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

1.1 Product identifier
   
<table>
<thead>
<tr>
<th>Product name</th>
<th>Lactozym® Pure 2600 L S</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Name</td>
<td>Enzyme preparation</td>
</tr>
<tr>
<td>Declared activity</td>
<td>Beta-galactosidase</td>
</tr>
</tbody>
</table>

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
   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>Respiratory sensitization</th>
<th>Category 1</th>
</tr>
</thead>
</table>

   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
Beta-galactosidase

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

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>Beta-galactosidase (aep)</td>
<td>1 - 2.5</td>
<td>9031-11-2</td>
<td>232-864-1</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>Beta-galactosidase</td>
<td>1 - 2.5</td>
<td>3.2.1.23</td>
<td>-</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
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.
Temperature 0-10 °C (32-50 °F)

7.3 Specific end uses
Handle in accordance with good industrial hygiene and safety practice
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DNEL/DMEL/PNEC

<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>Beta-galactosidase (aep)</td>
<td></td>
<td>DMEL = 60 ng/m³</td>
</tr>
</tbody>
</table>

Derived Minimal Effect Level (DMEL)

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**: light yellow
- **Odor**: Slight fermentation odor
- **Density (g/ml)**: 1.15
- **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>Beta-galactosidase (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, 487)</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>
<tbody>
<tr>
<td>Beta-galactosidase (aep)</td>
<td>EC50 (48 hours): 31.7 - 457 mg aep/l (OECD TG 202)</td>
<td>LC50 (96 hours): 58.3 - 326.7 mg aep/l (OECD TG 203)</td>
<td>ErC50 (72 hours): &gt;= 5.2 mg 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>Beta-galactosidase (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>Beta-galactosidase (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

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
The product complies with the recommended purity specifications for food-grade enzymes given by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemical Codex (FCC).

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

<table>
<thead>
<tr>
<th>GHS-Classification</th>
<th>The GHS calculation method has been used for classification of this mixture.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>Classification according to EU Directives 67/548/EEC or 1999/45/EC</td>
</tr>
<tr>
<td>Symbol(s)</td>
<td>Xn - Harmful</td>
</tr>
<tr>
<td>R-code(s)</td>
<td>R42</td>
</tr>
</tbody>
</table>

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.

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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