SAFETY DATA SHEETS

This SDS packet was issued with item:

077086259

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

077086242

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).

070215376 070483453 077083538



Printing date 01/09/2014 Version number 10

Reviewed on 12/17/2013

1 Identification

- · Product identifier
- · Trade name: Monobond-S
- · Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

- · Application of the substance / the preparation Bonding agent
- · 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

Flammable.

· 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 Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· Risk phrases:

Flammable.

· Safety phrases:

Keep container tightly closed.

Keep away from sources of ignition - No smoking.

This material and its container must be disposed of as hazardous waste.

(Contd. on page 2)

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 1)

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



Health = 0Fire = 2Reactivity = 0

· HMIS-ratings (scale 0 - 4)



 $0 \quad Health = 0$ Fire = 2

- · 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:

64-17-5 ethanol

50-100%

4 First-aid measures

- · Description of first aid measures
- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- · After skin contact:

Rinse with water.

Generally the product does not irritate the skin.

- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult 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.
- · Additional information Cool endangered receptacles with water spray.

(Contd. on page 3)

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 2)

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Dilute with plenty of water.

Do not allow to enter sewers/ surface or ground water.

· Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

· 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

- · Precautions for safe handling No special precautions are necessary if used correctly.
- · Information about protection against explosions and fires:

Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

- · Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
- · Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: 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:

64-17-5 ethanol

PEL 1900 mg/m³, 1000 ppm

REL 1900 mg/m³, 1000 ppm

TLV Short-term value: 1880 mg/m³, 1000 ppm

- · 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.

(Contd. on page 4)

- USA

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 3)

· 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

Information on basic physical and c	hemical properties
General Information	
Appearance:	
Form:	Fluid
Color:	Colorless
Odor:	Alcohol-like
Odour threshold:	Not determined.
pH-value at 20 °C (68 °F):	4
Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
Flash point:	25 °C (77 °F)
Ignition temperature:	425 °C (797 °F)
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product is not explosive. However, formation of explosive air/
	vapor mixtures are possible.
Explosion limits:	
Lower:	3.5 Vol %
Upper:	15.0 Vol %
Vapor pressure at 20 °C (68 °F):	59 hPa (44 mm Hg)
Density at 20 °C (68 °F):	0.913 g/cm³ (7.619 lbs/gal)
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Soluble.
Partition coefficient (n-octanol/wate	e r): Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
VOC content:	52.0 %

(Contd. on page 5)

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 4)

· 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:
- · Carcinogenic categories
- · IARC (International Agency for Research on Cancer)

64-17-5 ethanol

1

· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

- · Toxicity
- $\cdot \textbf{\textit{Aquatic toxicity:}} \ \textit{No further relevant information available}.$
- · Persistence and degradability No further relevant information available.
- · 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.

USA

(Contd. on page 6)

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 5)

13 Disposal considerations

- · Waste treatment methods
- · Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packagings:
- · Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agent: Water, if necessary with cleansing agents.

UN-Number	
DOT DOT	UN1170
ADR, IMDG, IATA	1170
UN proper shipping name ADR	1170 ETHANOL (ETHYL ALCOHOL), solution
IMDG	ETHANOL (ETHYL ALCOHOL), solution
IATA	ETHANOL, solution
Transport hazard class(es)	
DOT	
FLAMMABLE LIQUID	
3	
Class	3 Flammable liquids.
Label	3 Fiammable tiquias. 3
ADR	-
ADA	
3	
Class	3 (F1) Flammable liquids
Label	3
IMDG, IATA	
▼	2.51
Class Label	3 Flammable liquids. 3
	J
Packing group	Ш
DOT, ADR, IMDG, IATA	III
Environmental hazards:	V
Marine pollutant:	No
Special precautions for user Danger code (Kemler):	Warning: Flammable liquids 30

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 6)

 \cdot EMS Number: F-E,S-D

· 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.

