

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

1 Identification

- **Product identifier**
- **Trade name:** **IPS Ivocolor Glaze Paste / FLUO , Shades**
- **Application of the substance / the mixture** Stains and Glazes
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

Ivoclar Vivadent Inc.
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance:
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified, according to the Globally Harmonized System (GHS).

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	0	Health = 0
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.

(Contd. on page 2)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

Trade name: **IPS Ivocolor Glaze Paste / FLUO , Shades**· **vPvB:** Not applicable.

(Contd. of page 1)

3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Description:** dental ceramic

· **Dangerous components:**

CAS: 56-81-5	glycerol	<2.5%
--------------	----------	-------

4 First-aid measures

- **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.
- **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.
Mechanical effects only.
- **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

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing 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.
- **Advice for firefighters**
- **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:** 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.

(Contd. on page 3)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

Trade name: **IPS Ivocolor Glaze Paste / FLUO , Shades**

(Contd. of page 2)

· Protective Action Criteria for Chemicals

· PAC-1:

CAS: 56-81-5	glycerol	45 mg/m ³
--------------	----------	----------------------

· PAC-2:

CAS: 56-81-5	glycerol	180 mg/m ³
--------------	----------	-----------------------

· PAC-3:

CAS: 56-81-5	glycerol	1,100 mg/m ³
--------------	----------	-------------------------

7 Handling and storage

· Handling:

· Precautions for safe handling

Only adequately trained personnel should handle this product.

For use in dentistry only.

· Information about protection against explosions and fires: No special measures required.

· 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:

This product is hygroscopic.

Keep receptacle tightly sealed.

Store in dry conditions.

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see section 7.

· Control parameters

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

CAS: 56-81-5 glycerol

PEL	Long-term value: 15 * 5 ** mg/m ³ mist; *total dust **respirable fraction
-----	---

TLV	TLV withdrawn-insufficient data human occup. exp.
-----	---

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

· Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· 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.

(Contd. on page 4)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

Trade name: **IPS Ivocolor Glaze Paste / FLUO , Shades**

(Contd. of page 3)

- **Material of gloves**

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **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

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Pasty

Color: According to product specification

- **Odor:** Characteristic

- **Odor threshold:** Not determined.

- **pH-value:** Not determined.

- **Change in condition**

Melting point/Melting range: Undetermined.

Boiling point/Boiling range: Undetermined.

- **Flash point:** Undetermined.

- **Ignition temperature:** Product is not selfigniting.

- **Danger of explosion:** Product does not present an explosion hazard.

- **Explosion limits:**

Lower: Not determined.

Upper: Not determined.

- **Vapor pressure:** Not determined.

- **Density:** Not determined.

- **Relative density** Not determined.

- **Vapor density** Not determined.

- **Evaporation rate** Not determined.

- **Solubility in / Miscibility with**

Water: Partly soluble.

- **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.

(Contd. on page 5)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

Trade name: **IPS Ivocolor Glaze Paste / FLUO , Shades**

(Contd. of page 4)

- **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:**
- **LD/LC50 values that are relevant for classification:**
Based on available data, the classification criteria are not met.
- **Specific symptoms in biological assay:**
- **on the skin:** No irritant effect.
- **on the eye:** No irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:** No further relevant information available.

- **Carcinogenic categories**

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

*

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

US

(Contd. on page 6)

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

Trade name: **IPS Ivocolor Glaze Paste / FLUO , Shades**

(Contd. of page 5)

14 Transport information

- **UN-Number**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT, ADR/RID/ADN, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT, ADR/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 73/78 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**

- **Sara**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients is listed.

- **TSCA (Toxic Substances Control Act):**

All components have the value ACTIVE.

- **Hazardous Air Pollutants**

None of the ingredients is listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

(Contd. on page 7)

US

Safety Data Sheet

acc. to OSHA HCS

Printing date 09/15/2023

Version number 2

Reviewed on 09/15/2023

Trade name: **IPS Ivocolor Glaze Paste / FLUO , Shades**

(Contd. of page 6)

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **GHS label elements** Void

· **Hazard pictograms** Void

· **Signal word** Void

· **Hazard statements** Void

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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:**

· **Date of preparation / last revision** 09/15/2023

· **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

· *** Data compared to the previous version altered.**

US