SAFETY DATA SHEETS

This SDS packet was issued with item:

077155708

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070483453 077155039 077155716



Printing date 05/18/2015 Version number 7

Reviewed on 04/16/2015

1 Identification

- · Product identifier
- Trade name: IPS Empress Universal Glaze and Stain Liquid
- · CAS Number:

107-88-0

· EC number:

203-529-7

· 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
- · Details of the supplier of the safety data sheet
- · Manufacturer/Supplier:

Ivoclar Vivadent Inc.

175 Pineview Drive, Amherst, N.Y. 14228

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 substance 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)



Fire = 1Reactivity = 0

(Contd. on page 2)

Printing date 05/18/2015 Version number 7 Reviewed on 04/16/2015

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)



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

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description
 107-88-0 butane-1,3-diol
- $\cdot \textit{Identification number}(s)$
- · EC number: 203-529-7

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.
- · 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.

- · 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 Not required.
- 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).

 $(Contd.\ on\ page\ 3)$

- US

Printing date 05/18/2015 Version number 7 Reviewed on 04/16/2015

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 2)

· 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 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.

· 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 item 7.
- · Control parameters
- · Components 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.

- \cdot 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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

- · Breathing equipment: Not required.
- · Protection of hands:

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.

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.

· 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

IIS.

(Contd. on page 4)

Printing date 05/18/2015 Version number 7 Reviewed on 04/16/2015

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 3)

Information on basic physical and	chemical properties
General Information	
Appearance: Form:	Fluid
rorm: Color:	ruuu Colorless
Odor:	Nearly odorless
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/Melting range:	-50 °C (-58 °F)
Boiling point/Boiling range:	Undetermined.
Flash point:	109 °C (228 °F)
Flammability (solid, gaseous):	Not applicable.
Ignition temperature:	375 °C (707 °F)
Auto igniting:	Not determined.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapor pressure:	Not determined.
Density at 20 °C (68 °F):	1 g/cm³ (8.345 lbs/gal)
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
Partition coefficient (n-octanol/wat	t er): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Other information	No further relevant information available.

10 Stability and reactivity

- $\cdot \textit{Reactivity} \ \textit{No further relevant information available}.$
- · 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.

IC -

(Contd. on page 5)

Printing date 05/18/2015 Version number 7 Reviewed on 04/16/2015

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 4)

11 Toxicological information

- · Information on toxicological effects
- · Acute toxicity:
- · LD/LC50 values that are relevant for classification:

107-88-0 butane-1,3-diol

Oral LD50 18610 mg/kg (rat)

- · Primary irritant effect:
- · 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)

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- $\cdot \textit{Bioaccumulative potential No further relevant information available}.$
- · Mobility in soil No further relevant information available.
- $\cdot \textit{Additional ecological information:}$
- · General notes:

Water hazard class 1 (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.

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.

14 Transport information

- · UN-Number
- · DOT, ADR, ADN, IMDG, IATA Void

(Contd. on page 6)

Printing date 05/18/2015 Version number 7 Reviewed on 04/16/2015

Trade name: IPS Empress Universal Glaze and Stain Liquid

	(Contd. of p
· UN proper shipping name	
· DOT, ÂDN, IMDG, IATA	Void
$\cdot ADR$	Void
· Transport hazard class(es)	
DOT, ADR, ADN, IMDG, IATA	
·Class	Void
· Packing group	
· DOT, ADR, IMDG, IATA	Void
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
Transport in bulk according to Annex 1	II of
MARPOL73/78 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'':	_

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

Substance is not listed.

· TLV (Threshold Limit Value established by ACGIH)

Substance is not listed.

(Contd. on page 7)

Printing date 05/18/2015 Version number 7 Reviewed on 04/16/2015

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 6)

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

Substance is not 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 the Directive 93/42/EEC.

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.

- · Date of preparation / last revision 05/18/2015 / 6
- · 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

 ${\it HMIS: Hazardous\ Materials\ Identification\ System\ (USA)}$

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

·* Data compared to the previous version altered.

US



Printing date 06/12/2013

Version number 6

Reviewed on 06/12/2013

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

- · Product identifier
- · Trade name: IPS Empress Universal Glaze and Stain Liquid
- · CAS Number:

107-88-0

· EC number:

203-529-7

- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · Application of the substance / the preparation Auxiliary for manufacture of dental prothesis
- 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 MSDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazards identification

· Classification of the substance or mixture

The substance is not classified according to the Globally Harmonized System (GHS).