· 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:

64-17-5 ethanol

64-17-5 ethanol

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

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

MOCH C (N. J. 11 d)

A3

· 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 Preparations Directive 1999/45/EC usually if they are in the finished state and intended for the final user.

· Risk phrases:

Flammable.

· Safety phrases:

Keep container tightly closed.

Keep away from sources of ignition - No smoking.

This material and its container must be disposed of as hazardous waste.

(Contd. on page 8)

Printing date 01/09/2014 Version number 10 Reviewed on 12/17/2013

Trade name: Monobond-S

(Contd. of page 7)

- · 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.

* * Data compared to the previous version altered.

USA



Printing date 18.10.2019 Version number 8 Revision: 18.10.2019

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- · Product identifier
- · Trade name: Monobond Plus
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- Application of the substance / the mixture

Universal primer mediating a bond between metal, glass/oxid ceramics and resin

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

Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan

PRINCIPALITY OF LIECHTENSTEIN
Tel: +423 235 35 35 / Fax: +423 235 33 60

Importer:

Ivoclar Vivadent Pty. Ltd. 1- 5 Overseas Drive Noble Park North VIC 3174

Tel: + 61 3 9795 9599 / Fax: + 61 3 9795 9645

· Further information obtainable from:

Regulatory Affairs

sds@ivoclarvivadent.com

· Emergency telephone number: 131 126 (Poisons Information Centre - 24 hours / 7 days)

2 Hazard(s) Identification

· Classification of the substance or mixture

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Sens. 1 H317 May cause an allergic skin reaction.

- · Label elements
- · GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms





GHS02

GHS07

- · Signal word Danger
- · Hazard-determining components of labelling:

methacrylated phosphoric acid ester

· Hazard statements

Highly flammable liquid and vapour. May cause an allergic skin reaction.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

(Contd. on page 2)

Printing date 18.10.2019 Version number 8 Revision: 18.10.2019

Trade name: Monobond Plus

(Contd. of page 1)

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

Store in a well-ventilated place. Keep cool.

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

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 64-17-5	ethanol	50-100%
	Flam. Liq. 2, H225	
	methacrylated phosphoric acid ester	<2.5%
	Skin Irrit. 2, H315; Eye Irrit. 2A, H319; Skin Sens. 1, H317	

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

- · Description of first aid measures
- · 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: Immediately rinse with water.
- · After eye contact: Rinse opened eye for several minutes under running water. Then 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.
- · 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, 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.
- · Additional information

Cool endangered receptacles with water spray.

See Section 14 for Hazchem Code.

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.

(Contd. on page 3)

according to WHS Regulations Safety Data Sheet

Printing date 18.10.2019

Version number 8

Revision: 18.10.2019

Trade name: Monobond Plus

Reference to other sections

(Contd. of page 2)

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 fire and explosion protection: No special measures required.
- Conditions for safe storage, including any incompatibilities
- 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 container tightly sealed.

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

8 Exposure controls and personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- Control parameters
- Ingredients with limit values that require monitoring at the workplace:

CAS: 64-17-5 ethanol

NES Long-term value: 1880 mg/m³, 1000 ppm

WES Long-term value: 1880 mg/m³, 1000 ppm

Additional information: The lists valid during the making were used as basis.

- 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.

Respiratory protection: Not required.

Protection of hands:



Protective gloves

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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

the chemical mixture.

Material of gloves

(Contd. on page 4) 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

Printing date 18.10.2019 Version number 8 Revision: 18.10.2019

Trade name: Monobond Plus

(Contd. of page 3)

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.

· Not suitable are gloves made of the following materials:

Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.

· Eye protection: Safety glasses

9 Physical and Chemical Properties

·Infor	matior	on	basic	physical	and cl	hemical	properties

· General Information

· Appearance:

Form: Fluid
Colour: Colourless
Odour: Alcohol-like
Odour threshold: Not determined.

· pH-value: Not determined.

