Printing date 02.04.2013

Version number 4

Revision: 11.03.2013

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

· 1.1 Product identifier

- · Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.
- \cdot 1.2 Relevant identified uses of the substance or mixture and uses advised against
- No further relevant information available.
- · Application of the substance / the preparation Zinc phosphate cement
- \cdot 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: DENTSPLY DeTrey GmbH De-Trey-Str. 1 D-78467 Konstanz GERMANY Tel.: +49-(0)7531-583-0 Fax: +49-(0)7531-583-104 email: KonstanzDEU.info-sdb@dentsply.com

- · Further information obtainable from:
- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

2 Hazards identification

· 2.1 Classification of the substance or mixture

- · Classification according to Directive 67/548/EEC or Directive 1999/45/EC
- C; Corrosive
- R34: Causes burns.
- · Information concerning particular hazards for human and environment:
- The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- · Classification system:

The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

- · 2.2 Label elements
- · Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· Code letter and hazard designation of product:



C Corrosive

- Hazard-determining components of labelling: phosphoric acid
- · Risk phrases:

34 Causes burns.

- · Safety phrases:
- 20 When using do not eat or drink.
- Do not breathe gas/fumes/vapour/spray (appropriate wording to be specified by the manufacturer).
 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- *36/37/39* Wear suitable protective clothing, gloves and eye/face protection.
- 45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
- 60 This material and its container must be disposed of as hazardous waste.

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.

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

3 Composition/information on ingredients

· 3.2 Chemical characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

Dungerous compone	nus.		
CAS: 7664-38-2	phosphoric acid	C R34	50-100%
EINECS: 231-633-2		🐼 Met. Corr.1, H290; Skin Corr. 1B, H314	
Additional information For the wording of the listed risk phrases refer to section 16.			

4 First aid measures

- 4.1 Description of first aid measures
- · General information Immediately remove any clothing soiled by the product.
- After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing Drink plenty of water and provide fresh air. Call for a doctor immediately.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- \cdot 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Firefighting measures

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

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective clothing.
- · 6.2 Environmental precautions:
- Dilute with plenty of water.

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

- 6.3 Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Use neutralizing agent. Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.
 6.4 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.

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.

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7 Handling and storage

• 7.1 Precautions for safe handling Observe normal care for working with chemicals.

· Handling Product is intended for dental use only.

· Information about fire - and explosion protection: No special measures required.

· 7.2 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: Store in cool, dry conditions in well sealed receptacles.
- 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

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

· 8.1 Control parameters

· Ingredients with limit values that require monitoring at the workplace:

7664-38-2 phosphoric acid

OEL Short-term value: 3 mg/m3 Long-term value: 1 mg/m3

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

· 8.2 Exposure controls

- · Personal protective equipment
- General protective and hygienic measures Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing Wash hands before breaks and at the end of work. Avoid contact with the eyes and skin.
- Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands:



Protective gloves.

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 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.

Natural rubber, NR

Recommended thickness of the material: $\geq 0.6 \text{ mm}$

Permeation: Level ≥6

· Penetration time of glove material

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

• *Eye protection:* Safety glasses

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.

(Contd. of page 3)

Tightly sealed goggles.

· Body protection: Protective work clothing.

9 Physical and chemical properties

General Information		
Appearance:		
Form:	Liquid	
Colour:	Colourless	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value at 20 °C:	< 2	
Change in condition		
Melting point/Melting range:	undetermined	
Boiling point/Boiling range:	undetermined	
Flash point:	Not applicable	
Flammability (solid, gaseous)	Not applicable.	
Ignition temperature:		
Decomposition temperature:	Not determined.	
Self-igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure at 20 °C:	2 hPa	
Density at 20 °C:	1.56 g/cm ³	
Relative density	Not determined.	
Vapour density	Not determined.	
Evaporation rate	Not determined.	
Solubility in / Miscibility with		
Water:	Fully miscible	
Partition coefficient (n-octanol/wat	er): Not determined.	
Viscosity:		
dynamic:	Not determined.	
kinematic:	Not determined.	
Solvent content:		
Organic solvents:	0.0 %	
Solids content:	9%	
9.2 Other information	<i>No further relevant information available.</i>	

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.

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10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions No dangerous reactions known
- 10.4 Conditions to avoid No further relevant information available.
- \cdot 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity:

· LD/LC50 values relevant for classification:

7664-38-2 phosphoric acid

Oral LD50 1530 mg/kg (rat)

Dermal LD50 2740 mg/kg (rabbit)

- · Primary irritant effect:
- on the skin: Caustic effect on skin and mucous membranes.
- on the eye: Strong caustic effect.
- Sensitization: No sensitizing effects known.
- \cdot Additional toxicological information:

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version. Corrosive

Swallowing will lead to a burning respectively to a caustic effect on mouth and throat and to the danger of perforation of esophagus and stomach.

