

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 01.02.2023

Version number 3 (replaces version 2)

Revision: 01.02.2023

Start

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

- **1.1 Product identifier**
- **Trade name:** *Aquasil Bite Catalyst*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Dental impression material*
- **Uses advised against** *No further relevant information available.*
- **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@dentsplysirona.com
- **Further information obtainable from:** *Research and Development*
- **1.4 Emergency telephone number:** *+49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **Additional information:**
Due to the physical form (paste) classification with H373 is not appropriate. An inhalation of the product is not possible (refer to section 11).
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Additional information:**
As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.
EUH210 Safety data sheet available on request.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

- **Dangerous components:**

CAS: 14464-46-1	cristobalite	STOT RE 1, H372	≥ 2.5 – < 10%
EINECS: 238-455-4			

- **Additional information** *For the wording of the listed hazard phrases refer to section 16.*

SECTION 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.*

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Trade name: *Aquasil Bite Catalyst*

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- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** If symptoms persist consult doctor.
- **Information for doctor** No further relevant information available.
- **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.

SECTION 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:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:** 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).
- **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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** No special measures required.
- **Handling** Product is intended for dental use only.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in dry conditions.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **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**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.

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- **Hand protection**
- **Material of gloves** not applicable
- **Penetration time of glove material** not applicable
- **Eye/face protection** Not required.
- **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

- | | |
|---|------------------------|
| · Physical state | Fluid |
| · Colour: | White |
| · Odour: | Odourless |
| · Odour threshold: | Not determined. |
| · Melting point/freezing point: | undetermined |
| · Boiling point or initial boiling point and boiling range | Undetermined. |
| · Flammability | Not applicable. |
| · Lower and upper explosion limit | |
| · Lower: | Not determined. |
| · Upper: | Not determined. |
| · Flash point: | > 135 °C |
| · Ignition temperature: | Not applicable |
| · Decomposition temperature: | Not determined. |
| · pH | Not determined. |
| · Viscosity: | |
| · Kinematic viscosity | Not determined. |
| · dynamic: | Not determined. |
| · Solubility | |
| · Water: | Insoluble |
| · Partition coefficient n-octanol/water (log value) | Not determined. |
| · Vapour pressure: | Not determined. |
| · Density and/or relative density | |
| · Density at 20 °C: | 1.61 g/cm ³ |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |

· 9.2 Other information

- | | |
|--|---|
| · Appearance: | |
| · Form: | Pasty |
| · Important information on protection of health and environment, and on safety. | |
| · Auto-ignition temperature: | Product is not selfigniting. |
| · Explosive properties: | Product does not present an explosion hazard. |
| · Change in condition | |
| · Evaporation rate | Not determined. |

· Information with regard to physical hazard classes

- | | |
|--|------|
| · Explosives | Void |
| · Flammable gases | Void |
| · Aerosols | Void |
| · Oxidising gases | Void |
| · Gases under pressure | Void |
| · Flammable liquids | Void |
| · Flammable solids | Void |
| · Self-reactive substances and mixtures | Void |
| · Pyrophoric liquids | Void |
| · Pyrophoric solids | Void |

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- | | |
|---|------|
| · Self-heating substances and mixtures | Void |
| · Substances and mixtures, which emit flammable gases in contact with water | Void |
| · Oxidising liquids | Void |
| · Oxidising solids | Void |
| · Organic peroxides | Void |
| · Corrosive to metals | Void |
| · Desensitised explosives | Void |

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **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:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

- **LD/LC50 values relevant for classification:**

ATE (Acute Toxicity Estimate)

Inhalative	LC50/4 h	> 27.7 mg/l (rat)
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CAS: 14464-46-1 cristobalite

Oral	LD50	> 2,000 mg/kg (rat) (OECD 401)
Inhalative	LC50/4 h	> 2.6 mg/l (rat)

- **Additional toxicological information:**

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.

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- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 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.

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

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number
· ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

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· Relevant phrases*H372 Causes damage to organs through prolonged or repeated exposure.***· Department issuing SDS: Research & Development****· Contact: HotLine for urgent technical support: +49-7531-583-350****· Abbreviations and acronyms:***ADR: Accord relatif au transport international 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**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**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**STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1***· * Data compared to the previous version altered.**

GB

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Version number 3 (replaces version 2)

