SAFETY DATA SHEET
According to Regulation No. 453/2010

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

1.1 Product identifier

Product name: Lipex® 100 L

Chemical Name: Enzyme preparation

Declared activity: Lipase

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
Lipase

2.3 Other hazards

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>Lipase (aep)</td>
<td>1 - 2.5</td>
<td>9001-62-1</td>
<td>232-619-9</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.

### Regulated 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>Lipase</td>
<td>5 - 10</td>
<td>3.1.1.3</td>
<td>01-2119972939-13</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

**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>Lipase (aep)</td>
<td></td>
<td>DMEL = 60 ng/m³</td>
</tr>
</tbody>
</table>

Derived Minimal Effect Level (DMEL)

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 according to the manufacturers 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
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>Slight fermentation odor</td>
</tr>
<tr>
<td>Density (g/ml)</td>
<td>1.16</td>
</tr>
<tr>
<td>pH</td>
<td>Adjusted to the range where active enzyme is stable – typically pH 4 – 9</td>
</tr>
<tr>
<td>Solubility</td>
<td>Active component is readily soluble in application-relevant solutions at all levels of concentration, temperature and pH which may occur in normal usage</td>
</tr>
</tbody>
</table>

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>Lipase (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>
<tbody>
<tr>
<td>Lipase (aep)</td>
<td>EC50 (48 hours): &gt;37.4 mg aep/l (OECD TG 202)</td>
<td>LC50 (96 hours): &gt;68.3 mg aep/l (OECD TG 203)</td>
<td>ErC50 (72 hours): &gt; 18 mg aep/l (OECD TG 201)</td>
</tr>
</tbody>
</table>

12.2 Persistence and degradability

According to Regulation No. 453/2010
### Chemical Name | Persistence and degradability | Partition coefficient (n-octanol/water)
---|---|---
Lipase (aep) | Readily biodegradable (OECD 301) | LogPow: <0

### 12.3 Bioaccumulative potential

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Bioaccumulative potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lipase (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

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

GHS-Classification
The GHS calculation method has been used for classification of this mixture.

Classification and labelling according to Directive 67/548/EEC
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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