

Version number 2 Revision: 16.10.2014 Printing date 16.10.2014 SECTION 1: Identification of the substance/mixture and of the company/undertaking · 1.1 Product identifier · Trade name: ENDOMET PLAIN LIQUIDE · Article number / formula: 150S · 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 : dental product \cdot 1.3 Details of the supplier of the safety data sheet · Manufacturer/Supplier: SEPTODONT. 58 rue du Pont de Creteil 94100 Saint Maur des Fosses France *Téléphone:* +33(0)149767000 Fax: +33(0)148855401 msds@septodont.com http://www.septodont.com · 1.4 Emergency telephone number: France (ORFILA 24h/24) - Tel: +33 (0)1 45 42 59 59 Ireland - Tel: 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel : 112 **SECTION 2: Hazards identification** · 2.1 Classification of the substance or mixture · Classification according to Regulation (EC) No 1272/2008 : GHS07 Eve Irrit. 2 H319 Causes serious eye irritation. Skin Sens. 1 H317 May cause an allergic skin reaction. Aquatic Chronic 3 H412 Harmful to aquatic life with long lasting effects. · Classification according to Directive 67/548/EEC or Directive 1999/45/EC : Xi; Irritant R36. Irritating to eyes. Xi; Sensitising May cause sensitisation by skin contact. R43. *R52/53*: Harmful 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 in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU". · 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 Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

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(Contd. of page 1) · Hazard pictograms GHS07 · Signal word Warning · Hazard-determining components of labelling: Eugenol (E)-anethole dipentene · Hazard statements H319 Causes serious eye irritation. H317 May cause an allergic skin reaction. H412 Harmful to aquatic life with long lasting effects. · Precautionary statements P273 Avoid release to the environment. P280 Wear protective gloves/protective clothing/eye protection/face protection. P264 Wash hands thoroughly after handling. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. *P302+P352* IF ON SKIN: Wash with plenty of water. · 2.3 Other hazards · 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: consisting of the following components.

· Dangerous components:		
CAS: 97-53-0 EINECS: 202-589-1	Eugenol Xi R36; Xi R43	50-100%
CAS: 4180-23-8 EINECS: 224-052-0 RTECS: BZ 9275000	 ♦ Acute Tox. 4, H302; Eye Irrit. 2, H319; Skin Sens. 1, H317 (E)-anethole Xi R43; N R51/53 ♦ Aquatic Chronic 2, H411; ♦ Skin Sens. 1, H317 	2.5-10%
CAS: 89-78-1 EINECS: 201-939-0 RTECS: OT 0350000	menthol Xi R38 (1) Skin Irrit. 2, H315	≤2.5%
CAS: 138-86-3 EINECS: 205-341-0 Index number: 601-029-00-7 RTECS: OS 8100000	dipentene Xi R38; X R43; № N R50/53 R10 Flam. Liq. 3, H226; Asp. Tox. 1, H304; Aquatic Chronic 1, H410; Nkin Irrit. 2, H315; Skin Sens. 1, H317	<u>≤</u> 1%
• Additional information: For	the wording of the listed risk phrases, refer to section 16.	

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SECTION 4: First aid measures

• 4.1 Description of first aid measures

- General information: Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- After excessive inhalation: Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient in a stable laying down side position for transportation.
- After skin contact: Immediately wash with water and soap and rinse thoroughly.
- After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor. • *After swallowing:* Call for a doctor immediately.

- 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 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: No special measures required.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures : Not required.
- 6.2 Environmental precautions: Inform respective authorities in case of seepage into water course or sewage system. 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). 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 protective equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling :
- *Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols.*
- Information about fire and explosion protection: No special measures required.

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- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:

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- · 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 container tightly sealed.
- · 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 section 7.
- · 8.1 Control parameters
- · Ingredients with limit values that require monitoring at the workplace:
- The product does not contain any signifiant quantities of materials with critical values that have to be monitored at the workplace.
- · Additional information:
- As a basis for the production of this document, the most current valid lists were used.
- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Keep away from food, beverages and petfood. 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:



In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

• Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. • Gloves material :

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which may vary 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 before use.

