

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

1.1. Product identifier

Product form	: Mixture
Trade name	: LAFAZYM® EXTRACT
Type of product	: For œnological use
Product group	: Trade product
Other means of identification	: E330 - E331 (iii) - E508

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

1.2.1. Relevant identified uses

Main use category	: Professional use
Industrial/Professional use spec	: For professional users only
Use of the substance/mixture	: Pectolytic enzyme preparation purified in CE, specifically for skin contact during white wine vinification. Developed for extracting aroma precursors and varietal aromas for the production of highly aromatic, fruity white wines.
Use of the substance/mixture	: For œnological use

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

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LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Australia	NSW Poisons Information Centre The Children's Hospital at Westmead	Locked Bag 4001 NSW 2145 Westmead	13 11 26	
Canada	Ontario Poison Centre (OPC)	The Hospital for Sick Children 555 University Avenue ON M5G 1X8 Toronto	1-800-268-9017 (416) 813-5900	
Canada	BC Drug and Poison Information Centre (DPIC)	655 West 12th Avenue BC V5Z 4R4 Vancouver	1-800-567-8911 (604) 682-5050	
China	National Poison Control Center	Chinese Center for Disease Control and Prevention Nanwei road, No.29 100050 Beijing	+86 10 831 32 046	
Croatia	Centar za kontrolu otrovanja Institut za medicinska istraživanja i medicinu rada	Ksaverska Cesta 2 p.p. 291 10000 Zagreb	+385 1 234 8342	Information available 24/7 in Croatian and English
Czech Republic	Toxikologické informační středisko Klinika pracovního lékařství VFN a 1. LF UK	Na Bojišti 1 120 00 Praha 2	+420 224 919 293 +420 224 915 402	
Denmark	Gifftiljen	Bispebjerg Bakke 23 Opgang 20 C 2400 København NV	+45 82 12 12 12	
Georgia	National Toxicology Information Advisory Center	Tbilisi State Medical University Department of Toxicology - 7 Asatiani St. 380 077 Tbilisi	+995 99 533320	
Greece	Poisons Information Centre Children's Hospital P&A Kyriakou	11762 Athens	+30 2 10 779 3777	
Hungary	Országos Kémiai Biztonsági Intézet Egészségügyi Toxikológiai Tájékoztató Szolgálat	Nagyvárad tér 2. 1437 Budapest, Pf. 839 1097 Budapest	+36 80 20 11 99	
Israel	Israel Poison Information Center Rambam Health Care Campus	6 Ha'Aliya Street 31096 Haifa	+972 4 854 1900	
Japan	Japan Poison Information Center	Tsukuba Medical Center 1-1-1 Amakubo 305-0005 Tsukuba City, Ibaraki	+81-29-856-3566 +81-72-727-2499	
Jordan	National Drug & Poison Information Center of Jordan		0798506755 00962-6-5353444	
Kazakhstan	Republican Toxicology Center	Tole-bi 93 480083 Almaty	+7 3272 925 868	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD Msida	+356 2545 6504	
New Zealand	National Poisons Centre	Dunedin School of Medicine, University of Otago PO Box 913 9054 Dunedin	0800 764 766 +56 2 2 247 3600	
Poland	National Poisons Information Centre The Nofer Institute of Occupational Medicine (Łódź)	ul. Teresy 8 P.O. BOX 199 90950 Łódź	+48 42 63 14 724	
Romania	Department of Clinical Toxicology Spitalul de Urgenta Floreasca	Calea Floreasca Bucuresti	+40 21 230 8000	

