



Alcalase® 2.5 L

Revision date: 03/30/2015

Version No: 3

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name Alcalase® 2.5 L
Chemical Name Enzyme preparation
Declared activity Protease (Subtilisin)

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

Novozymes' enzyme preparations are biocatalysts used in a variety of industrial processes and in certain consumer products .

1.3 Details of the supplier of the safety data sheet

Novozymes A/S
Krogshøjvej 36
2880 Bagsvaerd
Denmark
Tel.: +45 44460000
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E-mail: SafetyDataSheet@novozymes.com
www.novozymes.com

1.4 Emergency telephone number

+45 44462223 (24/7)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

REGULATION (EC) No 1272/2008

Serious Eye Damage / Eye Irritation	Category 2
Respiratory sensitization	Category 1
Chronic aquatic toxicity	Category 3

The classification of eye effects is based on testing of a similar mixture.

Classification according to EU Directives 64/548/EEC or 1999/45/EC see section 16.

2.2 Label elements



Signal Word

Danger

Hazard Statements

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H412 - Harmful to aquatic life with long lasting effects

H319 - Causes serious eye irritation

Precautionary statements

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician

P285 - In case of inadequate ventilation wear respiratory protection.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 Other information

Human health effects

Repeated inhalation of enzyme dust or aerosols resulting from improper handling may induce sensitization and may cause allergic type 1 reactions in sensitized individuals. Repeated inhalation of enzyme dust or aerosols resulting from improper handling may induce sensitization and may cause allergic type 1 reactions in sensitized individuals.

Mild skin irritation
Mild eye irritation

Effects of overexposure

See Section 4

The mixture does not meet the criteria for PBT or vPvB.

See Section 11 and 12 for additional Toxicological information

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous Components

Chemical Name	Weight %	CAS-No	EC No.	EU Classification (67/548/EEC)	CLP Classification (No 1272/2008)
Protease (Subtilisin) (aep)	2.5 - 5	9014-01-1	232-752-2	Xn;R22 Xi;R37/38-41 R42 N;R50	Acute Tox. 4;H302 STOT SE 3;H335 Skin Irrit. 2;H315 Eye Dam. 1;H318 Resp. Sens. 1;H334 Aquatic Acute 1;H400 Aquatic Chronic 2; H411

Active enzyme protein (aep) is the part of the enzyme concentrate contributing to the classification of the mixture.

Regulatory information *

Chemical Name	Weight %	IUB No.	REACH Registration No.
Protease (Subtilisin)	10 - 20	3.4.21.62	01-2119480434-38

*: In the scope of REACH registration enzymes are defined as enzyme concentrate (dry matter basis)

For the full text of the R/H phrases mentioned in this Section, see Section 16

4. FIRST AID MEASURES

4.1 Description of first-aid measures

Inhalation

Effects	May cause allergic respiratory reaction
Symptoms	Shortness of breath, wheezing and coughing The effect of inhalation may be delayed
First Aid	Remove person to fresh air. If signs/symptoms continue, get medical attention Show this safety data sheet to the doctor in attendance

Skin contact

Effects	May cause slight irritation.
Symptoms	Slight irritation.
First Aid	Remove and wash contaminated clothing before re-use. Wash off immediately with plenty of water. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance.

Eye contact

Effects	May cause slight irritation.
Symptoms	Slight irritation
First Aid	Hold eye open and rinse slowly and gently with water for 15-20 min. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance

Ingestion

Effects	Ingestion may cause gastrointestinal irritation.
Symptoms	Irritation
First Aid	Rinse mouth with water and drink plenty of water. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance.

4.2 Most important symptoms and effects, both acute and delayed

See section 4.1

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically

5. FIRE-FIGHTING MEASURES**5.1 Extinguishing media**

Suitable extinguishing media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Unsuitable Extinguishing Media	none
Hazardous combustion products	None

5.2 Special hazards arising from the substance or mixture

May cause allergic respiratory reaction

5.3 Advice for firefighters

Self-contained breathing apparatus

6. ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

For personal protection see section 8

6.2 Environmental precautions

Collect spillage.

6.3 Methods and materials for containment and cleaning up

Avoid formation of dust and aerosols
 Spilled preparation should be removed immediately to avoid formation of dust from dried preparation. Take up by mechanical means preferably by a vacuum cleaner equipped with a high efficiency filter. Flush remainder carefully with plenty of water. Avoid splashing and high pressure washing (avoid formation of aerosols). Ensure sufficient ventilation. Wash contaminated clothing.

