SAFETY DATA SHEETS

This SDS packet was issued with item: 077175029

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 077086101 077175003 077175011 077175037 077175045 077175052 077175060 077175078 077175151 077175169 077175177 077175185 077175193 077175201 077175219 077175227 077175300 273005804 273010085 273010086 273015916 273017351

ivoclar vivadeni:

Safety Data Sheet acc. to OSHA HCS

Printing date 03/20/2017

Version number 4

Reviewed on 03/17/2017

1 Identification

· Product identifier

• Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

· 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 USA Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada Phone: +1 905 670 8499 Fax: +1 905 670 3102

• Information department: Quality Assurance / Regulatory Affairs

• Emergency telephone number: 24 Hour Emergency Assistance: Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

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

2 Hazard(s) identification

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

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



· HMIS-ratings (scale 0 - 4)

HEALTHImage: OOHealth = 0FIREImage: OFire = 0REACTIVITYImage: OReactivityO

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Printing date 03/20/2017

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Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

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10-<25%

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

3 Composition/information on ingredients

- · Chemical characterization: Mixtures
- · Description: dental ceramic
- · Dangerous components:
- CAS: 56-81-5 glycerol

4 First-aid measures

- · Description of first aid measures
- · General information: No special measures required.
- After inhalation:
- Supply fresh air; consult doctor in case of complaints.
- In case of unconsciousness place patient stably in side position for transportation.
- After skin contact:
- Rinse with water.
- Generally the product does not irritate the skin.
- After eye contact:
- *Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. Mechanical effects only.*
- After swallowing:
- Rinse out mouth and then drink plenty of water.
- If symptoms persist consult doctor.
- Information for doctor:
- · Most important symptoms and effects, both acute and delayed No further relevant information available.
- Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Fire-fighting measures

- · Extinguishing media
- Suitable extinguishing agents:
- CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- · Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures 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.

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Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

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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.
- Store in dry conditions.
- *Specific end use(s)* No further relevant information available.

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

· Control parameters

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

CAS: 56-81-5 glycerol

PEL Long-term value: 15* 5** mg/m³

mist; *total dust **respirable fraction

TLV TLV withdrawn-insufficient data human occup. exp.

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

· Exposure controls

- · Personal protective equipment:
- General protective and hygienic measures:
- Usual hygienic measures for dental practice and dental laboratories.
- Keep away from foodstuffs, beverages and feed.
- Wash hands before breaks and at the end of work.
- Breathing equipment:

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

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.

• Material of gloves

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

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.

(Contd. on page 4)

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

(Contd. of page 3)

· Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection: Safety glasses

9 Physical and chemical properties · Information on basic physical and chemical properties · General Information · Appearance: Form: Pasty Color: According to product specification · Odor: Characteristic · Odor threshold: Not determined. · pH-value: Not determined. · Change in condition Melting point/Melting range: Undetermined. Boiling point/Boiling range: Undetermined. · Flash point: Undetermined. • Auto igniting: Product is not selfigniting. Danger of explosion: Product does not present an explosion hazard. · Explosion limits: Not determined. Lower: Not determined. Upper: Not determined. · Vapor pressure: · Density: Not determined. · Relative density Not determined. · Vapor density Not determined. · Evaporation rate Not determined. · Solubility in / Miscibility with Water: Partly soluble. · Partition coefficient (n-octanol/water): Not determined. Viscosity: Dynamic: Not determined. Kinematic: Not determined. · Solvent content: **VOC** content: 15.0% **Other information** No further relevant information available.

10 Stability and reactivity

• *Reactivity* No further relevant information available.

· Chemical stability Stable under normal handling and storage conditions.

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions No dangerous reactions known.

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US -

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Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

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- \cdot 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

· IARC (International Agency for Research on Cancer)

CAS: 9003-39-8 Polyvinylpyrrolidon

·NTP (National Toxicology Program)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes:
- Water hazard class 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.

