

## **SAFETY DATA SHEETS**

**This SDS packet was issued with item:**

**077143910**

**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).**

077143902 077143928 077143936 077143944 077143951 077152952 077152960 077152978 077152986 077152994  
077153000 077153018 077153026 077153034 077153042 077153059 077153067 077153075 077153083 077153091  
077153109 077153117 077153125 077153133 077153141 077153158 077153166 077153174 077153182 077153190  
077153208 077153216 077153224 077153232 077153240 077153257 077153265 077153273 077153281 077153299  
077153307 077153315 077153323 077153331 077153349 077153356 077153604 077153612 077153620 077153638  
077153646 077153653 077153661 077153679 077153687 077153695 077153703 077153711 077153729 077153737  
077153745 077153752 077153760 077153778 077153786 077153794 077153802 077153810 077153828 077153836  
077153844 077153851 077153869 077153877 077153885 077153893 077153901 077153919 077153927 077153935  
077153943 077153950 077153968 077153976 077153984 077153992 077154008 077154016 077154024 077154032  
077154040 077154057 077154065 077154073 077154081 077154099 077154107 077154115 077154123 077154503  
077154511 077154529 077154537 077154545 077154552 077154560 077154578 077154586 077154594 077154602  
077154800 077154818 077154826 077154834 077154842 077154859 077155021

# Safety Data Sheet

acc. to OSHA HCS

Printing date 05/18/2015

Version number 4

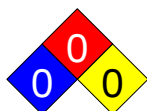
Reviewed on 04/16/2015

## 1 Identification

- **Product identifier**
- **Trade name:** IPS Empress CAD / IPS Empress CAD Multi
- **CAS Number:**  
66402-68-4
- **EC number:**  
266-340-9
- **Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **Application of the substance / the mixture**  
Manufacture of dental prothesis  
Leucite-reinforced glass-ceramic blocks for the CAD/CAM technique
- **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 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)**



Health = 0  
Fire = 0  
Reactivity = 0

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# Safety Data Sheet

acc. to OSHA HCS

Printing date 05/18/2015

Version number 4

Reviewed on 04/16/2015

Trade name: **IPS Empress CAD / IPS Empress CAD Multi**

· **HMIS-ratings (scale 0 - 4)**

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

- **Other hazards** Avoid breathing sanding dust /swarf.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**  
66402-68-4 ceramic materials
- **Identification number(s) ---**
- **EC number:** 266-340-9
- **Description:** Leucite-reinforced glass-ceramic blocks

## 4 First-aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**  
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Grinding dust: 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:** The product is not flammable.
- **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:** No special measures required.
- **Methods and material for containment and cleaning up:** Pick up mechanically.

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# Safety Data Sheet

acc. to OSHA HCS

Printing date 05/18/2015

Version number 4

Reviewed on 04/16/2015

Trade name: **IPS Empress CAD / IPS Empress CAD Multi**

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- **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:** None.
- **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:** Not required.
- **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.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:**  
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

|        |                                    |
|--------|------------------------------------|
| Form:  | Solid                              |
| Color: | According to product specification |
- **Odor:** Odorless
- **Odour threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

|                              |               |
|------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |

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US

# Safety Data Sheet

acc. to OSHA HCS

Printing date 05/18/2015

Version number 4

Reviewed on 04/16/2015

Trade name: **IPS Empress CAD / IPS Empress CAD Multi**

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|                                                   |                                               |
|---------------------------------------------------|-----------------------------------------------|
| · <b>Flash point:</b>                             | Not applicable.                               |
| · <b>Flammability (solid, gaseous):</b>           | Product is not flammable.                     |
| · <b>Auto igniting:</b>                           | Not determined.                               |
| · <b>Danger of explosion:</b>                     | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                        |                                               |
| Lower:                                            | Not determined.                               |
| Upper:                                            | Not determined.                               |
| · <b>Vapor pressure:</b>                          | Not applicable.                               |
| · <b>Density:</b>                                 | Not determined.                               |
| · <b>Relative density</b>                         | Not determined.                               |
| · <b>Vapour density</b>                           | Not applicable.                               |
| · <b>Evaporation rate</b>                         | Not applicable.                               |
| · <b>Solubility in / Miscibility with Water:</b>  | Insoluble.                                    |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                               |
| · <b>Viscosity:</b>                               |                                               |
| Dynamic:                                          | Not applicable.                               |
| Kinematic:                                        | Not applicable.                               |
| · <b>Other information</b>                        | 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.
- **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:** 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.

US

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# Safety Data Sheet

## acc. to OSHA HCS

Printing date 05/18/2015

Version number 4

Reviewed on 04/16/2015

Trade name: **IPS Empress CAD / IPS Empress CAD Multi**

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### 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:** Generally not hazardous for water
- **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

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

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# Safety Data Sheet

## acc. to OSHA HCS

Printing date 05/18/2015

Version number 4

Reviewed on 04/16/2015

Trade name: **IPS Empress CAD / IPS Empress CAD Multi**

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### 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 not 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.