6.4 Reference to other sections

For personal protection see section 8

7. HANDLING AND STORAGE**7.1 Precautions for safe handling**

Avoid formation of dust and aerosols

7. HANDLING AND STORAGE

Ensure adequate ventilation

Liquid enzyme preparations are dustfree preparations. However, inappropriate handling may cause formation of dust or aerosols.

7.2 Conditions for safe storage, including any incompatibilities

Keep tightly closed in a dry and cool place.

Temperature 0-25 °C (32-77 °F)

In unbroken packaging - dry and protect from the sun. The product has been formulated for optimal stability. Extended storage or adverse conditions such as higher temperatures or higher humidity may lead to a higher dosage requirement.

7.3 Specific end uses

Handle in accordance with good industrial hygiene and safety practice

When enzymes are used for spray products or hard surface cleaning, exposure of enzymes may exceed the safety level (15 ng/m³ DMEL). If you intend to develop such products, please contact Novozymes for further safety evaluation.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Hazardous Components

Chemical Name	ACGIH TLV
Protease (Subtilisin) (aep)	Ceiling: 0.00006 mg/m ³ Ceiling (as crystalline active enzyme, listed under Subtilisins)

Hazardous Components

Chemical Name	Belgium	Denmark	Finland	Germany	Ireland	Norway
Protease (Subtilisin) (aep)	0.00006 mg/m ³ Maximum Limit Value (8 hours)	Ceiling: 0.00006 mg/m ³		= 1 glycineunit/m ³ LLV = 3 glycineunit/m ³ LLV	TWA: 0.00006 mg/m ³ STEL: 0.00006 mg/m ³	0.00006 mg/m ³ Ceiling

Hazardous Components

Chemical Name	The Netherlands	Portugal	Spain	Sweden	Switzerland	The United Kingdom
Protease (Subtilisin) (aep)	Ceiling: 0.00006 mg/m ³	Ceiling: 0.00006 mg/m ³	VLA-EC: 0.00006 mg/m ³	1 glycineunit/m ³ LLV 3 glycineunit/m ³ LLV	STEL: 0.00006 mg/m ³	0.00004 mg/m ³ TWA

DNEL/DMEL/PNEC

Chemical Name	DNEL Dermal Acute Local (Workers)	DMEL Inhalation Long term Local (Workers)
Protease (Subtilisin) (aep)	DNEL = 0,2% in mixture (W/W)	DMEL = 60 ng/m ³

Chemical Name	DNEL Dermal Acute Local (Professional/Consumers)	DMEL Inhalation Long term Local (Professionals/Consumers)
Protease (Subtilisin) (aep)	DNEL = 0,2% in mixture (W/W)	DMEL = 15 ng/m ³
Protease (Subtilisin)	DNEL = 0,2% in mixture (W/W)	DMEL = 15 ng/m ³

Chemical Name	Fresh Water	Sea Water	Impact on Sewage Treatment
Protease (Subtilisin) (aep)	PNEC aqua (fresh water) = 0.06 µg/l	PNEC aqua (marine water) = 0.006 µg/l	PNEC STP = 65000 µg/L

Derived No Effect Level (DNEL)

Derived Minimal Effect Level (DMEL)

Predicted No Effect Concentration (PNEC)

When enzymes are used for spray products or hard surface cleaning, exposure of enzymes may exceed the safety level (15 ng/m³ DMEL). If you intend to develop such products, please contact Novozymes for further safety evaluation.

8.2 Exposure controls

Ensure adequate ventilation, especially in confined areas

Personal Protective Equipment

Respiratory Protection In case of insufficient ventilation wear an approved mask with a particle filter type P3 used according to the manufactures instruction

Eye protection Safety glasses with side-shields

Skin Protection Long sleeved clothing

Hand Protection Protective gloves of e.g. nitrile rubber or neoprene (thickness > 0.3 mm) according to EN 374-3. Expected breakthrough time: > 4 hours. The recommendation is a qualified estimate based on the knowledge of the components in the mixture

General hygiene considerations Handle in accordance with good industrial hygiene and safety practices

Environmental exposure controls Local authorities should be advised if significant spillages cannot be contained
Waste water should be discharged to sewage treatment plant

