1 Identification

· **Product name**
  · **Trade name:** Esperase® 8.0L
  · **Item number:** 06-3115

· **Details of the supplier of the safety data sheet**
  · **Manufacturer/Supplier:** Strem Chemicals, Inc.
    7 Mulliken Way
    NEWBURYPORT, MA 01950
    USA
    info@strem.com

· **Information department:** Technical Department

· **Emergency telephone number:**
  EMERGENCY: CHEMTREC: + 1 (800) 424-9300
  During normal opening times: +1 (978) 499-1600

2 Hazard(s) identification

· **Classification of the substance or mixture**

  ![GHS07]

  **Skin Irrit. 2** H315 Causes skin irritation.
  **Eye Irrit. 2A** H319 Causes serious eye irritation.

· **Label elements**
  · **GHS label elements** The product is classified and labeled according to the Globally Harmonized System (GHS).
  · **Hazard pictograms**

  ![GHS07]

· **Signal word** Warning

· **Hazard-determining components of labeling:**
  · **Subtilisin**

· **Hazard statements**
  · **H315** Causes skin irritation.
  · **H319** Causes serious eye irritation.

· **Precautionary statements**
  · **P235** Keep cool.
  · **P262** Do not get in eyes, on skin, or on clothing.
  · **P280** Wear protective gloves/protective clothing/eye protection/face protection.
  · **P261** Avoid breathing dust/fume/gas/mist/vapors/spray
  · **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).
3 Composition/information on ingredients

- Chemical characterization: Mixtures
- Description: Mixture of the substances listed below with nonhazardous additions.
- Dangerous components:
  - 9014-01-1 Subtilisin 10.0%

4 First-aid measures

- 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.
- Information for doctor:
  - Most important symptoms and effects, both acute and delayed No further relevant information available.
  - Indication of any immediate medical attention and special treatment needed
    No further relevant information available.

5 Fire-fighting measures

- Extinguishing media
- Suitable extinguishing agents:
  - CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- Special hazards arising from the substance or mixture No further relevant information available.
- Advice for firefighters
- Protective equipment: No special measures required.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures Not required.
7 Handling and storage

· Handling:
  · Precautions for safe handling
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  · Information about protection against explosions and fires: No special measures required.
  
· 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 receptacle tightly sealed.
  DO NOT FREEZE

· Recommended storage temperature: Store at temperatures not exceeding 4 °C.

· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

· Additional information about design of technical systems: No further data; see item 7.

· Control parameters

· Components with limit values that require monitoring at the workplace:

  9014-01-1 Subtilisin

  REL Short-term value: 0.00006* mg/m³
  *60-min
  TLV Ceiling limit value: 0.00006 mg/m³
  as 100% crystalline active pure enzyme

· Additional information: The lists that were valid during the creation were used as basis.

· 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.

· Breathing equipment:
  In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
42. 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 Physical and chemical properties

- Information on basic physical and chemical properties
  
  General Information
  
  Appearance:
  
  Form: Liquid
  Color: Brown
  Odor: Characteristic
  Odor 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:
  
  Decomposition temperature: Not determined.

- Auto igniting: Product is not selfigniting.

- Danger of explosion: Product does not present an explosion hazard.

- Explosion limits:
  
  Lower: Not determined.
  Upper: Not determined.

- Vapor pressure: Not determined.

- Density: Not determined.
Trade name: Esperase® 8.0L

| · Relative density | Not determined. |
| · Vapor 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. |

| · Solvent content: Organic solvents: | 0.0 % |
| · VOC content: | 0.0 g/l / 0.00 lb/gl |

| · Other information | No further relevant information available. |

10 Stability and reactivity

| · Reactivity | No further relevant information available. |
| · Chemical stability | |
| · Thermal decomposition / conditions to be avoided: | No decomposition if used according to specifications. |
| · Possibility of hazardous reactions | No dangerous reactions known. |
| · Conditions to avoid | No further relevant information available. |
| · Incompatible materials: | No further relevant information available. |
| · Hazardous decomposition products: | No dangerous decomposition products known. |

