

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 15.09.2023

Version number 2 (replaces version 1)

Revision: 15.09.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name: *IPS Ivocolor Essence Fluid***
- **1.2 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*
- **1.3 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
- **Further information obtainable from:**
Regulatory Affairs
sds@ivoclar.com
- **1.4 Emergency telephone number:** *+423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

Dangerous components:

CAS: 56-81-5	glycerol	substance with a Community workplace exposure limit	<2.5%
EINECS: 200-289-5			

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** *No special measures required.*
- **After inhalation:**
Supply fresh air; consult doctor in case of complaints.
In case of unconsciousness place patient stably in side position for transportation.

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- **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.
- **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Use respiratory protective device against the effects of fumes/dust/aerosol.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 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.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **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.
- **7.3 Specific end use(s)** No further relevant information available.

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SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with limit values that require monitoring at the workplace:

CAS: 56-81-5 glycerol

WEL Long-term value: 10 mg/m³

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

8.2 Exposure controls

Appropriate engineering controls No further data; see section 7.

Individual protection measures, such as 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.

Hand protection

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/face protection Safety glasses

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

- | | |
|---|-----------------|
| · Colour: | Colourless |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | Undetermined. |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | 109 °C |
| | Undetermined. |
| · pH | Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · Dynamic: | Not determined. |
| · Solubility | |
| · water: | Fully miscible. |

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- | | |
|--|-----------------|
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density and/or relative density | |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |
-
- | | |
|--|---|
| · 9.2 Other information | |
| · Appearance: | |
| · Form: | Liquid |
| · Important information on protection of health and environment, and on safety. | |
| · Ignition temperature: | Not determined. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Change in condition | |
| · Evaporation rate | Not determined. |
-
- | | |
|--|------|
| · Information with regard to physical hazard classes | |
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 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.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **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.

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- **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.
- **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and 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 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **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.

SECTION 13: Disposal considerations

- **13.1 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.

SECTION 14: Transport information

- | | |
|---------------------------------------|------|
| · 14.1 UN number or ID number | |
| · ADR/RID/ADN, ADN, IMDG, IATA | Void |
| · 14.2 UN proper shipping name | |
| · ADR/RID/ADN | Void |
| · ADN, IMDG, IATA | Void |

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· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA	
· Class	Void
· 14.4 Packing group	
· ADR/RID/ADN, IMDG, IATA	Void
· 14.5 Environmental hazards:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Maritime transport in bulk according to IMO instruments	Not applicable.
· Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **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).
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

- **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
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
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
- *** Data compared to the previous version altered.**