

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

1.1. Product identifier

Product form : Mixture
Product name : PROSEAL

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : For Rx Only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer/Importer/Representative/User/Distributor:

Reliance Orthodontic Products, Inc.
1540 W. Thorndale Ave
Itasca, IL 60143 USA
T 630-773-4009, during normal business hours
regulatory@relianceorthodontics.com
www.RelianceOrthodontics.com

Australian Sponsor:

Emergo Australia, 201 Sussex St.
Darling Park, Tower II, Level 20
Sydney, NSW 2000 Australia
T +61 2 9006 1662

Switzerland Representative:

MedEnvoy Global BV
Leidschendam-Voorburg, Zug Branch Office
Gotthardstrasse 28, 6302 Zug, Switzerland
T +41 41 462 01 42

U.S. Federal Register:

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012
/ Rules and Regulations
FDA Registration: 1420089

EC Representative:

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
T +31 70 345 8570

U.K. Person Responsible:

Emergo Consulting (UK) Limited
c/o Cr360 - UL International Compass House, Vision Park Histon
Cambridge CB24 9BZ
England, United Kingdom
T +44(0) 1223 772 671

1.4. Emergency telephone number

Emergency number : CHEMTREC - 24-Hour Hazmat Emergency Communications Center
Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 1	H318
Skin sensitisation, Category 1	H317
Reproductive toxicity, Category 2	H361
Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation	H335
Hazardous to the aquatic environment - Chronic Hazard, Category 2	H411

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS05

GHS07

GHS08

GHS09

Signal word (CLP)

: Danger

Contains

: Hexafunctional Urethane Acrylate Oligomer; Polyethylene Glycol (600) Diacrylate; Trifunctional Acid Ester; Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide

Hazard statements (CLP)

: H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H335 - May cause respiratory irritation.
H361 - Suspected of damaging fertility..
H411 - Toxic to aquatic life with long lasting effects.
Precautionary statements (CLP) : P261 - Avoid breathing fume, mist, vapours.
P264 - Wash hands thoroughly after handling.
P272 - Contaminated work clothing should not be allowed out of the workplace.
P273 - Avoid release to the environment.
P280 - Wear protective gloves, protective clothing, eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of soap and water.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P313 - IF exposed or concerned: Get medical advice/attention.
P312 - Call a POISON CENTER, doctor if you feel unwell.
P321 - Specific treatment (see supplemental first aid instruction on this label).
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 - Take off contaminated clothing and wash it before reuse.
P391 - Collect spillage.
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

Component	
Trifunctional Acid Ester(Proprietary)	The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethoxylated 3 Bisphenol A Diacrylate	CAS-No.: 64401-02-1 EC-No.: 613-584-2	10 - 30	Aquatic Chronic 2, H411
Hexafunctional Urethane Acrylate Oligomer	CAS-No.: Proprietary	10 - 30	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Dam. 1, H318 Skin Sens. 1, H317 Aquatic Chronic 2, H411
Polyethylene Glycol (600) Diacrylate	CAS-No.: 26570-48-9	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide	CAS-No.: 75980-60-8 EC-No.: 278-355-8 EC Index-No.: 015-203-00-X	5 - 10	Repr. 2, H361f Aquatic Chronic 2, H411
Trifunctional Acid Ester	CAS-No.: Proprietary	1 - 5	Eye Dam. 1, H318 Skin Sens. 1, H317

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice/attention if you feel unwell.
First-aid measures after ingestion	: Rinse mouth out with water. Do NOT induce vomiting. Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Irritation. May cause an allergic skin reaction.
Symptoms/effects after eye contact	: Serious damage to eyes.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid breathing fume, mist, vapours. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid breathing fume, mist, vapours. Avoid contact with skin and eyes. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Appearance	: Clear, colorless liquid.
Odour	: Acrylic.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available

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Relative vapour density at 20°C : Not available
Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Polyethylene Glycol (600) Diacrylate (26570-48-9)

LD50 oral rat	> 5000 mg/kg (Rat, Oral)
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Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)

LD50 oral rat	> 5000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 401 (Acute Oral Toxicity), Remarks on results: other:
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LD50 dermal rat	> 2000 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 402 (Acute Dermal Toxicity), Guideline: EU Method B.3 (Acute Toxicity (Dermal)), Guideline: EPA OPPTS 870.1200 (Acute Dermal Toxicity), Guideline: other:, Remarks on results: other:
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Skin corrosion/irritation : Causes skin irritation.