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Country	Organisation/Company	Address	Emergency number	Comment
Russia	Информационно-консультативный центр по токсикологии (РТИАС) Министерство здравоохранения Российской Федерации	3 Сухаревская Площадь Блок 7 129090 г. Москва	+7 495 628 1687 (только на русском)	
Serbia	Nacionalni centar za kontrolu trovanja - VMA	Crnotravska 17 11000 Beograd	+381 11 360 84 40	
Slovenia	Center za klinično toksikologijo in farmakologijo Interna klinika, UKCL	Zaloška 7 1000 Ljubljana	+386 522 52 83	
South Africa	Tygerberg Poison Information Centre	Division of Clinical Pharmacology Faculty of Medicine and Health Sciences Stellenbosch University - PO Box 241 8 000 Cape Town	0861 555 777 +56 2 2 247 3600	
Sweden	Giftinformationscentralen	Solna Strandväg 21 171 54 Solna	112 - begär Giftinformation	
Turkey	Ulusal Zehir Merkezi (UZEM) Refik Saydam Hıfzısıhha Merkezi Başkanlığı	Cemal Gürsel Cd. No: 18 Sıhhiye Çankaya 06590 Ankara	114	Information is provided to public and medical personnel on poisoning incidents via 114.
United Kingdom	National Poisons Information Service (Belfast Centre) Royal Victoria Hospital	Grosvenor Road BT12 6BA Belfast	0344 892 0111	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	
United Kingdom	National Poisons Information Service (Cardiff Centre) Gwenwyn Ward, Llandough Hospital	Penarth CF64 2XX Cardiff	0344 892 0111	
United Kingdom	National Poisons Information Service Edinburgh Royal Infirmary of Edinburgh	Little France Crescent EH16 4SA Edinburgh	0344 892 0111	
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	+44 20 7188 7188	
United Kingdom	National Poisons Information Service (Newcastle Centre) Regional Drugs and Therapeutics Centre, Wolfson Unit	Claremont Place Newcastle-upon-Tyne NE1 4LP Newcastle	0344 892 0111	
United States of America	American Association of Poison Control Centers	515 King St., Suite 510 VA 22314 Alexandria	1-800-222-1222 +56 2 2 247 3600	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Respiratory sensitisation, Category 1

H334

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

Adverse physicochemical, human health and environmental effects

No additional information available

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Danger
Contains : Polygalacturonase enzyme
Hazard statements (CLP) : H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements (CLP) : P261 - Avoid breathing dust, fume, gas, mist, vapours, spray.
P280 - Wear protective gloves, protective clothing/ eye protection/face protection.
P284 - In case of inadequate ventilation wear respiratory protection.
P304+P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P342+P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

2.3. Other hazards

Other hazards which do not result in classification : May cause sensitization by inhalation and skin contact. mild eye irritation. mild skin irritation.

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

SECTION 3: Composition/Information on Ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Polygalacturonase enzyme	CAS-No.: 9032-75-1 EC-No.: 232-885-6 EC Index-No.: IUB n°3.2.1.15	1 - 5	Resp. Sens. 1, H334

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 : If symptoms persist call a doctor. Sensitisation : contact can cause allergic reactions in humans.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If symptoms persist, call a physician.
First-aid measures after skin contact : After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water and soap. If symptoms persist, call a physician.
First-aid measures after eye contact : In case of eye contact, immediately rinse with clean water for 10-15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion : If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting. Immediately give plenty of water. Never give anything by mouth to an unconscious person. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects : More detailed information: See section 11.
Symptoms/effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled. Cough, difficult breathing or other symptoms of poisoning may occur within some hours.
Symptoms/effects after skin contact : Slight irritation.
Symptoms/effects after eye contact : mild eye irritation.
Symptoms/effects after ingestion : May cause irritation to the digestive tract.

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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 : If there is a fire close by, use suitable extinguishing agents. carbon dioxide (CO₂), powder, alcohol-resistant foam, water spray.
- Unsuitable extinguishing media : Do not use water jet.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : In case of fire and/or explosion do not breathe fumes.
- Hazardous decomposition products in case of fire : Under normal conditions of storage and use, hazardous decomposition products should not be produced. Hazardous decomposition products may be released during prolonged heating like smokes, carbon monoxide and dioxide. May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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.
- Other information : Do not contaminate ground and surface water. Dispose in a safe manner in accordance with local/national regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Do not handle until all safety precautions have been read and understood. Evacuate personnel to a safe area. Ensure adequate air ventilation.

6.1.1. For non-emergency personnel

- Protective equipment : Wear personal protective equipment.
- Emergency procedures : Ventilate spillage area. Do not touch or walk on the spilled product. Avoid contact with skin and eyes. Avoid breathing dust, mist or spray.
- Measures in case of dust release : Avoid dust formation.

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

Do not flush into surface water or sewer system. Notify authorities if product enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Dust deposited may be vacuum cleaned or the area hosed down with water. Mechanically recover the product. Contain leaking substance, pump over in suitable containers. Clean contaminated surfaces with an excess of water.
- Other information : Dispose of materials or solid residues at an authorized site. Do not allow to enter drains or water courses.

