

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 30.07.2016

Revision: 30.07.2016

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

- **1.1 Product identifier**
- **Trade name:** Alcalase® 2.5L
- **Item number:** 06-3112
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**  
No further relevant information available.
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Strem Chemicals, Inc.  
7 Mulliken Way  
NEWBURYPORT, MA 01950  
USA  
info@strem.com
- **Further information obtainable from:** Technical Department
- **1.4 Emergency telephone number:**  
EMERGENCY: CHEMTREC: + 1 (800) 424-9300  
During normal opening times: +1 (978) 499-1600

**SECTION 2: Hazards identification**

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



GHS07

- Skin Irrit. 2 H315 Causes skin irritation.
- Eye Irrit. 2 H319 Causes serious eye irritation.
- STOT SE 3 H335 May cause respiratory irritation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
Subtilisin
- **Hazard statements**  
H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.
- **Precautionary statements**  
P101 If medical advice is needed, have product container or label at hand.  
P102 Keep out of reach of children.  
P103 Read label before use.  
P235 Keep cool.

(Contd. on page 2)

**Safety data sheet**  
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Revision: 30.07.2016

**Trade name: Alcalase® 2.5L**

(Contd. of page 1)

- P284 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.
- P321 Specific treatment (see on this label).
- P403+P233 Store in a well-ventilated place. Keep container tightly closed.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Additional information:**

Contains Subtilisin. May produce an allergic reaction.

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients**

· **3.2 Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 9014-01-1	Subtilisin	20.0%
EINECS: 232-752-2	⚠ Resp. Sens. 1, H334; ⚠ Eye Dam. 1, H318; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335	

· **Additional information:** For the wording of the listed risk phrases refer to section 16.

**SECTION 4: First aid measures**

· **4.1 Description of first aid measures**

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:** In case of unconsciousness place patient stably in side position for transportation.

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:** If symptoms persist consult doctor.

· **4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.

· **4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**SECTION 5: Firefighting measures**

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· **5.3 Advice for firefighters**

· **Protective equipment:** No special measures required.

**SECTION 6: Accidental release measures**

· **6.1 Personal precautions, protective equipment and emergency procedures** Not required.

(Contd. on page 3)

**Safety data sheet**  
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Printing date 30.07.2016

Revision: 30.07.2016

**Trade name: Alcalase® 2.5L**

(Contd. of page 2)

- **6.2 Environmental precautions:**  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Ensure adequate ventilation.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**  
· **Storage:** Keep cool.  
· **Requirements to be met by storerooms and receptacles:** No special requirements.  
· **Information about storage in one common storage facility:** Not required.  
· **Further information about storage conditions:**  
Keep container tightly sealed.  
**DO NOT FREEZE**
- **Recommended storage temperature:** Store at temperatures not exceeding 4 °C.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see item 7.
- **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

**9014-01-1 Subtilisin**

WEL	Long-term value: 0.00004 mg/m <sup>3</sup>
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· **Additional information:** The lists valid during the making were used as basis.

- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

(Contd. on page 4)

**Safety data sheet**  
according to 1907/2006/EC, Article 31

Printing date 30.07.2016

Revision: 30.07.2016

**Trade name: Alcalase® 2.5L**

(Contd. of page 3)

· **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.  
Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

· **9.1 Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

· <b>Form:</b>	Liquid
· <b>Colour:</b>	Brown
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.

· **pH-value:** Not determined.

· **Change in condition**

· <b>Melting point/Melting range:</b>	Undetermined.
· <b>Boiling point/Boiling range:</b>	Undetermined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not determined.

· **Ignition temperature:**

· **Decomposition temperature:** Not determined.

· **Self-igniting:** Product is not selfigniting.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits:**

· <b>Lower:</b>	Not determined.
· <b>Upper:</b>	Not determined.

· **Vapour pressure:** Not determined.

· **Density:** Not determined.

· **Relative density** Not determined.

· **Vapour density** Not determined.

· **Evaporation rate** Not determined.

(Contd. on page 5)

**Safety data sheet**  
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Printing date 30.07.2016

Revision: 30.07.2016

**Trade name: Alcalase® 2.5L**

(Contd. of page 4)

- |   |  |
|---|--|
| · <b>Solubility in / Miscibility with water:</b>  | Fully miscible.                            |
| · <b>Partition coefficient (n-octanol/water):</b> | Not determined.                            |
| · <b>Viscosity:</b>                               |  |
| <b>Dynamic:</b>                                   | Not determined.                            |
| <b>Kinematic:</b>                                 | Not determined.                            |
| · <b>Solvent content:</b>                         |  |
| <b>Organic solvents:</b>                          | 0.0 %                                      |
| <b>VOC (EC)</b>                                   | 0.00 %                                     |
| · <b>9.2 Other information</b>                    | No further relevant information available. |

**SECTION 10: Stability and reactivity**

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

**SECTION 11: Toxicological information**

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

**9014-01-1 Subtilisin**

Oral	LD50	3700 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation**  
Causes skin irritation.
- **Serious eye damage/irritation**  
Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**  
May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.

(Contd. on page 6)

**Safety data sheet**  
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Revision: 30.07.2016

**Trade name: Alcalase® 2.5L**

(Contd. of page 5)

- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**

- |  |                 |
|--|-----------------|
| · <b>14.1 UN-Number</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | not regulated   |
| · <b>14.2 UN proper shipping name</b>  |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  | not regulated   |
| · <b>14.3 Transport hazard class(es)</b>   |                 |
| · <b>ADR, ADN, IMDG, IATA</b>  |                 |
| · <b>Class</b>   | not regulated   |
| · <b>14.4 Packing group</b>  |                 |
| · <b>ADR, IMDG, IATA</b>   | not regulated   |
| · <b>14.5 Environmental hazards:</b>   | Not applicable. |
| · <b>14.6 Special precautions for user</b>                                       | Not applicable. |
| · <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>  | not regulated   |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

(Contd. on page 7)

**Safety data sheet**  
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(Contd. of page 6)

- **National regulations:**
- **Waterhazard class:** Water hazard class 1 (Self-assessment): slightly hazardous for water.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

*This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.*

· **Relevant phrases**

*H315 Causes skin irritation.*

*H318 Causes serious eye damage.*

*H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.*

*H335 May cause respiratory irritation.*

· **Department issuing MSDS:** Technical Department.

· **Contact:** Technical Director

· **Abbreviations and acronyms:**

*ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*

*IMDG: International Maritime Code for Dangerous Goods*

*IATA: International Air Transport Association*

*GHS: Globally Harmonised System of Classification and Labelling of Chemicals*

*EINECS: European Inventory of Existing Commercial Chemical Substances*

*ELINCS: European List of Notified Chemical Substances*

*CAS: Chemical Abstracts Service (division of the American Chemical Society)*

*VOC: Volatile Organic Compounds (USA, EU)*

*LC50: Lethal concentration, 50 percent*

*LD50: Lethal dose, 50 percent*

*PBT: Persistent, Bioaccumulative and Toxic*

*vPvB: very Persistent and very Bioaccumulative*

*Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2*

*Eye Dam. 1: Serious eye damage/eye irritation, Hazard Category 1*

*Eye Irrit. 2: Serious eye damage/eye irritation, Hazard Category 2*

*Resp. Sens. 1: Sensitisation - Respirat., Hazard Category 1*

*STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3*