



## Savinase® 16 L

Revision date: 03/30/2015

Version No: 3

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

#### 1.1 Product identifier

**Product name** Savinase® 16 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  
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

##### REGULATION (EC) No 1272/2008

|                                     |            |
|-------------------------------------|------------|
| Serious Eye Damage / Eye Irritation | Category 2 |
| Respiratory sensitization           | Category 1 |
| Chronic aquatic toxicity            | Category 3 |

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.

### **Contains**

Protease (Subtilisin)

## 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. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.2 Mixtures

##### Hazardous Components

| Chemical Name               | Weight % | CAS-No    | EC No.    | EU Classification (67/548/EEC)   | CLP Classification (No 1272/2008)   |
|-----------------------------|----------|-----------|-----------|----------------------------------|---|
| Protease (Subtilisin) (aep) | 2.5 - 5  | 9014-01-1 | 232-752-2 | Xn;R22 Xi;R37/38-41<br>R42 N;R50 | Acute Tox. 4;H302<br>STOT SE 3;H335<br>Skin Irrit. 2;H315<br>Eye Dam. 1;H318<br>Resp. Sens. 1;H334<br>Aquatic Acute 1;H400<br>Aquatic Chronic 2; H411 |

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

##### Regulatory information \*

| Chemical Name         | Weight % | IUB No.   | REACH Registration No. |
|-----------------------|----------|-----------|------------------------|
| Protease (Subtilisin) | 5 - 10   | 3.4.21.62 | 01-2119480434-38       |

\*: 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

|                  |  |
|------------------|--|
| <b>Effects</b>   | May cause allergic respiratory reaction  |
| <b>Symptoms</b>  | Shortness of breath, wheezing and coughing<br>The effect of inhalation may be delayed  |
| <b>First Aid</b> | Remove person to fresh air. If signs/symptoms continue, get medical attention<br>Show this safety data sheet to the doctor in attendance |

##### Skin contact

|                  |  |
|------------------|--|
| <b>Effects</b>   | May cause slight irritation.   |
| <b>Symptoms</b>  | Slight irritation.   |
| <b>First Aid</b> | 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

|                 |                              |
|-----------------|------------------------------|
| <b>Effects</b>  | May cause slight irritation. |
| <b>Symptoms</b> | 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/m<sup>3</sup> DMEL). If you intend to develop such products, please contact Novozymes for further safety evaluation.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### 8.1 Control parameters

#### Hazardous Components

| Chemical Name               | ACGIH TLV   |
|-----------------------------|---|
| Protease (Subtilisin) (aep) | Ceiling: 0.00006 mg/m <sup>3</sup> Ceiling (as crystalline active enzyme, listed under Subtilisins) |

#### Hazardous Components

| Chemical Name               | Belgium  | Denmark                            | Finland | Germany  | Ireland   | Norway                            |
|-----------------------------|--|------------------------------------|---------|--|---|-----------------------------------|
| Protease (Subtilisin) (aep) | 0.00006 mg/m <sup>3</sup><br>Maximum Limit Value (8 hours) | Ceiling: 0.00006 mg/m <sup>3</sup> |         | = 1 glycineunit/m <sup>3</sup> LLV<br>= 3 glycineunit/m <sup>3</sup> LLV | TWA: 0.00006 mg/m <sup>3</sup><br>STEL: 0.00006 mg/m <sup>3</sup> | 0.00006 mg/m <sup>3</sup> Ceiling |

#### Hazardous Components

| Chemical Name               | The Netherlands                    | Portugal                           | Spain                             | Sweden   | Switzerland                     | The United Kingdom            |
|-----------------------------|------------------------------------|------------------------------------|-----------------------------------|--|---------------------------------|-------------------------------|
| Protease (Subtilisin) (aep) | Ceiling: 0.00006 mg/m <sup>3</sup> | Ceiling: 0.00006 mg/m <sup>3</sup> | VLA-EC: 0.00006 mg/m <sup>3</sup> | 1 glycineunit/m <sup>3</sup> LLV<br>3 glycineunit/m <sup>3</sup> LLV | STEL: 0.00006 mg/m <sup>3</sup> | 0.00004 mg/m <sup>3</sup> TWA |

#### 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 <sup>3</sup>               |

| Chemical Name         | DNEL Dermal Acute Local<br>(Professional/Consumers) | DMEL Inhalation Long term Local<br>(Professionals/Consumers) |
|-----------------------|---|--|
| Protease (Subtilisin) | DNEL = 0,2% in mixture (W/W)                        | DMEL = 15 ng/m <sup>3</sup>                                  |

| 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)

When enzymes are used for spray products or hard surface cleaning, exposure of enzymes may exceed the safety level (15 ng/m<sup>3</sup> 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) | 1.16   |
| 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 |

### 9.2 Other information

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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 sensitization     | 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

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

R50 - Very toxic to aquatic organisms

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

H411 - Toxic to aquatic life with long lasting effects

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

### 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 64/548/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](http://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](http://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