12 Ecological information

- · 12.1 Toxicity
- Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Must not reach sewage water or drainage ditch undiluted or unneutralized.

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · **vPvB:** Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.

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13 Disposal considerations

· 13.1 Waste treatment methods

· Recommendation



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

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

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

14.1 UN-Number ADR, IMDG, IATA	UN1805
	011805
14.2 UN proper shipping name	
ADR	1805 PHOSPHORIC ACID, SOLUTION
IMDG, IATA	PHOSPHORIC ACID, SOLUTION
14.3 Transport hazard class(es)	
ADR	
S S S S S S S S S S S S S S S S S S S	
Class	8 (C1) Corrosive substances.
Label	8
Class	8 Corrosive substances.
Label	8
	8
14.4 Packing group	
ADR, IMDG, IATA	III
14.5 Environmental hazards:	
Marine pollutant:	No
14.6 Special precautions for user	Warning: Corrosive substances.
17.0 Special precaulous for user	80
	00
Danger code (Kemler): EMS Number:	<i>F-A,S-B</i>
Danger code (Kemler):	
Danger code (Kemler): EMS Number:	F-A,S-B Acids

GB -

GB

Safety data sheet according to 1907/2006/EC, Article 31

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc liq.

	(Contd. of pa	age 6)
· Transport/Additional information:		
·ADR		
· Limited quantities (LQ)	5L	
· Transport category	3	
• Tunnel restriction code	E	

15 Regulatory information

· 15.2 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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· Relevant phrases

H290 May be corrosive to metals. H314 Causes severe skin burns and eye damage.

R34 Causes burns.

· Department issuing MSDS: Analytical Research

· Contact: HotLine for urgent technical support: +49-7531-583-333

 \cdot * Data compared to the previous version altered.

Printing date 28.03.2013

Version number 2

Revision: 11.03.2013

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

· 1.1 Product identifier

· Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc powd.

· Application: Zinc phosphate cement

• 1.2 Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.

• Application of the substance / the preparation Zinc phosphate cement

1.3 Details of the supplier of the safety data sheet
Manufacturer/Supplier: DENTSPLY DeTrey GmbH De-Trey-Str. 1 D-78467 Konstanz GERMANY Tel.: +49-(0)7531-583-0 Fax: +49-(0)7531-583-104

email: KonstanzDEU.info-sdb@dentsply.com

 \cdot Further information obtainable from:

- Departement Analytical Research / Research & Development for technical information
- Departement Marketing & Sales for distribution of the safety data sheets
- 1.4 Emergency telephone number: +49-(0)7531-583-0 8:00 17:00 (GMT + 1:00)

2 Hazards identification

· 2.1 Classification of the substance or mixture

· Classification according to Directive 67/548/EEC or Directive 1999/45/EC

N; Dangerous for the environment

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

• Information concerning particular hazards for human and environment:

The product has to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.

• *Classification system:* The classification is according to the latest editions of the EU-lists, and extended by company and literature data.

· 2.2 Label elements

· Labelling according to EU guidelines:

The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials

· Code letter and hazard designation of product:



N Dangerous for the environment

· Risk phrases:

50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

- · Safety phrases:
- 57 Use appropriate container to avoid environmental contamination.
- 60 This material and its container must be disposed of as hazardous waste.
- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.

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GB -

Printing date 28.03.2013

Version number 2

Revision: 11.03.2013

Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc powd.

• **vPvB:** Not applicable.

3 Composition/information on ingredients

· 3.2 Chemical characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

 Dangerous comp 	onents:
------------------------------------	---------

CAS: 1314-13-2	zinc oxide	₩ N R50/53	50-100%
EINECS: 215-222-5		line and the second sec	
Additional information For the wording of the listed wich physics refer to section 16			

Additional information For the wording of the listed risk phrases refer to section 16.

4 First aid measures

· 4.1 Description of first aid measures

- · After inhalation Supply fresh air; consult doctor in case of complaints.
- After skin contact Immediately wash with water and soap and rinse thoroughly.
- After eye contact Rinse opened eye for several minutes under running water.
- · After swallowing If symptoms persist consult doctor.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed
- No further relevant information available.

5 Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents
- CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- · 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Self-contained respiratory protective device.

6 Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Avoid formation of dust.
- 6.2 Environmental precautions: Inform respective authorities in case of seepage into water course or sewage system. Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- · 6.4 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

• 7.1 Precautions for safe handling Observe normal care for working with chemicals.

· Handling Product is intended for dental use only.

· Information about fire - and explosion protection: No special measures required.

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc powd.