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · Information concerning particular hazards for human and environment: Not applicable.
- · Label elements
- · Additional information: Void
- · Classification system:
- · NFPA ratings (scale 0 4)



Health = 0 Fire = 1Reactivity = 0

(Contd. on page 2)

Printing date 06/12/2013 Version number 6 Reviewed on 06/12/2013

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 1)

· HMIS-ratings (scale 0 - 4)



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

3 Composition/information on ingredients

- · Chemical characterization: Substances
- · CAS No. Description 107-88-0 butane-1,3-diol
- · Identification number(s)
- · EC number: 203-529-7

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.
- · 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.

- · 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 Firefighting 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 Not required.
- · 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).

(Contd. on page 3)

Printing date 06/12/2013 Version number 6 Reviewed on 06/12/2013

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 2)

· 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 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.

· 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 item 7.
- · Control parameters
- · Components 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 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.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

- · Breathing equipment: Not required.
- · Protection of hands:

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.

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.

· 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.

(Contd. on page 4)

- C/

Printing date 06/12/2013 Version number 6 Reviewed on 06/12/2013

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 3)

· Eye protection: Safety glasses

Fluid Colorless Nearly odorless Not determined. Not determined. -50 °C Undetermined.
Colorless Nearly odorless Not determined. Not determined. -50 °C
Colorless Nearly odorless Not determined. Not determined. -50 °C
Nearly odorless Not determined. Not determined. -50 °C
Not determined. Not determined. -50 °C
Not determined50 °C
-50 °C
Undetermined
опистинки.
109 °C
Not applicable.
375 °C
Not determined.
Product does not present an explosion hazard.
Not determined.
Not determined.
Not determined.
1 g/cm³
Not determined.
Not determined.
Not determined.
Fully miscible.
): Not determined.
Not determined.
Not determined.

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.

(Contd. on page 5)

C **A**

Printing date 06/12/2013 Version number 6 Reviewed on 06/12/2013

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 4)

· 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:

107-88-0 butane-1,3-diol

Oral LD50 18610 mg/kg (rat)

- · Primary irritant effect:
- · on the skin: No irritant effect.
- · on the eye: No irritating effect.
- · Sensitization: No sensitizing effects known.
- · Additional toxicological information: The substance is not subject to classification.
- · Carcinogenic categories
- · NTP (National Toxicology Program)

Substance is not 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.
- $\cdot \textit{\textbf{Mobility in soil}} \ \textit{No further relevant information available}.$
- · Additional ecological information:
- · General notes:

Water hazard class 1 (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.

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.

CA

(Contd. on page 6)

Printing date 06/12/2013 Version number 6 Reviewed on 06/12/2013

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 5)

· UN-Number	
· DOT, TDG, ADN, IMDG, IATA	Void
· UN proper shipping name	
· DOT, TDG, ADN, IMDG, IATA	Void
· Transport hazard class(es)	
· DOT, TDG, ADN, IMDG, IATA	
· Class	Void
· Packing group	
· DOT, TDG, IMDG, IATA	Void
Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II o	of
MARPOL73/78 and the IBC Code	Not applicable.

15 Regulatory information

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Sara
- · Section 355 (extremely hazardous substances):

Substance is not listed.

· Section 313 (Specific toxic chemical listings):

Substance is not listed.

· TSCA (Toxic Substances Control Act):

Substance is listed.

- · Proposition 65
- · Chemicals known to cause cancer:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for females:

Substance is not listed.

· Chemicals known to cause reproductive toxicity for males:

Substance is not listed.

· Chemicals known to cause developmental toxicity:

Substance is not listed.

- · Carcinogenic categories
- · EPA (Environmental Protection Agency)

Substance is not listed.

· TLV (Threshold Limit Value established by ACGIH)

Substance is not listed.

(Contd. on page 7)

Printing date 06/12/2013 Version number 6 Reviewed on 06/12/2013

Trade name: IPS Empress Universal Glaze and Stain Liquid

(Contd. of page 6)

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

Substance is not listed.

· OSHA-Ca (Occupational Safety & Health Administration)

Substance is not listed.

· Canadian substance listings:

· Canadian Domestic Substances List (DSL)

Substance is listed.

· Canadian Ingredient Disclosure list (limit 0.1%)

Substance is listed.

· Canadian Ingredient Disclosure list (limit 1%)

Substance is not listed.

- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-directive 93/42/EEC.

· 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.

· Abbreviations and acronyms:

ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial 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

CA