11 Toxicological information

| · Information on toxicological effects | |
| · Acute toxicity: | |
| · LD/LC50 values that are relevant for classification: | |
| 9014-01-1 Subtilisin | |
| Oral LD50 3700 mg/kg (rat) | |
| · Primary irritant effect: | |
| · on the skin: | Irritant to skin and mucous membranes. |
| · on the eye: | Irritating effect. |
| · Sensitization: | No sensitizing effects known. |
| · Additional toxicological information: | The product shows the following dangers according to internally approved calculation methods for preparations: |
| | Irritant |
| | |
| · Carcinogenic categories | |
| · IARC (International Agency for Research on Cancer) | None of the ingredients is listed. |
| · NTP (National Toxicology Program) | None of the ingredients is listed. |
Safety Data Sheet  
according to OSHA HCS

Trade name: Esperase® 8.0L

12 Ecological information

- Toxicity
  - Aquatic toxicity: No further relevant information available.
  - Persistence and degradability: No further relevant information available.
  - Behavior in environmental systems:
  - Bioaccumulative potential: No further relevant information available.
  - Mobility in soil: No further relevant information available.
  - Additional ecological information:
    - General notes:
      Water hazard class 1 (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.
    - Results of PBT and vPvB assessment
      - PBT: Not applicable.
      - vPvB: Not applicable.
    - Other adverse effects: No further relevant information available.

13 Disposal considerations

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

14 Transport information

- UN-Number
  - DOT, ADN, IMDG, IATA: not regulated
- UN proper shipping name
  - DOT, ADN, IMDG, IATA: not regulated
- Transport hazard class(es)
  - DOT, ADN, IMDG, IATA: not regulated
- Packing group
  - DOT, IMDG, IATA: not regulated
- Environmental hazards:
  - Not applicable.
- Special precautions for user:
  - Not applicable.
- Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
  - Not applicable.
Trade name: Esperase® 8.0L

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- Sara
  - Section 355 (extremely hazardous substances):
    None of the ingredients is listed.
  - Section 313 (Specific toxic chemical listings):
    None of the ingredients is listed.
  - TSCA (Toxic Substances Control Act):
    All ingredients are listed.
- Proposition 65
  - Chemicals known to cause cancer:
    None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity for females:
    None of the ingredients is listed.
  - Chemicals known to cause reproductive toxicity for males:
    None of the ingredients is listed.
  - Chemicals known to cause developmental toxicity:
    None of the ingredients is listed.
- Carcinogenic categories
  - EPA (Environmental Protection Agency)
    None of the ingredients is listed.
  - TLV (Threshold Limit Value established by ACGIH)
    None of the ingredients is listed.
  - NIOSH-Ca (National Institute for Occupational Safety and Health)
    None of the ingredients is listed.
- GHS label elements
  - The product is classified and labeled according to the Globally Harmonized System (GHS).
  - Hazard pictograms

GHS07

- Signal word Warning
- Hazard-determining components of labeling:
  Subtilisin
- Hazard statements
  H315 Causes skin irritation.
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- Precautionary statements
  P235 Keep cool.
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**Trade name:** Esperase® 8.0L

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- **P280** Wear protective gloves/protective clothing/eye protection/face protection.
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- **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).

**National regulations:**

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

### 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.

- **Department issuing SDS:** Technical Department.
- **Contact:** Technical Director
- **Date of preparation / last revision** 07/30/2016 / -
- **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
  - **DOT:** US Department of Transportation
  - **IATA:** International Air Transport Association
  - **ACGIH:** American Conference of Governmental Industrial Hygienists
  - **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)
  - **NFPA:** National Fire Protection Association (USA)
  - **HMIS:** Hazardous Materials Identification System (USA)
  - **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
  - **NIOSH:** National Institute for Occupational Safety
  - **OSHA:** Occupational Safety & Health
  - **TLV:** Threshold Limit Value
  - **PEL:** Permissible Exposure Limit
  - **REL:** Recommended Exposure Limit
  - **Skin Irrit. 2:** Skin corrosion/irritation, Hazard Category 2
  - **Eye Irrit. 2A:** Serious eye damage/eye irritation, Hazard Category 2A