

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

Printing date 18.09.2015

Version number 1

Revision: 18.09.2015

### 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** Auxiliary for manufacture of dental prothesis
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Ivoclar Vivadent AG  
Bendererstrasse 2  
FL-9494 Schaan  
PRINCIPALITY OF LIECHTENSTEIN
- Tel: +423 235 35 35  
Fax: +423 235 33 60
- **Further information obtainable from:**  
Regulatory Affairs  
sds@ivoclarvivadent.com
- **1.4 Emergency telephone number:** +423 / 235 33 13 (Ivoclar Vivadent AG, FL-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 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 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

|                   |          |                                                     |           |
|-------------------|----------|-----------------------------------------------------|-----------|
| CAS: 56-81-5      | glycerol | substance with a Community workplace exposure limit | 0.1-<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. If symptoms persist, 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:**  
CO<sub>2</sub>, 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** Not required.
- **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.

### SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

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#### · 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/m<sup>3</sup>
 · **Additional information:** The lists valid during the making were used as basis.

#### · 8.2 Exposure controls

##### · **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.

##### · **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

## SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic 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/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

 · **Flash point:** 109 °C  
Undetermined.
· **Flammability (solid, gaseous):** Not applicable.· **Self-igniting:** Not determined.· **Danger of explosion:** Product does not present an explosion hazard.

##### · **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

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|                                                   |                                            |
|---------------------------------------------------|--------------------------------------------|
| · <b>Vapour pressure:</b>                         | Not determined.                            |
| · <b>Density:</b>                                 | Not determined.                            |
| · <b>Relative density</b>                         | Not determined.                            |
| · <b>Vapour density</b>                           | Not determined.                            |
| · <b>Evaporation rate</b>                         | Not determined.                            |
| · <b>Solubility in / Miscibility with water:</b>  | Fully miscible.                            |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |                                            |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| · <b>9.2 Other information</b>                    | No further relevant information available. |

### 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 toxicological effects**
- **Acute toxicity**
- **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.
- **Additional toxicological information:** No further relevant information available.
- **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.

### 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.

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

### 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

- |                                                                                  |                                                                                |
|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| · <b>14.1 UN-Number</b>                                                          |                                                                                |
| · <b>ADR,RID,ADN, ADN, IMDG, IATA</b>                                            | Void                                                                           |
| · <b>14.2 UN proper shipping name</b>                                            |                                                                                |
| · <b>ADR,RID,ADN, ADN, IMDG, IATA</b>                                            | Void                                                                           |
| · <b>14.3 Transport hazard class(es)</b>                                         |                                                                                |
| · <b>ADR,RID,ADN, ADN, IMDG, IATA</b>                                            |                                                                                |
| · <b>Class</b>                                                                   | Void                                                                           |
| · <b>14.4 Packing group</b>                                                      |                                                                                |
| · <b>ADR,RID,ADN, IMDG, IATA</b>                                                 | Void                                                                           |
| · <b>14.5 Environmental hazards:</b>                                             |                                                                                |
| · <b>Marine pollutant:</b>                                                       | No                                                                             |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable.                                                                |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable.                                                                |
| · <b>Transport/Additional information:</b>                                       | Product is not classified as a dangerous good for transport (ADR, IMDG, IATA). |
| · <b>UN "Model Regulation":</b>                                                  | 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.

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- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
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.

**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 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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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