Hexafunctional Urethane Acrylate Oligomer (Proprietary)

pH	≈ 7
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Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)

pH	6.8 - 7.2
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Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
pH	4 - 7
Serious eye damage/irritation	: Causes serious eye damage.
Hexafunctional Urethane Acrylate Oligomer (Proprietary)	
pH	≈ 7
Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)	
pH	6.8 - 7.2
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
pH	4 - 7
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Hexafunctional Urethane Acrylate Oligomer (Proprietary)	
IARC group	4 - Probably not carcinogenic to humans
Trifunctional Acid Ester (Proprietary)	
IARC group	4 - Probably not carcinogenic to humans
Reproductive toxicity	: Suspected of damaging fertility..
STOT-single exposure	: May cause respiratory irritation.
Polyethylene Glycol (600) Diacrylate (26570-48-9)	
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
Viscosity, kinematic	No data available
11.2. Information on other hazards	
No additional information available	
SECTION 12: Ecological information	
12.1. Toxicity	
Ecology - general	: Toxic to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Toxic to aquatic life with long lasting effects.
Polyethylene Glycol (600) Diacrylate (26570-48-9)	
LC50 - Fish [1]	11.911 mg/l Source: ECOSAR
EC50 96h - Algae [1]	32.341 mg/l Source: ECOSAR
Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)	
LC50 - Fish [1]	1.4 mg/l Test organisms (species): Cyprinus carpio
EC50 - Crustacea [1]	3.53 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	> 2.01 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

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Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)

EC50 96h - Algae [1]	3.829 mg/l Source: Ecological Structure Activity Relationships
Threshold limit - Algae [1]	> >10/100,EC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Algae

12.2. Persistence and degradability

Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)

Persistence and degradability	Inherently biodegradable.
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Polyethylene Glycol (600) Diacrylate (26570-48-9)

Persistence and degradability	Biodegradability in water: no data available.
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Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)

Persistence and degradability	Not readily biodegradable in water.
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12.3. Bioaccumulative potential

Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)

Partition coefficient n-octanol/water (Log Pow)	2.45 - 3.91 (Practical experience/observation, OECD 117: Partition Coefficient (n-octanol/water), HPLC method)
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Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).
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Polyethylene Glycol (600) Diacrylate (26570-48-9)

Bioaccumulative potential	No bioaccumulation data available.
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Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)

BCF - Fish [1]	< 40 (OECD 305: Bioconcentration: Flow-Through Fish Test, Cyprinidae sp., Experimental value, Chronic)
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Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).
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12.4. Mobility in soil

Ethoxylated 3 Bisphenol A Diacrylate (64401-02-1)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	1.97 - 3 (log Koc, Calculated value)
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Ecology - soil	Low potential for adsorption in soil.
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Diphenyl(2,4,6-Trimethylbenzoyl)phosphine Oxide (75980-60-8)

Mobility in soil	784.8 Source: Quantitative Structure Activity Relation
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Ecology - soil	No (test)data on mobility of the substance available.
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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

No additional information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

14.1. UN number or ID number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not regulated
Proper Shipping Name (IMDG) : Not regulated
Proper Shipping Name (IATA) : Not regulated
Proper Shipping Name (ADN) : Not regulated
Proper Shipping Name (RID) : Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not regulated

IMDG

Transport hazard class(es) (IMDG) : Not regulated

IATA

Transport hazard class(es) (IATA) : Not regulated

ADN

Transport hazard class(es) (ADN) : Not regulated

RID

Transport hazard class(es) (RID) : Not regulated

14.4. Packing group

Packing group (ADR) : Not regulated
Packing group (IMDG) : Not regulated
Packing group (IATA) : Not regulated
Packing group (ADN) : Not regulated
Packing group (RID) : Not regulated

14.5. Environmental hazards

Dangerous for the environment : Yes
Marine pollutant : Yes
Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

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Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Revision date	Added	
	Issue date	Removed	
	Supersedes version of	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	

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Indication of changes			
Section	Changed item	Change	Comments
2.2	Hazard pictograms (CLP)	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
6.1	Emergency procedures	Modified	
7.1	Precautions for safe handling	Modified	
7.2	Storage conditions	Modified	

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment - Chronic Hazard, Category 2
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H361	Suspected of damaging fertility or the unborn child.
H361f	Suspected of damaging fertility.
H411	Toxic to aquatic life with long lasting effects.
Repr. 2	Reproductive toxicity, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.