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

1.1 Product identifier
- **Trade name:** Alcalase® 2.4L FG
- **Item number:** 06-3110

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](image)
  - **Eye Irrit. 2 H319** Causes serious eye 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](image)

- **Signal word** Warning

- **Hazard-determining components of labelling:**
  - Subtilisin

- **Hazard statements**
  - H319 Causes serious eye 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.
  - P262 Do not get in eyes, on skin, or on clothing.
  - P280 Wear protective gloves/protective clothing/eye protection/face 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.
  - P403+P233 Store in a well-ventilated place. Keep container tightly closed.
Trade name: Alcalase® 2.4L FG

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: 56-81-5 EINECS: 200-289-5 glycerol substance with a Community workplace exposure limit 50.0%
    - CAS: 9014-01-1 EINECS: 232-752-2 Subtilisin Resp. Sens. 1, H334; Eye Dam. 1, H318; Skin Irrit. 2, H315; STOT SE 3, H335 9.0%
  - 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
  - After inhalation: Supply fresh air; consult doctor in case of complaints.
  - After skin contact: Generally the product does not irritate the skin.
  - 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: CO2, 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.
- 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.

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
No special precautions are necessary if used correctly.

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:

56-81-5 glycerol
WEL Long-term value: 10 mg/m³

9014-01-1 Subtilisin
WEL Long-term value: 0.00004 mg/m³

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.
Avoid contact with the eyes and skin.

Respiratory protection: Not required.

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:**
    - Form: Liquid
    - Colour: Brown
  - **Odour:** Characteristic
  - **Odour threshold:** Not determined.
  - **pH-value:** Not determined.
  - **Change in condition**
    - Melting point/Melting range: Undetermined.
    - Boiling point/Boiling range: Undetermined.
  - **Flash point:** Not applicable.
  - **Flammability (solid, gaseous):** Not determined.
  - **Ignition temperature:** 400 °C
  - **Decomposition temperature:** Not determined.
  - **Self-igniting:** Product is not selfigniting.
  - **Danger of explosion:** Product does not present an explosion hazard.
  - **Explosion limits:**
    - Lower: 0.9 Vol %
    - Upper: 0.0 Vol %
  - **Vapour pressure at 20 °C:** 23 hPa
  - **Density at 20 °C:** 1.17 g/cm³
  - **Relative density** Not determined.
  - **Vapour density** Not determined.
  - **Evaporation rate** Not determined.
  - **Solubility in / Miscibility with water:** Fully miscible.
  - **Partition coefficient (n-octanol/water):** Not determined.
  - **Viscosity:**
    - Dynamic: Not determined.
    - Kinematic: Not determined.
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:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Oral LD50</th>
</tr>
</thead>
<tbody>
<tr>
<td>9014-01-1 Subtilisin</td>
<td>3700 mg/kg (rat)</td>
</tr>
</tbody>
</table>

Primary irritant effect:

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/irritation
Causes serious eye irritation.

Respiratory or skin sensitisation
Based on available data, the classification criteria are not met.

CMR effects (carcinogenicity, 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
Based on available data, the classification criteria are not met.

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.

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.
Trade name: Alcalase® 2.4L FG

· 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

· 14.1 UN-Number
  · ADR, ADN, IMDG, IATA: not regulated
· 14.2 UN proper shipping name
  · ADR, ADN, IMDG, IATA: not regulated
· 14.3 Transport hazard class(es)
  · ADR, ADN, IMDG, IATA: not regulated
· 14.4 Packing group
  · ADR, IMDG, IATA: not regulated
· 14.5 Environmental hazards: Not applicable.
· 14.6 Special precautions for use: Not applicable.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Not applicable.
· UN "Model Regulation": 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.
  · National regulations:
    · Water hazard 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.
Trade name: Alcalase® 2.4L FG

- 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