.
· **Explosion limits:**	
· **Lower:**	Not determined.
· **Upper:**	Not determined.
· **Vapour pressure:**	Not determined.
· **Density at 20 °C:**	1.949 g/cm³
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with**	
· **water:**	Nearly insoluble.
· **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.
Photoreactive (Danger of polymerization).

· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.

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· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid**
Protect from exposure to the light.
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** Based on available data, the classification criteria are not met.
· **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
· **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
· **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
· **Carcinogenicity** Based on available data, the classification criteria are not met.
· **Reproductive toxicity**
May damage fertility or the unborn child.
· **STOT-single exposure** Based on available data, the classification criteria are not met.
· **STOT-repeated exposure** Based on available data, the classification criteria are not met.
· **Aspiration hazard** Based on available data, the classification criteria are not met.
· **Additional toxicological information:** No further relevant information available.

12 Ecological information

· **Toxicity**
· **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 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
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.

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14 Transport information

· **UN-Number**	
· **NZS/RID/ADN, ADN, IMDG, IATA**	Void
· **UN proper shipping name**	
· **NZS/RID/ADN, ADN, IMDG, IATA**	Void
· **Transport hazard class(es)**	
· **NZS/RID/ADN, ADN, IMDG, IATA**	
· **Class**	Void
· **Packing group**	
· **NZS/RID/ADN, IMDG, IATA**	Void
· **Environmental hazards:**	
· **Marine pollutant:**	No
· **Special precautions for user**	Not applicable.
· **Transport in bulk according to Annex II of Marpol and the IBC Code**	Not applicable.
· **Transport/Additional information:**	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· **UN "Model Regulation":**	Void

15 Regulatory information

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

· **New Zealand Inventory of Chemicals**	
CAS: 6701-13-9	1,10-decandiol dimethacrylate
CAS: 72869-86-4	urethane dimethacrylate
CAS: 10287-53-3	ethyl p-dimethylaminobenzoate

· **HSNO Approval numbers**
None of the ingredients is listed.

· **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).
· **Hazard pictograms**

GHS07 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**
aromatic aliphatic urethane dimethacrylate
ethyl p-dimethylaminobenzoate
1,10-decandiol dimethacrylate
tricyclodecane dimethanol dimethacrylate
urethane dimethacrylate
· **Hazard statements**
May cause an allergic skin reaction.
May damage fertility or the unborn child.

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Harmful to aquatic life with long lasting effects.

· ***Precautionary statements***
Obtain special instructions before use.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wear protective gloves / eye protection / face protection.
IF ON SKIN: Wash with plenty of water.
Store locked up.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· ***Directive 2012/18/EU***
· ***Named dangerous substances - ANNEX I*** *None of the ingredients is listed.*

· ***National regulations:***
· ***Other regulations, limitations and prohibitive regulations***
The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
· ***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***
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H360 May damage fertility or the unborn child.
H411 Toxic to aquatic life with long lasting effects.
· ***Contact:***
· ***Abbreviations and acronyms:***
IMO: International Maritime Organization
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
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
Eye irritation Category 2: Serious eye damage/eye irritation – Category 2
Skin sensitisation Category 1: Skin sensitisation – Category 1
Skin sensitisation Sub-category 1B: Skin sensitisation – Category 1B
Reproductive toxicity Category 1: Reproductive toxicity – Category 1
Hazardous to the aquatic environment chronic Category 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2
Hazardous to the aquatic environment chronic Category 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3