6.4. Reference to other sections

Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : Avoid dust formation. Ensure good ventilation of the work station. Local exhaust is recommended where dust may occur. Avoid contact with skin and eyes. Wear recommended personal protective equipment. Store tightly closed in a dry and cool place.
- Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. If on skin, take off contaminated clothing. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Keep only in the original container.
- Storage conditions : Keep in a well-ventilated room. Store tightly closed in a dry and cool place. Keep out of direct sunlight. Keep container tightly closed to prevent moisture pick-up.
- Heat and ignition sources : Keep away from ignition sources (including static discharges).

7.3. Specific end use(s)

For oenological use.

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

LAFAZYM® EXTRACT	
DNEL/DMEL (Workers)	
Long-term - local effects, inhalation	0,00006 mg/m ³ Polygalacturonase enzyme

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

8.2.2. Personal protection equipment

Personal protective equipment:

Refer to protective measures listed in Sections 7 and 8.

8.2.2.1. Eye and face protection

Eye protection:

Safety glasses with side shields. EN 166

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses	Dust	With side shields	EN 166

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

In case of repeated or prolonged contact wear gloves. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear. Nitrile rubber gloves. Butyl rubber gloves. Latex gloves. EN 374. Wash hands immediately after handling the product

Other skin protection

Materials for protective clothing:

Long sleeved protective clothing

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Extra personal protection: P3 filter respirator for toxic particles

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Do not allow into drains or water courses. Avoid release to the environment. May be discharged to wastewater treatment installation.

Other information:

Do not eat, drink or smoke during work. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Off-white, brown.
Appearance	: Granulate.
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive limits	: Not applicable
Lower explosive limit (LEL)	: Not applicable
Upper explosive limit (UEL)	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in water.
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	: ≈ 0,65
Relative vapour density at 20 °C	: Not applicable
Particle size	: Not available

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

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

Heat. flames or sparks. Moisture.

10.5. Incompatible materials

None to our knowledge.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. See Heading 5.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

Polygalacturonase enzyme (9032-75-1)

LD50 oral	> 2000 mg/kg bodyweight OECD TG 401, 420
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Skin corrosion/irritation	: Not irritating to skin (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not irritating to eyes (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

LFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

No additional information available

11.2.2. Other information

Potential adverse human health effects and symptoms : Sensitisation : contact can cause allergic reactions in humans

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.

Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

Polygalacturonase enzyme (9032-75-1)

LC50 - Fish [1]	58,3 - 326,7 mg/l
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EC50 - Crustacea [1]	31,7 - 457 mg/l
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ErC50 algae	> 5,2 mg/l 72h
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12.2. Persistence and degradability

Polygalacturonase enzyme (9032-75-1)

Persistence and degradability	Biodegradable.
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12.3. Bioaccumulative potential

Polygalacturonase enzyme (9032-75-1)

Partition coefficient n-octanol/water (Log Pow)	< 0
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Bioaccumulative potential	There is no bioaccumulation.
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12.4. Mobility in soil

No additional information available

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

Other adverse effects : No other effects known, Do not allow to enter drains or water courses

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

Sewage disposal recommendations : No known adverse effects on the functioning of water treatment plants under normal use conditions as recommended. Do not flush into surface water or sewer system.

Product/Packaging disposal recommendations : Empty remaining contents. Dispose of contents/ container in accordance with licensed collector's sorting instructions.

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR)	: Not regulated
UN-No. (IMDG)	: Not regulated
UN-No. (IATA)	: Not regulated
UN-No. (ADN)	: Not regulated
UN-No. (RID)	: Not regulated

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	: No
Marine pollutant	: No
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

Inland waterway transport

Not regulated

LAFAZYM® EXTRACT

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 1, Slightly hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Polygalacturonase enzyme is listed

SZW-lijst van mutagene stoffen : Polygalacturonase enzyme is listed

SZW-lijst van reprotoxische stoffen – Borstvoeding : None of the components are listed

SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : None of the components are listed

SZW-lijst van reprotoxische stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK) : LK 6.1 - Toxic materials

15.2. Chemical safety assessment

No chemical safety assessment has been carried out for the substance or the mixture by the supplier

SECTION 16: Other information

Indication of changes

Section	Changed item	Change	Comments
1.3	Manufacturer/Supplier	Modified	

Full text of H- and EUH-statements:

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Resp. Sens. 1	Respiratory sensitisation, Category 1

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.