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	liquid
Color	amber
Odor	Slight fermentation odor
Density (g/ml)	1.08
pH	Adjusted to the range where active enzyme is stable – typically pH 4 – 9
Solubility	none

9.2 Other information

No information available

10. STABILITY AND REACTIVITY

10.1 Reactivity

Not relevant

10.2 Chemical stability

Stable under recommended storage conditions

10.3 Possibility of hazardous reactions

None under normal processing

10.4 Conditions to Avoid

None

10.5 Incompatible Materials

None

10.6 Hazardous Decomposition Products

None

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Chemical Name	Acute oral toxicity	Respiratory sensitization	Genetic toxicity	Skin corrosion/irritation	Serious eye damage/eye irritation
Protease (Subtilisin) (aep)	LD50: 1800 mg/kg bw (OECD TG 401)	Sensitizer (Human experience)	No indication of mutagenic effects (OECD TG 471, 473, 476)	Slightly irritating (OECD TG 404)	Slightly irritating (OECD TG 405)

Chemical Name	Acute inhalation toxicity	Specific target organ toxicity – single exposure
Protease (Subtilisin) (aep)	Exposure based waiving	Irritating, respiratory tract (ACGIH 2001)

12. ECOLOGICAL INFORMATION

12.1 Toxicity

Chemical Name	Daphnia, acute	Acute fish toxicity =	Algae, Acute
Protease (Subtilisin) (aep)	EC50 (48 hours): 586 µg aep/l (OECD TG 202)	LC50 (96 hours): 8.2 mg aep/l (OECD TG 203)	ErC50 (72 hours): 830 µg aep/l (OECD TG 201)

12.2 Persistence and degradability

Chemical Name	Persistence and degradability	Partition coefficient (n-octanol/water)
Protease (Subtilisin) (aep)	Readily biodegradable (OECD TG 301B)	LogPow: <0

12.3 Bioaccumulative potential

Chemical Name	Bioaccumulative potential

Protease (Subtilisin) (aep)	Does not bioaccumulate
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12.4 Mobility in soil

Not relevant

12.5 Results of PBT and vPvB assessment

Components do not meet PBT or vPvB criteria according to REACH Annex XIII

12.6 Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods**

Dispose of in accordance with local regulations

Waste water should be discharged to sewage treatment plant

Waste codes should be assigned by the user based on the application for which the product was used

14. TRANSPORT INFORMATION**Transport Regulations**

No dangerous goods according to transport regulations

No special precautions required

14.1

UN number Not applicable

14.2

UN proper shipping name Not applicable

14.3

Transport hazard class(es) Not applicable

14.4

Packing group Not applicable

14.5

Environmental hazards Not applicable

14.6

Special precautions for user Not applicable

14.7

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

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

WGK Classification 1

15. REGULATORY INFORMATION

15.2 Chemical Safety Report

No chemical safety assessment has been carried out

16. OTHER INFORMATION

Text of R/H phrases mentioned in Section 2&3

R42 - May cause sensitization by inhalation

R41 - Risk of serious damage to eyes

R22 - Harmful if swallowed

R37/38 - Irritating to respiratory system and skin

Full text of H-Statements referred to under Sections 2 and 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H335 - May cause respiratory irritation

H318 - Causes serious eye damage

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H400 - Very toxic to aquatic life

H411 - Toxic to aquatic life with long lasting effects

GHS-Classification

The classification of eye effects is based on testing of a similar mixture.
The GHS calculation method has been used for classification of this mixture.

Classification according to EU Directives 64/548/EEC or 1999/45/EC

Symbol(s) Xn - Harmful

R-code(s) R42

Further information

This SDS is in compliance with EU Regulation No. 453/2010

For further information please consult available product documentation including 'Product Application Guidelines' and/or 'Application Sheets', which are available on www.mynovozymes.com or from Novozymes sales representatives. Enzymes are catalysts and reacts with various substrates. Enzymes will continue to react until deactivated or removed from the substrates. Consideration of where the activity is desired or undesired should be made before use.

Training advice

Details on the safe handling of this product can be found in the "Handling enzymes" on www.novozymes.com

Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text. Furthermore, as the conditions of use are beyond the control of Novozymes, it is the responsibility of the customer to determine the conditions of safe use of these products.

End of Safety Data Sheet**Version No:** 3 / EU / English / 03/30/2015