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Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

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UN-Number	
DOT, ADR, RID, ADN, ADN, IMDG, IATA	Void
· UN proper shipping name · DOT, ADR,RID,ADN, ADN, IMDG, IATA	Void
• Transport hazard class(es)	
DOT, ADR, RID, ADN, ADN, IMDG, IATA	
· Class	Void
Packing group	
DOT, ÅDR, RID, ADN, 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.

• 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.

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Version number 4

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste, Glaze Paste Fluo

(Contd. of page 6)

• TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

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

None of the ingredients is listed.

· GHS label elements Void

· Hazard pictograms Void

· Signal word Void

· Hazard statements Void

· National regulations:

• Other regulations, limitations and prohibitive regulations The product is a medical device according to 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 03/20/2017 / 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) 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 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) VOC: Volatile Organic Compounds (USA, EU) PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit • * Data compared to the previous version altered.

Printing date 03/08/2013

vivadeni:

Version number 2

Reviewed on 03/07/2013

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

· Product identifier

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

• *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
- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.
- · 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: The product is not subject to identification regulations according to directives on hazardous materials.

• Classification system: • NFPA ratings (scale 0 - 4)

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(Contd. on page 2)

USA

Printing date 03/08/2013

Version number 2

Reviewed on 03/07/2013

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

(Contd. of page 1)

10-<25%

· HMIS-ratings (scale 0 - 4)

HEALTHImage: OHealth = 0FIREImage: OFire = 0REACTIVITYReactivity = 0

• Other hazards

· Results of PBT and vPvB assessment

• **PBT:** Not applicable.

• **vPvB:** Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

• **Description:** dental ceramic

· Dangerous components:

56-81-5 glycerol

4 First aid measures

· Description of first aid measures

- · General information: No special measures required.
- · After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

• After skin contact:

Rinse with water.

Generally the product does not irritate the skin.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. Mechanical effects only.

· After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

• Information for doctor:

• Most important symptoms and effects, both acute and delayed No further relevant information available.

· Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 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.

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Printing date 03/08/2013

Version number 2

Reviewed on 03/07/2013

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

(Contd. of page 2)

- $\cdot \textit{Environmental precautions: } Do not allow to enter sewers/ \textit{surface or ground water.}$
- *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:
- This product is hygroscopic. Keep receptacle tightly sealed. Store in dry conditions.
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

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

56-81-5 glycerol

PEL () 15* 5** mg/m³ *total dust **respirable fraction TLV () 10* ppm *Mist

• 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. Keep away from foodstuffs, beverages and feed. Wash hands before breaks and at the end of work.
- Breathing equipment:

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

- Protection of hands:
- *The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. After use of gloves apply skin-cleaning agents and skin cosmetics.*

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Printing date 03/08/2013

Version number 2

Reviewed on 03/07/2013

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

(Contd. of page 3)

• *Material of gloves* Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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

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:	Undetermined.	
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:	Not determined.	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Partly soluble.	
Partition coefficient (n-octanol/wat	t er): Not determined.	
Viscosity:		
Dynamic:	Not determined.	
Kinematic:	Not determined.	
Solvent content:		
VOC content:	15.0 %	

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Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

· Other information

No further relevant information available.

10 Stability and reactivity

- · Reactivity No further relevant information available.
- · *Chemical stability Stable under normal handling and storage conditions.*
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- 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:
- The product is not subject to classification according to internally approved calculation methods for preparations:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

9003-39-8 Polyvinylpyrrolidon

- · 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 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.

(Contd. on page 6)

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Version number 2

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

(Contd. of page 5)

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 MARPOL73/78 and the IBC Code	II of 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.

• 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.

(Contd. on page 7)

USA

Printing date 03/08/2013

Version number 2

Reviewed on 03/07/2013

Trade name: IPS e.max CAD Crystall./Shades, Stains, Glaze Paste

(Contd. of page 6)

· 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)

None of the ingredients is listed.

· 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:

The product is not subject to identification regulations according to directives on hazardous materials.

· National regulations:

• Other regulations, limitations and prohibitive regulations

The product is a medical device according to the EC-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.