

Printing date 15.09.2023 Version number 2 Revision: 15.09.2023

1 Identification of the substance or mixture and of the supplier

- · Product identifier
- · Trade name: IPS Ivocolor Essence Fluid
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the mixture Stains and Glazes
- · 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

The product is not classified, according to the Globally Harmonised System (GHS).

- · Label elements
- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · 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: 56-81-5 glycerol

EINECS: 200-289-5

<2.5%

4 First aid measures

- · General information: No special measures required.
- · After inhalation:

Supply fresh air; consult doctor in case of complaints.

(Contd. on page 2)

Printing date 15.09.2023 Version number 2 Revision: 15.09.2023

Trade name: IPS Ivocolor Essence Fluid

(Contd. of page 1)

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.

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.
- · Protective equipment: No special measures required.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Use respiratory protective device against the effects of fumes/dust/aerosol.

- · Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

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

· 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: 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.

(Contd. on page 3)

Printing date 15.09.2023 Version number 2 Revision: 15.09.2023

Trade name: IPS Ivocolor Essence Fluid

(Contd. of page 2)

· Ingredients with limit values that require monitoring at the workplace:

CAS: 56-81-5 glycerol

WES Long-term value: 10 mg/m³

mist

· Additional information: The lists valid during the making were used as basis.

· Personal protective equipment:

· General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

Usual hygienic measures for dental practice and dental laboratories.

· Respiratory protection:

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.

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: Safety glasses

9 Physical and chemical properties

· General Information

· Appearance:

Form: Liquid
Colour: Colourless
Odour: Characteristic
Odour threshold: Not determined.
pH-value: Not determined.

· Change in condition

• Melting point/freezing point:
• Initial boiling point and boiling range: Undetermined.
• Flash point:

109 °C

Flammability (solid, gas): Not applicable.
Ignition temperature: Not determined.

• Explosive properties: Product does not present an explosion hazard.

· 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 determined.

· Solubility in / Miscibility with

• water: Fully miscible.

(Contd. on page 4)

Printing date 15.09.2023 Version number 2 Revision: 15.09.2023

Trade name: IPS Ivocolor Essence Fluid

(Contd. of page 3)

· 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.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · 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.
- LD/LC50 values relevant for classification: 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 Based on available data, the classification criteria are not met.
- · 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 Based on available data, the classification criteria are not met.
- · 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 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.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

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Printing date 15.09.2023 Version number 2 Revision: 15.09.2023

Trade name: IPS Ivocolor Essence Fluid

(Contd. of page 4)

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.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

UN-Number	77.1
NZS/RID/ADN, ADN, IMDG, IATA	Void
UN proper shipping name	
NZS/RID/ADN	Void
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	
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

All ingredients are listed.

· HSNO Approval numbers

None of the ingredients is listed.

- · GHS label elements Void
- · Hazard pictograms Void
- · Signal word Void
- · Hazard statements Void
- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.

(Contd. on page 6)

Printing date 15.09.2023 Version number 2 Revision: 15.09.2023

Trade name: IPS Ivocolor Essence Fluid

(Contd. of page 5)

- · 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.

- · Contact:
- · Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international 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

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

PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

* Data compared to the previous version altered.

N7