SAFETY DATA SHEETS

This SDS packet was issued with item:

077125081

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).

077083538 077124506 077124514 077124522 077124530 077125008 077125016 077125024 077125032 077125040 077125057 077125065 077125073 077125099 077125107 077125115 077125123 077125131 077125149 077125156 077125164 077125172 077125180 077125198 077125206 077125214 077125222 077125230 077125248 077125255 077125263 077125271 077125289 077125297 077125305 077125313 077125321 077125339 077125503 077125511 077125529 077125537 077125545 077125552 077125560 077125578 077125586 077125594 077125602 077125610 077125628 077125636 077125644 077125651 077125669 077125677 077125685 077125693 077125701 077125719 077125727 077125735 077125743 077125750 077125768 077125776 077125784 077125792 077125800 077125818 077125826 077125834 077126055

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2013 Version number 2 Reviewed on 09/19/2013

1 Identification

· **Product identifier**

· **Trade name:** **IPS Empress Direct**

· **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
· **Application of the substance / the preparation** Light-curing resin-based dental restorative material

· **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 Hazard(s) identification

· **Classification of the substance or mixture**

· **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
Irritant
Irritating to eyes. May cause sensitisation by skin contact.
· **Classification system:**
The classification was made according to the latest editions of international substances lists, and expanded upon from company and literature data.

· **Label elements**

· **Labelling according to EU guidelines:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Code letter and hazard designation of product:**

Irritant

(Contd. on page 2)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2013 Version number 2 Reviewed on 09/19/2013

Trade name: IPS Empress Direct

(Contd. of page 1)

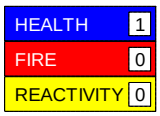
· **Hazard-determining components of labeling:**
urethane dimethacrylate

· **Risk phrases:**
Irritating to eyes.
May cause sensitisation by skin contact.

· **Safety phrases:**
Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.
· **Classification system:**
· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 0

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

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**		
72869-86-4	urethane dimethacrylate	10-25%
43048-08-4	tricyclodocane dimethanol dimethacrylate	2.5-10%
1565-94-2	Bis-GMA	2.5-10%

4 First-aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Rinse with water.
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** If symptoms persist consult doctor.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** No further relevant information available.

(Contd. on page 3)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Trade name: IPS Empress Direct

(Contd. of page 2)

· **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:** 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.

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:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
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.

(Contd. on page 4)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2013 Version number 2 Reviewed on 09/19/2013

Trade name: IPS Empress Direct

(Contd. of page 3)

· **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.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
· **Breathing equipment:** Not required.
· **Protection of hands:**

Protective gloves

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. 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

· **Information on basic physical and chemical properties**	
· **General Information**	
· **Appearance:**	
Form:	Pasty
Color:	According to product specification
· **Odor:**	Characteristic
· **Odour threshold:**	Not determined.
· **pH-value:**	Not determined.
· **Change in condition**	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· **Flash point:**	Not applicable.
· **Auto igniting:**	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.

(Contd. on page 5)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2013 Version number 2 Reviewed on 09/19/2013

Trade name: IPS Empress Direct

(Contd. of page 4)

· **Density at 20 °C (68 °F):**	1.94 g/cm³ (16.189 lbs/gal)
· **Relative density**	Not determined.
· **Vapour density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with Water:**	Nearly insoluble.
· **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.
Photoreactive (Danger of polymerization).
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
· **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:**
· **Primary irritant effect:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Irritant

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**
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.

(Contd. on page 6)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2013 Version number 2 Reviewed on 09/19/2013

Trade name: IPS Empress Direct

(Contd. of page 5)

· **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 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
· **UN proper shipping name** · **DOT, ADR, ADN, IMDG, IATA**	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 II 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):**
None of the ingredients is listed.

(Contd. on page 7)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Printing date 09/19/2013 Version number 2 Reviewed on 09/19/2013

Trade name: IPS Empress Direct

(Contd. of page 6)

· **Section 313 (Specific toxic chemical listings):**
None of the ingredients is listed.

· **TSCA (Toxic Substances Control Act):**
All ingredients are 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.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**
None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

13760-80-0	ytterbium trifluoride	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**
None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**
None of the ingredients is listed.

· **Product related hazard informations:**
Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Dangerous Substance Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· **Hazard symbols:**

Irritant

· **Hazard-determining components of labeling:**
urethane dimethacrylate

· **Risk phrases:**
Irritating to eyes.
May cause sensitisation by skin contact.

· **Safety phrases:**
Avoid contact with skin.
In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Wear suitable gloves.
This material and its container must be disposed of as hazardous waste.

· **National regulations:**
· **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.

