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
Krogshoejvej 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

REGULATION (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Eye Damage / Eye Irritation</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>1</td>
</tr>
<tr>
<td>Chronic aquatic toxicity</td>
<td>3</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Weight %</th>
<th>CAS-No</th>
<th>EC No.</th>
<th>EU Classification (67/548/EEC)</th>
<th>CLP Classification (No 1272/2008)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>2.5 - 5</td>
<td>9014-01-1</td>
<td>232-752-2</td>
<td>Xn;R22 Xi;R37/38-41 R42 N;R50</td>
<td>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</td>
</tr>
</tbody>
</table>

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

Regulatory information *

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Weight %</th>
<th>IUB No.</th>
<th>REACH Registration No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin)</td>
<td>10 - 20</td>
<td>3.4.21.62</td>
<td>01-2119480434-38</td>
</tr>
</tbody>
</table>

*: 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

<table>
<thead>
<tr>
<th>Chemical Components</th>
<th>ACGIH TLV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>Ceiling: 0.00006 mg/m³ Ceiling (as crystalline active enzyme, listed under Subtilisins)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous Components</th>
<th>Belgium</th>
<th>Denmark</th>
<th>Finland</th>
<th>Germany</th>
<th>Ireland</th>
<th>Norway</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>0.00006 mg/m³ Maximum Limit Value (8 hours)</td>
<td>Ceiling: 0.00006 mg/m³</td>
<td>= 1 glycineunit/m³ LLV = 3 glycineunit/m³ LLV</td>
<td>TWA: 0.00006 mg/m³ STEL: 0.00006 mg/m³</td>
<td>0.00006 mg/m³ Ceiling</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous Components</th>
<th>The Netherlands</th>
<th>Portugal</th>
<th>Spain</th>
<th>Sweden</th>
<th>Switzerland</th>
<th>The United Kingdom</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>Ceiling: 0.00006 mg/m³</td>
<td>Ceiling: 0.00006 mg/m³</td>
<td>VLA-EC: 0.00006 mg/m³</td>
<td>1 glycineunit/m³ LLV</td>
<td>STEL: 0.00006 mg/m³</td>
<td>0.00004 mg/m³ TWA</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DNEL/DMEL/PNEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Name</td>
</tr>
<tr>
<td>Protease (Subtilisin) (aep)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>DNEL Dermal Acute Local (Professional/Consumers)</th>
<th>DMEL Inhalation Long term Local (Professional/Consumers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>DNEL = 0.2% in mixture (W/W)</td>
<td>DMEL = 15 ng/m³</td>
</tr>
<tr>
<td>Protease (Subtilisin)</td>
<td>DNEL = 0.2% in mixture (W/W)</td>
<td>DMEL = 15 ng/m³</td>
</tr>
</tbody>
</table>
### 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

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute inhalation toxicity</th>
<th>Specific target organ toxicity – single exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>Exposure based waiving</td>
<td>Irritating, respiratory tract (ACGIH 2001)</td>
</tr>
</tbody>
</table>

12. ECOLOGICAL INFORMATION

12.1 Toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Daphnia, acute</th>
<th>Acute fish toxicity</th>
<th>Algae, Acute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>EC50 (48 hours): 586 μg aep/l (OECD TG 202)</td>
<td>LC50 (96 hours): 8.2 mg aep/l (OECD TG 203)</td>
<td>ErC50 (72 hours): 830 μg aep/l (OECD TG 201)</td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Partition coefficient (n-octanol/water)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protease (Subtilisin) (aep)</td>
<td>Readily biodegradable (OECD TG 301B)</td>
<td>LogPow: &lt;0</td>
</tr>
</tbody>
</table>

12.3 Bioaccumulative potential

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Bioaccumulative potential</th>
</tr>
</thead>
</table>
Protease (Subtilisin) (aep)  

| Does not bioaccumulate |

### 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 67/548/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 react 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