· Eye protection:



Tightly sealed goggles

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ical properties iquid imber coloured ight yellow Characteristic Not determined. Not determined. Undetermined. Undetermined. Not applicable. Not applicable.
Amber coloured Light yellow Characteristic Not determined. Not determined. Undetermined. Judetermined. Not applicable.
Amber coloured Light yellow Characteristic Not determined. Not determined. Undetermined. Judetermined. Not applicable.
ight yellow Characteristic Not determined. Indetermined. Indetermined. Indetermined. Not applicable.
Characteristic Not determined. Not determined. Undetermined. Not applicable. Not applicable.
Not determined. Not determined. Undetermined. Undetermined. Not applicable. Not applicable.
Indetermined. Indetermined. Not applicable. Not applicable.
Indetermined. Not applicable. Not applicable.
Indetermined. Not applicable. Not applicable.
Vot applicable. Not applicable.
lot applicable.
Not applicable.
lot determined.
Product is not self igniting.
Product does not present an explosion hazard.
Not determined.
Not determined.
Not determined.
.045-1.065 g/cm ³
lot determined.
Not determined.
Not determined.
Fully miscible.
lot determined.
Not determined.
Not determined.
0.18 % <i>Jo further relevant information available</i> .

SECTION 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.

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• 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:
- · LD/LC50 values relevant for classification:
- 97-53-0 Eugenol

Oral LD50 1930 mg/kg (rat)

- Primary irritant effect:
- On the skin: Irritant to skin and mucous membranes.
- On the eyes: Irritating effect.
- · Sensitisation:
- Sensitisation possible through inhalation. Sensitisation possible through skin contact.
- Additional toxicological information:

The product shows the following hasards according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version: Harmful

Irritant

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.
- · Ecotoxical effects:
- · Remark: Harmful to fish
- 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.

Harmful to aquatic organisms

- · 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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SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation :



Must not be disposed of 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.

SECTION 14: Transport information

· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
· 14.2 UN proper shipping name · ADR, ADN, IMDG, IATA	Not classified as hazardous for transport
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	Not classified as hazardous for transport
· 14.4 Packing group · ADR, IMDG, IATA	Not classified as hazardous for transport
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Anne MARPOL73/78 and the IBC Code	x II of Not applicable.
· UN ''Model Regulation'':	-

SECTION 15: Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

• 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.

· Relevant phrases

H226 Flammable liquid and vapour.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

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H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H410	•
H411	Toxic to aquatic life with long lasting effects.
R10	Flammable.
R36	Irritating to eyes.
R38	Irritating to skin.
R43	May cause sensitisation by skin contact.
	3 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	3 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
	viations and acronyms:
	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the Internation
	ge of Dangerous Goods by Road)
IMDG: I	International Maritime Code for Dangerous Goods
	International Air Transport Association
	Globally Harmonised System of Classification and Labelling of Chemicals
	S: European Inventory of Existing Commercial Chemical Substances
	S: European List of Notified Chemical Substances
	'hemical Abstracts Service (division of the American Chemical Society)
	Volatile Organic Compounds (USA, EU)
	Lethal concentration, 50 percent
	Lethal dose, 50 percent .iq. 3: Flammable liquids, Hazard Category 3
	ox. 4: Acute toxicity, Hazard Category 4
	it. 2: Skin corrosion/irritation, Hazard Category 2
	it. 2: Serious eye damage/eye irritation, Hazard Category 2
	ns. 1: Sensitisation - Skin, Hazard Category 1
	x. 1: Aspiration hazard, Hazard Category 1
	Chronic 1: Hazardous to the aquatic environment - Chronic Hazard, Category 1
	Chronic 2: Hazardous to the aquatic environment - Chronic Hazard, Category 2
Aquatic	Chronic 3: Hazardous to the aquatic environment - Chronic Hazard, Category 3



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SECTION 1: Identification of the substance/mixture and of the company/undertaking
· 1.1 Product identifier
· Trade name: <u>ENDOMET PLAIN POUDRE</u>
 Article number / formula: 144S 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 : dental product
 1.3 Details of the supplier of the safety data sheet Manufacturer/Supplier: SEPTODONT. 58 rue du Pont de Creteil 94100 Saint Maur des Fosses France Téléphone: +33(0)149767000 Fax: +33(0)148855401 msds@septodont.com http://www.septodont.com 1.4 Emergency telephone number: France (ORFILA 24h/24) - Tel : +33 (0)1 45 42 59 59 Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel : 112
SECTION 2: Hazards identification
· 2.1 Classification of the substance or mixture
· Classification according to Regulation (EC) No 1272/2008 : GHS05
Skin Corr. 1B H314 Causes severe skin burns and eye damage.
GHS09
Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.
GHS07
Acute Tox. 4 H302 Harmful if swallowed.
• Classification according to Directive 67/548/EEC or Directive 1999/45/EC :
C; Corrosive
R34: Causes burns.
Xn; Harmful
R22: Harmful if swallowed.
<i>N; Dangerous for the environment</i> (Contd. on page 2)
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• **Description:** Mixture: consisting of the following components.