Revision: 01.02.2023

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

- **1.1 Product identifier**
- **Trade name:** *Aquasil Bite Base*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the mixture** *Dental impression material*
- **Uses advised against** *No further relevant information available.*
- **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@dentsplysirona.com*
- **Further information obtainable from:** *Research and Development*
- **1.4 Emergency telephone number:** *+49-(0)7531-583-0 8:00 - 17:00 (GMT + 1:00)*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
The product is not classified, according to the GB CLP regulation.
- **Additional information:**
Due to the physical form (paste) classification with H372 is not appropriate. An inhalation of the product is not possible (refer to section 11).
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** *Void*
- **Hazard pictograms** *Void*
- **Signal word** *Void*
- **Hazard statements** *Void*
- **Additional information:**
*As this product is a medical device in the meaning of Directive 93/42/EEC and regulation (EC) 2017/745 and intended for use by the end consumer and is applied in an invasive manner or body contact, it is exempt from the labelling requirements according to regulation (EC) 1272/2008.
 EUH210 Safety data sheet available on request.*
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

- **3.2 Mixtures**
- **Description:** *Mixture of substances listed below with nonhazardous additions.*

- **Dangerous components:**

CAS: 14464-46-1	cristobalite	STOT RE 1, H372	10 – 25%
EINECS: 238-455-4			

- **Additional information** *For the wording of the listed hazard phrases refer to section 16.*

SECTION 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.*

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Trade name: *Aquasil Bite Base*

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- **After eye contact** Rinse opened eye for several minutes under running water.
- **After swallowing** Do not induce vomiting; call for medical help immediately.
- **Information for doctor** No further relevant information available.
- **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.

SECTION 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:** Self-contained respiratory protective device.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures** Not required.
- **6.2 Environmental precautions:**
Do not allow product to reach sewage system or any water course.
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).
- **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.

* SECTION 7: Handling and storage

- **7.1 Precautions for safe handling** Observe normal care for working with chemicals.
- **Information about fire - and explosion protection:** No special measures required.
- **Handling** Product is intended for dental use only.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage**
- **Requirements to be met by storerooms and receptacles:**
Store only in the original receptacle.
Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Store in dry conditions.
- **Maximum storage temperature:** 28 °C
- **Minimum storage temperature** 2 °C
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **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.

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Trade name: Aquasil Bite Base

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- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not necessary if room is well-ventilated.
- **Hand protection** Not required.
- **Material of gloves** not applicable
- **Penetration time of glove material** not applicable
- **Eye/face protection** Not required.
- **Body protection:** Protective work clothing.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Fluid
- **Colour:** Violet
- **Odour:** Odourless
- **Odour threshold:** Not determined.
- **Melting point/freezing point:** undetermined
- **Boiling point or initial boiling point and boiling range** Undetermined.
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** > 135 °C
- **Ignition temperature:** Not applicable
- **Decomposition temperature:** Not determined.
- **pH** Not determined.
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **dynamic:** Not determined.
- **Solubility**
- **Water:** Insoluble
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapour pressure:** Not determined.
- **Density and/or relative density**
- **Density:** Not determined
- **Relative density** Not determined.
- **Vapour density** Not determined.

- **9.2 Other information**
- **Appearance:**
- **Form:** Pasty
- **Important information on protection of health and environment, and on safety.**
- **Auto-ignition temperature:** Product is not selfigniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate** Not determined.

- **Information with regard to physical hazard classes**
- **Explosives** Void
- **Flammable gases** Void
- **Aerosols** Void

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· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **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:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity**

· **LD/LC50 values relevant for classification:**

CAS: 14464-46-1 cristobalite

Oral	LD50	> 2,000 mg/kg (rat) (OECD 401)
Inhalative	LC50/4 h	> 2.6 mg/l (rat)

· **Additional toxicological information:**

EC regulation 1272/2008 annex 1, section 1.1.1.5: "For the purpose of classification of health hazards (part 3), the route of exposure, information on mechanisms and metabolism studies are useful for determining the relevance of effects in humans. If this information raises doubts as to their relevance in humans, in spite of the indisputable data legitimacy and quality, a lower classification may be justified. When there is scientific evidence that the mechanism or mode of action is not relevant to humans, the substance or mixture should not be classified."

· **11.2 Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 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.

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Trade name: Aquasil Bite Base

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- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 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.

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

SECTION 14: Transport information

- | | |
|---|-----------------|
| · 14.1 UN number or ID number
· ADR, IMDG, IATA | Void |
| · 14.2 UN proper shipping name
· ADR, IMDG, IATA | Void |
| · 14.3 Transport hazard class(es)
· ADR, ADN, IMDG, IATA
· Class | Void |
| · 14.4 Packing group
· ADR, IMDG, IATA | Void |
| · 14.5 Environmental hazards: | Not applicable. |
| · 14.6 Special precautions for user | Not applicable. |
| · 14.7 Maritime transport in bulk according to IMO instruments | Not applicable. |
| · UN "Model Regulation": | Void |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

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SECTION 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

H372 Causes damage to organs through prolonged or repeated exposure.

· Department issuing SDS: Research & Development**· Contact: HotLine for urgent technical support: +49-7531-583-350****· Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1

· * Data compared to the previous version altered.

GB