· Change in condition

Melting point/freezing point: -114.5 °C Initial boiling point and boiling range: 78 °C

· Flash point: 13 °C
· Ignition temperature: 425 °C

• Ignition temperature: 425 °C
• Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product is not explosive. However, formation of explosive air/

vapour mixtures are possible.

· Explosion limits:

 Lower:
 3.5 Vol %

 Upper:
 15 Vol %

· Vapour pressure at 20 °C: 59 hPa

Density at 20 °C: 0.794 g/cm³
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

water: Soluble.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic:Not determined.Kinematic:Not determined.

• Other information No further relevant information available.

10 Stability and Reactivity

- · Reactivity No further relevant information available.
- · Chemical stability Stable under normal handling and storage conditions.

(Contd. on page 5)

Printing date 18.10.2019 Version number 8 Revision: 18.10.2019

Trade name: Monobond Plus

(Contd. of page 4)

- 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
- · LD/LC50 values relevant for classification:

Oral LD50 >5000 mg/kg (rat)

- · Skin corrosion/irritation No irritant effect.
- · Serious eye damage/irritation No irritating effect.
- · Respiratory or skin sensitisation Sensitisation possible through skin contact.
- · Additional toxicological information: No further relevant information available.

12 Ecological Information

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

Water hazard class 1 (German Regulation) (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

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

- · UN-Number
- · ADG, IMDG, IATA

1170

(Contd. on page 6)

Printing date 18.10.2019 Version number 8 Revision: 18.10.2019

Trade name: Monobond Plus

	(Contd. of page
UN proper shipping name	
ADG	1170 ETHANOL (ETHYL ALCOHOL) solution
IMDG	ETHANOL (ETHYL ALCOHOL), solution
IATA	ETHANOL, solution
Transport hazard class(es)	
ADG	
Class	3 (F1) Flammable liquids.
Label	3
IMDG, IATA	
Class	3 Flammable liquids.
Label	3
Packing group ADG, IMDG, IATA	II
Environmental hazards:	
Marine pollutant:	No
Special precautions for user	Warning: Flammable liquids.
Danger code (Kemler):	33
Hazchem or Emergency Action Code:	•2 <i>YE</i>
EMS Number:	F-E,S-D
Transport in bulk according to Annex II of M	Marpol
and the IBC Code	Not applicable.
Transport/Additional information:	
ADG	
Limited quantities (LQ)	LQ4
Transport category	2
Tunnel restriction code	D/E
UN "Model Regulation":	UN 1170 ETHANOL (ETHYL ALCOHOL) SOLUTIO
-	3, II

15 Regulatory information

- $\cdot \textit{Safety, health and environmental regulations/legislation specific for the substance or \textit{mixture}}$
- · Australian Inventory of Chemical Substances

CAS: 64-17-5 ethanol

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· GHS label elements

The product is classified and labelled according to the Globally Harmonised System (GHS).

(Contd. on page 7)

Printing date 18.10.2019 Version number 8 Revision: 18.10.2019

Trade name: Monobond Plus

(Contd. of page 6)

· Hazard pictograms





- · Signal word Danger
- · Hazard-determining components of labelling:

methacrylated phosphoric acid ester

· Hazard statements

Highly flammable liquid and vapour.

May cause an allergic skin reaction.

· Precautionary statements

Keep away from heat/sparks/open flames/hot surfaces. No smoking.

Keep container tightly closed.

Avoid breathing dust/fume/gas/mist/vapours/spray.

Wear protective gloves/protective clothing/eye protection/face protection.

If skin irritation or rash occurs: Get medical advice/attention.

Store in a well-ventilated place. Keep cool.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Seveso category P5c FLAMMABLE LIQUIDS
- · Qualifying quantity (tonnes) for the application of lower-tier requirements 5000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t
- · National regulations:
- · Other regulations, limitations and prohibitive regulations

The product is a medical device according to the Directive 93/42/EEC.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

· Abbreviations and acronyms:

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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids – Category 2

Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation - Category 2A

Skin Sens. 1: Skin sensitisation - Category 1