

SAFETY DATA SHEETS

This SDS packet was issued with item:

077111180

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

070829424 070829432 071317957 071317965 071317973 077109507 077109515 077109523 077109564 077109572
077109580 077109598 077109606 077109655 077109663 077109671 077109689 077109697 077109754 077109762
077109770 077109788 077111156 077111198 077111263 077111289 077111297 077111305

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).

0273000007 0273000008 071245075 071245083 071245091 077060239 077109440 077109531 077109549
077111164 077111172 077111248 077111271 077115405 077115413 077115421 077115439 273000007 273000008

Safety Data Sheet

acc. to OSHA HCS

Printing date 10/11/2019

Reviewed on 10/11/2019

1 Identification

- **Product identifier**
- **Trade name:** *VOCO Profluorid Varnish*
- **Application of the substance / the mixture** *Dental varnish*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven
- **Information department:** *Scientific department tel. +49 (0)4721-719-0*
- **Emergency telephone number:** *Scientific department tel. +49 (0)4721-719-0*

2 Hazard(s) identification

Health effects are based on the unmixed/uncured material.
Under FDA regulations this product is classified as a medical device.
Medical devices are exempt from the labelling provisions of GHS according to the Hazard Communication Standard (HCS).

- **Classification of the substance or mixture**



Flame

Flam. Liq. 3 H226 Flammable liquid and vapor.



Acute Tox. 4 H302 Harmful if swallowed.

- **Label elements**
- **Hazard pictograms** *GHS02, GHS07*
- **Signal word** *Warning*
- **Hazard statements**
Flammable liquid and vapor.
Harmful if swallowed.
- **Precautionary statements**
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Avoid breathing vapours.
Wear protective gloves / eye protection.
Wear protective clothing.
IF SWALLOWED: Call a doctor if you feel unwell.
Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Other hazards**
Material should only be used with extreme caution in individuals who may have control over their swallowing reflex (e.g. pre-school children and the disabled).
Use only for intended scope of application
- **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	Flam. Liq. 2, H225	10-25%
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Trade name: **VOCO Profluorid Varnish**

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7681-49-4 sodium fluoride

Acute Tox. 3, H301
Skin Irrit. 2, H315; Eye Irrit. 2, H319

2.5-5%

4 First-aid measures

- **Description of first aid measures**
- **After inhalation:** Supply fresh air; consult doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:**
Swallowing of larger amounts can lead to nausea, vomiting and/or diarrhoea.
Immediately call a 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** No further relevant information available.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **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.
See Section 13 for disposal information.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling** For dental use only.
- **Information about protection against explosions and fires:** Keep ignition sources away - Do not smoke.
- **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:** Do not store together with acids.
- **Further information about storage conditions:**
See storage instructions on package
Keep receptacle tightly sealed.
- **Specific end use(s)** No further relevant information available.

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Safety Data Sheet

acc. to OSHA HCS

Printing date 10/11/2019

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Trade name: *VOCO Profluorid Varnish*

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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:**
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 that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures for handling chemicals should be followed.
- **Breathing equipment:** Not required.
- **Protection of hands:** Not required.
- **Material of gloves:** Not required.

9 Physical and chemical properties

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

Form:	Fluid
Color:	Colorless
Odor:	Fruit-like
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** 36 °C (97 °F)
- **Auto igniting:** Product is not selfigniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Density at 20 °C (68 °F):** 1.02 g/cm³ (8.512 lbs/gal)
- **Solubility in / Miscibility with Water:** Not miscible or difficult to mix.
- **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**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions:** Contact with acids releases toxic gases.
- **Conditions to avoid:** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

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11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

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

7681-49-4 sodium fluoride		
Oral	LD50	52 mg/kg (rat)

- **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)**

The component 64-17-5 Ethanol is listed by IARC as Group 1 but in alcoholic beverages consumption only.

This product is not an alcoholic beverage.

7681-49-4	sodium fluoride	3
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- **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:**

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.

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Printing date 10/11/2019

Reviewed on 10/11/2019

Trade name: *VOCO Profluorid Varnish*

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14 Transport information

· UN-Number	
· DOT, ADR, IMDG, IATA	UN1170
· UN proper shipping name	
· DOT	Ethanol
· ADR	1170 Ethanol
· IMDG	ETHANOL (ETHYL ALCOHOL)
· IATA	ETHANOL
· Transport hazard class(es)	
· DOT	
	
· Class	3 Flammable liquids
· Label	3
· ADR, IMDG, IATA	
	
· Class	3 Flammable liquids
· Label	3
· Packing group	
· DOT, ADR, IMDG, IATA	III
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Warning: Flammable liquids
· Danger code (Kemler):	30
· EMS Number:	F-E,S-D
· Stowage Category	A
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	UN 1170 ETHANOL, 3, III

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 are listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients are listed.

· TSCA (Toxic Substances Control Act):

All ingredients are listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients are listed.

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Trade name: **VOCO Profluorid Varnish**

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· Chemicals known to cause reproductive toxicity for females:
None of the ingredients are listed

· Chemicals known to cause reproductive toxicity for males:
None of the ingredients are listed

· Chemicals known to cause developmental toxicity:
64-17-5 ethanol

· Carcinogenicity categories
· EPA (Environmental Protection Agency)
None of the ingredients are listed

· TLV (Threshold Limit Value established by ACGIH)	
64-17-5 ethanol	A3
7681-49-4 sodium fluoride	A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients are listed

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS02, GHS07

- **Signal word** Warning

- **Hazard statements**

Flammable liquid and vapor.

Harmful if swallowed.

- **Precautionary statements**

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

Avoid breathing vapours.

Wear protective gloves / eye protection.

Wear protective clothing.

