



SAFETY DATA SHEET ALCALASE 2.5 L PF

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

1.1. Product identifier

Product name ALCALASE 2.5 L PF

Product number 50883

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

Identified uses Enzyme

1.3. Details of the supplier of the safety data sheet

Supplier

Univar
Aquarius House
6 Mid Point Business Park
Bradford
BD3 7AY
+44 1274 267300
sds@univar.com
+44 1274 267306

1.4. Emergency telephone number

Emergency telephone SGS - +32 (0)3 575 55 55 (24h)

Sds No. 50883

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Eye Irrit. 2 - H319 Resp. Sens. 1 - H334

Environmental hazards Aquatic Chronic 3 - H412

Classification (67/548/EEC or 1999/45/EC) Xi; R36. R42, R52/53

2.2. Label elements

Pictogram



Signal word

Danger

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Hazard statements	H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H412 Harmful to aquatic life with long lasting effects.
Precautionary statements	P261 Avoid breathing vapour/ 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 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. P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor. P501 Dispose of contents/ container in accordance with national regulations.
Contains	SUBTILISIN

2.3. Other hazards

No information available.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

SUBTILISIN		2.5% - 5%
CAS number: 9014-01-1	EC number: 232-752-2	REACH registration number: 01-2119480434-38-XXXX
M factor (Acute) = 1		
Classification		Classification (67/548/EEC or 1999/45/EC)
Acute Tox. 4 - H302		Xn; R22. Xi; R41, R37/38. N; R50, R51/53. R42
Skin Irrit. 2 - H315		
Eye Dam. 1 - H318		
Resp. Sens. 1 - H334		
STOT SE 3 - H335		
Aquatic Acute 1 - H400		
Aquatic Chronic 2 - H411		

The Full Text for all R-Phrases and Hazard Statements are Displayed in Section 16.

Composition comments The data shown are in accordance with the latest EC Directives.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Move affected person to fresh air at once. Rinse nose and mouth with water. Get medical attention. Effects may be delayed.
Ingestion	Rinse mouth thoroughly with water. Do not induce vomiting. If vomiting occurs, the head should be kept low so that stomach vomit doesn't enter the lungs. Give plenty of water to drink. Get medical attention if any discomfort continues.
Skin contact	Remove affected person from source of contamination. Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if any discomfort continues.
Eye contact	Remove any contact lenses and open eyelids wide apart. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes. Get medical attention immediately. Continue to rinse.

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

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Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Shortness of breath. Wheezing/breathing difficulties.
Ingestion	The product irritates mucous membranes and may cause abdominal discomfort if swallowed. Nausea, vomiting. Diarrhoea.
Skin contact	Causes mild skin irritation.
Eye contact	Causes serious eye irritation.

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

Notes for the doctor	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards May cause respiratory allergy.

Hazardous combustion products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

5.3. Advice for firefighters

Special protective equipment for firefighters Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid inhalation of vapours and contact with skin and eyes. Wear protective clothing as described in Section 8 of this safety data sheet. Provide adequate ventilation.

6.2. Environmental precautions

Environmental precautions Do not discharge into drains or watercourses or onto the ground. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Stop leak if possible without risk. Absorb in vermiculite, dry sand or earth and place into containers. Avoid the spillage or runoff entering drains, sewers or watercourses.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Avoid inhalation of vapours and contact with skin and eyes. Provide adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Store at temperatures between 0°C and 10°C.

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7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure Controls/personal protection

8.1. Control parameters

Occupational exposure limits

SUBTILISIN

Long-term exposure limit (8-hour TWA): WEL 0.00004 mg/m³

Sen

WEL = Workplace Exposure Limit

Sen = Capable of causing occupational asthma.

SUBTILISIN (CAS: 9014-01-1)

DMEL

Workers - Inhalation; Long term local effects: 0.06 mg/m³

Professional, Consumer - Inhalation; Long term local effects: 0.015 mg/m³

PNEC

- Fresh water; 0.06 mg/l

- Marine water; 0.006 mg/l

- STP; 65000 mg/l

8.2. Exposure controls

Protective equipment



Appropriate engineering controls

Provide adequate ventilation. Provide eyewash station and safety shower.

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Wear chemical splash goggles. EN 166

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. It is recommended that gloves are made of the following material: Nitrile rubber. Neoprene. (>0.3mm coating thickness) The selected gloves should have a breakthrough time of at least 4 hours. EN 374

Other skin and body protection

Wear appropriate clothing to prevent any possibility of liquid contact and repeated or prolonged vapour contact.

Hygiene measures

Wash at the end of each work shift and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Take off immediately all contaminated clothing and wash it before reuse.

Respiratory protection

If ventilation is inadequate, suitable respiratory protection must be worn. Particulate filter, type P3. EN 136/140/145/143/149

SECTION 9: Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Appearance

Liquid.

Colour

Brown.

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Odour	Slight.
pH	No information available.
Melting point	No information available.
Initial boiling point and range	No information available.
Flash point	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	1.19
Solubility(ies)	No information available.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Oxidising properties	No information available.

9.2. Other information

Other information	No information required.
Refractive index	No information available.
Particle size	No information available.
Molecular weight	No information available.
Volatility	No information available.
Saturation concentration	No information available.
Critical temperature	No information available.
Volatile organic compound	No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	Stable at normal ambient temperatures and when used as recommended.
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10.2. Chemical stability

Stability	Stable at normal ambient temperatures.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	None known.
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10.4. Conditions to avoid

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Conditions to avoid Avoid excessive heat for prolonged periods of time.

10.5. Incompatible materials

Materials to avoid None known.