· Dangerous components:

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CAS: 1314-13-2 EINECS: 215-222-5 Index number: 030-013-00-7 RTECS: ZH 4810000 Reg.nr.: 01-2119463881-32	zinc oxide N R50/53 Aquatic Acute 1, H400; Aquatic Chronic 1, H410	Contd. of page 2) 50-100%
CAS: 552-22-7	iodothymol ☑ C R34; 🗙 Xn R22 ♦ Skin Corr. 1B, H314; () Acute Tox. 4, H302	10-25%

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

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- After excessive inhalation: Supply fresh air; consult a 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: Call for a doctor immediately.
- · 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 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: No special measures required.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures : Not required.
- · 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: Dispose contaminated material as waste according to item 13.
- · 6.4 Reference to other sections : See Section 7 for information on safe handling. See Section 8 for information on personal protective equipment. See Section 13 for disposal information.

SECTION 7: Handling and storage

• 7.1 Precautions for safe handling : No special precautions are necessary if used correctly.

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Trade name: ENDOMET PLAIN POUDRE

· 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: None.

• 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 section 7.

· 8.1 Control parameters

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

7727-43-7 barium sulphate, natural (2.5-10%)

WEL (Great Britain) Long-term value: 10* 4** mg/m³ *inhalable dust **respirable dust

· Additional information:

As a basis for the production of this document, the most current valid lists were used.

- · 8.2 Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures: Keep away from food, beverages and petfood. Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- Protection of hands:
- The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.
- · Gloves material :

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which may vary 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 before use.

• Eye protection: Not required.

SECTION 9: Physical and chemical properties

 9.1 Information on basic physical an General Information 	d chemical properties	
· Appearance:		
Form:	Powder	
Colour:	Light beige	
Odour:	Characteristic	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/Melting range:	Undetermined.	
Boiling point/Boiling range:	Undetermined.	
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Flash point:	Not applicable.	
Flammability (solid, gaseous):	Not determined.	
Ignition temperature:	Not applicable.	
Decomposition temperature:	Not determined.	
Self-igniting:	Product is not self igniting.	
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.	
Segregation coefficient (n-octanol/w	ater): Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Solvent content:		
VOC (EC)	0.00 %	
9.2 Other information :	No further relevant information available.	

SECTION 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.

SECTION 11: Toxicological information

·11.1 Information on toxicological effects

• Acute toxicity:

- · LD/LC50 values relevant for classification:
- 1314-13-2 zinc oxide

Oral LD50 7950 mg/kg (mouse)

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

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• On the eyes: No irritant effect.

· Sensitisation: No sensitising effects known.

· Additional toxicological information:

The product shows the following hasards according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version: Harmful

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.
- · Ecotoxical effects:
- **Remark:** Very toxic for fish
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water



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. Also poisonous for fish and plankton in water bodies. Very toxic for aquatic organisms

- 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 of 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, IMDG, IATA

UN3077

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· Transport category

· Tunnel restriction code

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

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Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g

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· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	5 kg Code: E1 Maximum net quantity per inner packaging: 30 g Maximum net quantity per outer packaging: 1000 g
· UN "Model Regulation":	UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (zinc oxide), 9, III

SECTION 15: Regulatory information

• 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture No further relevant information available.

• 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.

· Relevant phrases

	H302	Harmful if	swallowed.
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- H314 Causes severe skin burns and eye damage.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.
- R22 Harmful if swallowed.
- R34 Causes burns.

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

• 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 Inventory of Existing Commercial Chemical ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- VOC: Volatile Organic Compounds (USA, EU)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- Acute Tox. 4: Acute toxicity, Hazard Category 4
- Skin Corr. 1B: Skin corrosion/irritation, Hazard Category 1B
- Aquatic Acute 1: Hazardous to the aquatic environment AcuteHazard, Category 1
- Aquatic Chronic 1: Hazardous to the aquatic environment Chronic Hazard, Category 1