SAFETY DATA SHEET
According to Regulation (EC) No 453/2010

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

1.1 Product identifier
   Product name
   Stainzyme® 12 L
   Chemical Name
   Enzyme preparation
   Declared activity
   Alpha-amylase

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
   Respiratory sensitization
   Category 1

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

**Precautionary statements**
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P285 - In case of inadequate ventilation wear respiratory protection
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing

Contains
Alpha-amylase

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
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

<table>
<thead>
<tr>
<th>Hazardous Components</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>Alpha-amylase (aep)</td>
<td>1 - 2.5</td>
<td>9000-90-2</td>
<td>232-565-6</td>
<td>R42</td>
<td>Resp. Sens. 1; H334</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>Alpha-amylase</td>
<td>5 - 10</td>
<td>3.2.1.1</td>
<td>01-2119938627-26</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
- **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

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 Name</th>
<th>DNEL Dermal Acute Local (Workers)</th>
<th>DMEL Inhalation Long term Local (Workers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-amylase (aep)</td>
<td></td>
<td>DMEL = 60 ng/m³</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 (Professionals/Consumers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-amylase</td>
<td></td>
<td>DMEL = 15 ng/m³</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Fresh Water</th>
<th>Sea Water</th>
<th>Impact on Sewage Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha-amylase (aep)</td>
<td>PNEC aqua (fresh water) = 5.2 μg/l</td>
<td>PNEC aqua (marine water) = 0.52 μg/l</td>
<td>PNEC STP = 65000 μg/L</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**
  Skin should be washed after contact

- **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): 1.14
   - 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>Alpha-amylase (aep)</td>
<td>LD50: &gt; 2000 mg/kg bw (OECD TG 401, 420)</td>
<td>Sensitizer (Human experience)</td>
<td>No indication of mutagenic effects (OECD TG 471, 476)</td>
<td>Not irritating (OECD TG 404)</td>
<td>Not irritating (OECD TG 405)</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>
</table>

According to Regulation No. 453/2010
12. ECOLOGICAL INFORMATION

Alpha-amylase (aep)  
EC50 (48 hours): 31.7 - 457 mg aep/l (OECD TG 202)  
LC50 (96 hours): 58.3 - 326.7 mg aep/l (OECD TG 203)  
ErC50 (72 hours): >= 5.2 mg aep/l (OECD TG 201)

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>Alpha-amylase (aep)</td>
<td>Readily biodegradable (OECD 301)</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>
<tbody>
<tr>
<td>Alpha-amylase (aep)</td>
<td>Does not bioaccumulate</td>
</tr>
</tbody>
</table>

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

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
15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
WGK Classification 1

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
Full text of H-Statements referred to under Sections 2 and 3
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

GHS-Classification
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 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

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