10.6. Hazardous decomposition products

Hazardous decomposition products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological effects No information available.

Acute toxicity - oral

ATE oral (mg/kg) 72,000.0

Skin corrosion/irritation

Animal data Causes mild skin irritation.

Serious eye damage/irritation

Serious eye damage/irritation Irritating.

Respiratory sensitisation

Respiratory sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation

Skin sensitisation No information available.

Germ cell mutagenicity

Genotoxicity - in vitro No information available.

Carcinogenicity

Carcinogenicity No information available.

Reproductive toxicity

Reproductive toxicity - fertility No information available.

Specific target organ toxicity - single exposure

STOT - single exposure No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available.

Aspiration hazard

Aspiration hazard No information available.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingestion The product irritates mucous membranes and may cause abdominal discomfort if swallowed.
Nausea, vomiting. Diarrhoea.

Skin contact Causes mild skin irritation.

Eye contact Causes serious eye irritation.

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ALCALASE 2.5 L PF**Acute toxicity - oral**

Acute toxicity oral (LD₅₀ mg/kg) 1,800.0

Species Rat

Notes (oral LD₅₀) OECD 401

ATE oral (mg/kg) 1,800.0

Skin corrosion/irritation

Animal data OECD 404 Irritating.

Serious eye damage/irritation

Serious eye damage/irritation Slightly irritating.

Respiratory sensitisation

Respiratory sensitisation Sensitising.

Germ cell mutagenicity

Genotoxicity - in vitro This substance has no evidence of mutagenic properties.

SECTION 12: Ecological Information

Ecotoxicity Harmful to aquatic life with long lasting effects.

12.1. Toxicity

Acute toxicity - fish No information available.

SUBTILISIN**Acute aquatic toxicity**

LE(C)₅₀ 0.1 < L(E)C₅₀ ≤ 1

M factor (Acute) 1

Acute toxicity - fish LC₅₀, 96 hours: 8.2 mg/l,

Acute toxicity - aquatic invertebrates EC₅₀, 48 hours: 0.586 mg/l, Daphnia magna

Acute toxicity - aquatic plants EC₅₀, 72 hours: 0.83 mg/l, Fish

12.2. Persistence and degradability

Persistence and degradability There are no data on the degradability of this product.

SUBTILISIN

Persistence and degradability The substance is readily biodegradable.

12.3. Bioaccumulative potential

Bioaccumulative potential No data available on bioaccumulation.

Partition coefficient No information available.

ALCALASE 2.5 L PF**SUBTILISIN**

Bioaccumulative potential Bioaccumulation is unlikely.

Partition coefficient log Pow: < 0

12.4. Mobility in soil

Mobility No data recorded.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

12.6. Other adverse effects

Other adverse effects None known.

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

General information Waste is classified as hazardous waste. Do not puncture or incinerate, even when empty.

Disposal methods Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

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EU legislation

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended).

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended).

Commission Regulation (EU) No 2015/830 of 28 May 2015.

15.2. Chemical safety assessment

Not applicable.

SECTION 16: Other information

Abbreviations and acronyms used in the safety data sheet

ATE: Acute Toxicity Estimate.
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
 CAS: Chemical Abstracts Service.
 DNEL: Derived No Effect Level.
 IATA: International Air Transport Association.
 IMDG: International Maritime Dangerous Goods.
 Kow: Octanol-water partition coefficient.
 LC₅₀: Lethal Concentration to 50 % of a test population.
 LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).
 PBT: Persistent, Bioaccumulative and Toxic substance.
 PNEC: Predicted No Effect Concentration.
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
 RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
 vPvB: Very Persistent and Very Bioaccumulative.
 IARC: International Agency for Research on Cancer.
 MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978.
 cATpE: Converted Acute Toxicity Point Estimate.
 BCF: Bioconcentration Factor.
 BOD: Biochemical Oxygen Demand.
 EC₅₀: 50% of maximal Effective Concentration.
 LOAEC: Lowest Observed Adverse Effect Concentration.
 LOAEL: Lowest Observed Adverse Effect Level.
 NOAEC: No Observed Adverse Effect Concentration.
 NOAEL: No Observed Adverse Effect Level.
 NOEC: No Observed Effect Concentration.
 LOEC: Lowest Observed Effect Concentration.
 DMEL: Derived Minimal Effect Level.
 EL50: Exposure Limit 50
 hPa: Hectopascal
 LL50: Lethal Loading fifty
 OECD: Organisation for Economic Co-operation and Development
 POW: Octanol-water partition coefficient
 SCBA: self-contained breathing apparatus
 STP: Sewage Treatment Plant
 VOC: Volatile Organic Compounds

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Classification abbreviations and acronyms	Acute Tox. = Acute toxicity Aquatic Acute = Hazardous to the aquatic environment (acute) Aquatic Chronic = Hazardous to the aquatic environment (chronic)
Key literature references and sources for data	Supplier's information.
Revision comments	This is first issue.
Revision date	08/02/2017
Revision	01
SDS number	50883
Version number	1.000
Signature	K Winter
Risk phrases in full	R22 Harmful if swallowed. R36 Irritating to eyes. R37/38 Irritating to respiratory system and skin. R41 Risk of serious damage to eyes. R42 May cause sensitisation by inhalation. R50 Very toxic to aquatic organisms. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Hazard statements in full	H302 Harmful if swallowed. H315 Causes skin irritation. H318 Causes serious eye damage. H319 Causes serious eye irritation. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H335 May cause respiratory irritation. H400 Very toxic to aquatic life. H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.