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- · 7.2 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: Store away from oxidizing agents.
- Further information about storage conditions: None.
- 7.3 Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- · 8.1 Control parameters
- Ingredients 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 valid during the making were used as basis.

- · 8.2 Exposure controls
- · Personal protective equipment
- · General protective and hygienic measures Wash hands before breaks and at the end of work.
- · Respiratory protection: Not necessary if room is well-ventilated.
- · Protection of hands:

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 degradation Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

· 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 trough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection: Safety glasses

· Body protection: Protective work clothing.

9.1 Information on basic physical of General Information	nd chemical properties	
· Appearance: Form:	Powder	
Form: Colour:	Yellowish	
· Odour:	Odourless	
Odour threshold:	Not determined.	
· pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	undetermined	
Boiling point/Boiling range:	undetermined	
· Flash point:	Not applicable	

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc powd.

	(C	ontd. of page
Flammability (solid, gaseous)	Not determined.	
Ignition temperature:		
Decomposition temperature:	Not determined.	
Self-igniting:	Product is not selfigniting.	
Danger of explosion:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not applicable.	
Density:	Not determined	
Relative density	Not determined.	
Vapour density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
Water:	Insoluble	
Partition coefficient (n-octanol/wa	ter): Not determined.	
Viscosity:		
dynamic:	Not applicable.	
kinematic:	Not applicable.	
Solvent content:		
Organic solvents:	0.0 %	
Solids content:	100.0 %	
9.2 Other information	No further relevant information available.	

10 Stability and reactivity

- · 10.1 Reactivity
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known
- 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: strong oxidants
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known

11 Toxicological information

· 11.1 Information on toxicological effects

• Acute toxicity:

· LD/LC50 values relevant for classification:

1314-13-2 zinc oxide

Oral LD50 >5000 mg/kg (rat)

- · Primary irritant effect:
- on the skin: No irritant effect.

• on the eye: No irritating effect.

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc powd.

· Sensitization: No sensitizing effects known.

12 Ecological information · 12.1 Toxicity · Aquatic toxicity: 1314-13-2 zinc oxide EC50/48h 0.098 mg/L (daphnia) LC50/96h 1.1 mg/l (fish) · 12.2 Persistence and degradability No further relevant information available. · 12.3 Bioaccumulative potential No further relevant information available. · 12.4 Mobility in soil No further relevant information available. · Ecotoxical effects: · Remark: Very toxic for fish · Additional ecological information: · General notes: Also poisonous for fish and plankton in water bodies. *Very toxic for aquatic organisms* Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground. · 12.5 Results of PBT and vPvB assessment · **PBT:** Not applicable.

- · vPvB: Not applicable. · 12.6 Other adverse effects No further relevant information available.

13 Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation



*

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

· European waste catalogue

18 01 06* chemicals consisting of or containing dangerous substances

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

14.1 UN-Number	
ADR, IMDG, IATA	UN3077
14.2 UN proper shipping name	
ADR	3077 ENVIRONMENTALLY HAZARDOUS SUBSTANC
	SOLID, N.O.S. (zinc oxide)

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	(Contd. of page
IMDG IATA	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLII N.O.S. (zinc oxide), MARINE POLLUTANT ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLII N.O.S. (zinc oxide)
14.3 Transport hazard class(es)	
ADR	
Class Label	9 (M7) Miscellaneous dangerous substances and articles. 9
Class Label	9 Miscellaneous dangerous substances and articles. 9
14.4 Packing group	· · · · · · · · · · · · · · · · · · ·
ADR, IMDG, IATA	III
14.5 Environmental hazards:	Product contains environmentally hazardous substances: zin oxide
Marine pollutant:	Yes
Special marking (ADR):	Symbol (fish and tree) Symbol (fish and tree)
Special marking (ADR): Special marking (IATA):	Symbol (fish and tree) Symbol (fish and tree)
14.6 Special precautions for user	Warning: Miscellaneous dangerous substances and articles.
Danger code (Kemler):	90
EMS Number:	F-A,S-F
14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	x II of Not applicable.
Transport/Additional information:	**
ADR	
Limited quantities (LQ)	5 kg
Transport category	3
Tunnel restriction code	Ε

15 Regulatory information

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

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Trade name: Crown&Bridge/Fixodont Plus/De Trey Zinc powd.

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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.

The attached safety data sheet covers the dangers and measures to be taken when large quantities of material are released, for example due to accidents during transport or storage by the dealer. For quantities of material typically used in clinical practice, information necessary for safe use and storage of the product is given in the DFU.

· Relevant phrases

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

· Department issuing MSDS: Analytical Research

· Contact: HotLine for urgent technical support: +49-7531-583-333

• * Data compared to the previous version altered.