· 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 / 3

· 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)

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US

**Safety Data Sheet**  
**acc. to OSHA HCS**

Printing date 05/18/2015

Version number 4

Reviewed on 04/16/2015

**Trade name: IPS Empress CAD / IPS Empress CAD Multi**

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

US

## Safety Data Sheet according to HPR, Schedule 1

Printing date 04/24/2018

Version number 4.1

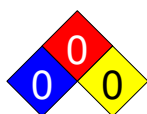
Reviewed on 04/24/2018

### 1 Identification

- **Product identifier**
- **Trade name:** **IPS Empress CAD / IPS Empress CAD Multi**
- **CAS Number:**  
66402-68-4
- **EC number:**  
266-340-9
- **Application of the substance / the mixture**  
Manufacture of dental prothesis  
Leucite-reinforced glass-ceramic blocks for the CAD/CAM technique
- **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**  
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)**



Health = 0  
Fire = 0  
Reactivity = 0

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CA

# Safety Data Sheet

## according to HPR, Schedule 1

Printing date 04/24/2018

Version number 4.1

Reviewed on 04/24/2018

**Trade name: IPS Empress CAD / IPS Empress CAD Multi**

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· **HMIS-ratings (scale 0 - 4)**

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

· **Other hazards** Avoid breathing sanding dust /swarf.

### 3 Composition/Information on ingredients

- **Chemical characterization: Substances**
- **CAS No. Description**  
66402-68-4 ceramic materials
- **Identification number(s) ---**
- **EC number:** 266-340-9
- **Description:** Leucite-reinforced glass-ceramic blocks

### 4 First aid measures

- **Description of first aid measures**
- **General information:** No special measures required.
- **After inhalation:** Grinding dust: Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:**  
Grinding dust: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.  
Mechanical effects only.
- **After swallowing:**  
Grinding dust: 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:** The product is not flammable.
- **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:** No special measures required.
- **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.

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CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 04/24/2018

Version number 4.1

Reviewed on 04/24/2018

**Trade name: IPS Empress CAD / IPS Empress CAD Multi**

See Section 13 for disposal information.

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### 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:** None.
- **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:** Not required.
- **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.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.
- **Protection of hands:** Not required.
- **Material of gloves -**
- **Penetration time of glove material -**
- **Eye protection:**  
Always wear safety goggles during mechanical processing (grinding, sawing /cutting, drilling, milling).

### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

|        |                                    |
|--------|------------------------------------|
| Form:  | Solid                              |
| Color: | According to product specification |
- **Odor:** Odorless
- **Odor threshold:** Not determined.
- **pH-value:** Not applicable.
- **Change in condition**

|                              |               |
|------------------------------|---------------|
| Melting point/Melting range: | Undetermined. |
| Boiling point/Boiling range: | Undetermined. |
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Product is not flammable.

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CA

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 04/24/2018

Version number 4.1

Reviewed on 04/24/2018

**Trade name: IPS Empress CAD / IPS Empress CAD Multi**

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|                                                   |                                               |
|---------------------------------------------------|-----------------------------------------------|
| · <b>Auto igniting:</b>                           | Not determined.                               |
| · <b>Danger of explosion:</b>                     | Product does not present an explosion hazard. |
| · <b>Explosion limits:</b>                        |                                               |
| Lower:                                            | Not determined.                               |
| Upper:                                            | Not determined.                               |
| · <b>Vapor pressure:</b>                          | Not applicable.                               |
| · <b>Density:</b>                                 | Not determined.                               |
| · <b>Relative density</b>                         | Not determined.                               |
| · <b>Vapor density</b>                            | Not applicable.                               |
| · <b>Evaporation rate</b>                         | Not applicable.                               |
| · <b>Solubility in / Miscibility with Water:</b>  | Insoluble.                                    |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                               |
| · <b>Viscosity:</b>                               |                                               |
| Dynamic:                                          | Not applicable.                               |
| Kinematic:                                        | Not applicable.                               |
| · <b>Other information</b>                        | 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.
- **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:** 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.

### 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.

(Contd. on page 5)

## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 04/24/2018

Version number 4.1

Reviewed on 04/24/2018

**Trade name: IPS Empress CAD / IPS Empress CAD Multi**

(Contd. of page 4)

- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **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 packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

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

### 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.

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## Safety Data Sheet

### according to HPR, Schedule 1

Printing date 04/24/2018

Version number 4.1

Reviewed on 04/24/2018

**Trade name: IPS Empress CAD / IPS Empress CAD Multi**

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

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** 04/24/2018 / 4

· **Abbreviations and acronyms:**

ICAO: International Civil Aviation Organisation

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

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.**

CA