(Contd. on page 8)

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
acc. to OSHA HCS

Trade name: IPS Empress Direct

(Contd. of page 7)

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.

USA

Obtained by Global Safety Management, Inc. -Tel: 1-813-435-5161 - www.globalsafetynet.com

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 *Version number 3.1* *Reviewed on 04/16/2018*

1 Identification

· **Product identifier**

· **Trade name:** **IPS Empress Direct**

· **Application of the substance / the mixture** Light-curing resin-based dental restorative material

· **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 identification

· **Classification of the substance or mixture**
Skin Irritation - Category 2 H315 Causes skin irritation.
Eye Irritation - Category 2A H319 Causes serious eye irritation.
Skin Sensitizer - Category 1 H317 May cause an allergic skin reaction.

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
urethane dimethacrylate
Bis-GMA
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.

(Contd. on page 2)

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 *Version number 3.1* *Reviewed on 04/16/2018*

Trade name: IPS Empress Direct

(Contd. of page 1)

May cause an allergic skin reaction.

· **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with local/regional/national/international regulations.

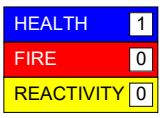
· **Additional information:**
Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**

Health = 1
Fire = 0
Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 1
Fire = 0
Reactivity = 0

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**
· **Description:** *Mixture of the substances listed below with nonhazardous additions.*

· **Dangerous components:**		
CAS: 72869-86-4	*urethane dimethacrylate*	*10-13% w/w*
CAS: 13760-80-0	*ytterbium trifluoride*	*5-<10% w/w*
CAS: 43048-08-4	*tricyclodocane dimethanol dimethacrylate*	*3-5% w/w*
CAS: 1565-94-2	*Bis-GMA*	*1-<3% w/w*

4 First aid measures

· **Description of first aid measures**
· **After inhalation:**
Supply fresh air and to be sure call for a doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** *Rinse with water.*
· **After eye contact:**
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
· **After swallowing:** *If symptoms persist consult doctor.*
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed** *No further relevant information available.*

(Contd. on page 3)

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 Version number 3.1 Reviewed on 04/16/2018

Trade name: IPS Empress Direct

(Contd. of page 2)

· **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:** 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.

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:**
Protect from exposure to the light.
Protect from heat and direct sunlight.
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.

(Contd. on page 4)

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 Version number 3.1 Reviewed on 04/16/2018

Trade name: IPS Empress Direct

(Contd. of page 3)

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
Usual hygienic measures for dental practice and dental laboratories.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.
· **Breathing equipment:** Not required.
· **Protection of hands:**

Protective gloves

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. 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

· **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:**	Not applicable.
· **Auto igniting:**	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 at 20 °C:**	1.94 g/cm³

(Contd. on page 5)

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 Version number 3.1 Reviewed on 04/16/2018

Trade name: IPS Empress Direct

(Contd. of page 4)

· **Relative density**	Not determined.
· **Vapor density**	Not determined.
· **Evaporation rate**	Not determined.
· **Solubility in / Miscibility with Water:**	Nearly insoluble.
· **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.
Photoreactive (Danger of polymerization).
· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
· **Possibility of hazardous reactions** No dangerous reactions known.
· **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
· **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:**
· **on the skin:** No irritant effect.
· **on the eye:** Irritating effect.
· **Sensitization:** Sensitization possible through skin contact.
· **Additional toxicological information:** No further relevant information available.

· **Carcinogenic categories**

· **NTP (National Toxicology Program)**
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

(Contd. on page 6)

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 Version number 3.1 Reviewed on 04/16/2018

Trade name: IPS Empress Direct

(Contd. of page 5)

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, TDG, ADN, IMDG, IATA**	*Void*
· **UN proper shipping name**	
· **DOT, ADN, IMDG, IATA**	*Void*
· **TDG**	*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 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":**	*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.

(Contd. on page 7)

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/16/2018 Version number 3.1 Reviewed on 04/16/2018

Trade name: IPS Empress Direct

(Contd. of page 6)

· **TSCA (Toxic Substances Control Act):**
All ingredients are listed.

· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
· **Hazard pictograms**

GHS07

· **Signal word** Warning

· **Hazard-determining components of labeling:**
urethane dimethacrylate
Bis-GMA
· **Hazard statements**
Causes skin irritation.
Causes serious eye irritation.
May cause an allergic skin reaction.
· **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapours/spray.
Wash thoroughly after handling.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
IF ON SKIN: Wash with plenty of water.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Specific treatment (see on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with local/regional/national/international regulations.

· **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** 04/16/2018 / 3
· **Abbreviations and acronyms:**
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)
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
· *** Data compared to the previous version altered.**