IF SWALLOWED: Call a doctor if you feel unwell.

Dispose of contents/container in accordance with local/regional/national/international regulations.

16 Other information

The information contained herein is based on our present knowledge and is believed to be correct at the date issued. The information is subject to change without notice. However, all information, statements, recommendations or suggestions shall not constitute any guarantee, representation or warranty, expressed or implied.

Final determination whether the product is fit and suitable for a particular purpose and the user's method of use or application is the sole responsibility of the user.

- **Department issuing SDS:** Scientific department

- **Contact:** Tel.: +49 (0)4721-719-0

- **Date of preparation / last revision:** 10/11/2019 / 21

- **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

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)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

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

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Trade name: VOCO Profluorid Varnish

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*PEL: Permissible Exposure Limit**REL: Recommended Exposure Limit**Flam. Liq. 2: Flammable liquids – Category 2**Flam. Liq. 3: Flammable liquids – Category 3**Acute Tox. 3: Acute toxicity – Category 3**Acute Tox. 4: Acute toxicity – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**** Data compared to the previous version altered.**

US

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

Printing date 20.09.2016

Version number 9

Revision: 20.09.2016

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

- **1.1 Product identifier**
- **Trade name:** *Rebilda DC base*
- **1.2 Relevant identified uses of the substance or mixture and uses advised against** *Non-dental use.*
- **Application of the substance / the mixture** *Core-build up material*
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*VOCO GmbH
Anton-Flettner-Str. 1-3
D-27472 Cuxhaven*
- **Further information obtainable from:** *Scientific department tel. +49 (0)4721-719-0*
- **1.4 Emergency telephone number:** *Poison Control Center Mainz +49 (0)6131-19240*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
Skin Sens. 1 H317 May cause an allergic skin reaction.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
As a medical device the product is not subject to labelling regulations under 1272/2008/EC.
- **Hazard pictograms** *GHS07*
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
*Wear protective gloves / eye protection.
Wear protective clothing.
IF INHALED: Call a POISON CENTER/doctor if you feel unwell.
If skin irritation or rash occurs: Get medical advice/attention.
If eye irritation persists: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **2.3 Other hazards** *Use only for intended scope of application*
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

SECTION 3: Composition/information on ingredients

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

Dangerous components:		
CAS: 72869-86-4	Urethanedimethacrylate	10-25%
EINECS: 276-957-5	Aquatic Chronic 3, H412	
	DDMA	5-10%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 1565-94-2	BIS GMA	2.5-5%
	Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After inhalation:** *Seek medical treatment 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:** *If symptoms persist consult doctor.*

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Version number 9

Revision: 20.09.2016

Trade name: *Rebilda DC base*

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- 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:* Use fire extinguishing methods suitable to surrounding conditions.
- 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.

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:* Pick up mechanically.
- 6.4 *Reference to other sections* No dangerous substances are released.

SECTION 7: Handling and storage

- 7.1 *Precautions for safe handling* 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:* No special requirements.
- *Information about storage in one common storage facility:* Not required.
- *Further information about storage conditions:* See storage instructions on package
- 7.3 *Specific end use(s)* No further relevant information available.

SECTION 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:*
The usual precautionary measures are to be adhered to when handling chemicals.
- *Respiratory protection:* Not required.
- *Protection of hands:*



Protective gloves

- *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.

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

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Revision: 20.09.2016

Trade name: *Rebilda DC base*· *Eye protection: Safety glasses*

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SECTION 9: Physical and chemical properties· **9.1 Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	<i>Pasty</i>
· Colour:	<i>According to product specification</i>
· Odour:	<i>Characteristic</i>

· **pH-value:** *Not determined.*· **Change in condition**

· Melting point/Melting range:	<i>Undetermined.</i>
· Boiling point/Boiling range:	<i>Undetermined.</i>

· **Flash point:** *Not applicable.*· **Self-igniting:** *Product is not selfigniting.*· **Danger of explosion:** *Product does not present an explosion hazard.*· **Density:** *Not determined.*· **Solubility in / Miscibility with water:** *Not miscible or difficult to mix.*· **Viscosity:**

· Dynamic:	<i>Not determined.</i>
· Kinematic:	<i>Not determined.</i>

· **9.2 Other information** *No further relevant information available.***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 toxicological effects**· **Acute toxicity** *Based on available data, the classification criteria are not met.*· **Primary irritant effect:**· **Skin corrosion/irritation**· *Testing according to ISO 10993-1/10993-10 showed no skin irritation for this product when fully cured*· **Serious eye damage/irritation** *Based on available data, the classification criteria are not met.*· **Respiratory or skin sensitisation**· *May cause an allergic skin reaction.*· **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**· **Germ cell mutagenicity** *Based on available data, the classification criteria are not met.*· **Carcinogenicity** *Based on available data, the classification criteria are not met.*· **Reproductive toxicity** *Based on available data, the classification criteria are not met.*· **STOT-single exposure** *Based on available data, the classification criteria are not met.*· **STOT-repeated exposure** *Based on available data, the classification criteria are not met.*

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Trade name: *Rebilda DC base*

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· **Aspiration hazard** Based on available data, the classification criteria are not met.

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.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water
Do not allow product 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.

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	
· ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name	
· ADR, ADN, 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:	
· Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	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.

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Trade name: **Rebilda DC base**

REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

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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.

· **Department issuing SDS:** Scientific department

· **Contact:** Tel.: +49 (0)4721-719-0

· **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

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Skin Irrit. 2: Skin corrosion irritation - Category 2

Eye Irrit. 2: Serious eye damage eye irritation - Category 2

Skin Sens. 1: Skin sensitisation - Category 1

STOT SE 3: Specific target organ toxicity (single exposure) - Category 3

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3

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

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