

Alcalase 2.4 L FG

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

1.1 Product Identifier

Product Name	Alcalase® 2.4 L FG
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 within food manufacturing

1.3 Details of the supplier of the safety data sheet

Novozymes A/S
Krogshøjvej 36
2880 Bagsvaerd
Denmark
Tel.: +45 44460000
Fax.: +45 44469999
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

Skin corrosion/irritation	Category 3
Serious eye damage/eye irritation	Category 2
Respiratory sensitisation	Category 1
Acute aquatic toxicity	Category 2
Chronic aquatic toxicity	Category 3

2.2 Label elements



Signal word
Danger

Hazard statements

H316 - Causes mild skin irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H401 - Toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects
H319 - Causes serious eye irritation

Precautionary Statements

P402 + P404 - Store in a dry place. Store in a closed container

P501 - Dispose of contents/containers in accordance with local regulations

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

P284 - In case of inadequate ventilation wear respiratory protection

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

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

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

Mild skin irritation

May cause eye irritation

Physical and Chemical Hazards

None known

Specific hazards

None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No	IUB No.	Weight-%
Protease (Subtilisin) (aep.)	9014-01-1	3.4.21.62	1 - 5

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

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

Irritating to eyes

Symptoms

Irritation. Redness

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 material 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

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

The product can be transported at ambient temperature. Following delivery, the product should be stored as recommended. 0-10 °C (32-50 °F)

7.3 Specific end use(s)

Handle in accordance with good industrial hygiene and safety practice

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

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

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	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)

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	Wear safety glasses with side shields (or goggles)
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 practice
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
Colour	Brown
Odour	Slight fermentation odor
Melting point / freezing point	No information available
Initial boiling point and boiling range	Not available
Flammability (solid, gas)	Not available
Upper/lower flammability or explosive limits	Not available

Flash Point	> 100 °C
Autoignition temperature	Not available
Decomposition temperature	Not available
pH	Adjusted to the range where active enzyme is stable – typically pH 4 – 9
Solubility	Active component is readily soluble in application-relevant solutions at all levels of concentration, temperature and pH which may occur in normal usage
Partition Coefficient (n-octanol/water)	Not available
Vapour Pressure	Not available
Density (g/ml)	1.17
Vapour density	Not available
Particle characteristics	Not applicable
Evaporation rate	Not available
Oxidising Properties	Not available

9.2 Other information

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 sensitisation	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

12.4 Mobility in soil

Not relevant

12.5 Results of PBT and vPvB assessment

The components in this formulation do not meet the criteria for classification as PBT or vPvB

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

This product is not classified as dangerous goods according to UN GHS classification criteria.

IATA Not regulated

IMDG/IMO Not regulated

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

Please check the consequences of national regulations on this product yourself.

16. OTHER INFORMATION

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.

Further information

This SDS is compiled according to the UN GHS rev. 5 Guideline.

For further information please consult available product documentation including 'Product Application Guidelines' and/or 'Application Sheets', which are available on market.novozymes.com or from Novozymes sales representatives.

Training advice

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

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