SAFETY DATA SHEET

1. Identification

Product identifier: Lactase

Other means of identification:
- Catalog number: 1356698
- Chemical name: beta-Galactosidase
- Synonym(s): Tilactase * Beta-D-galactoside galactohydrolase

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
  Rockville
  MD
  20852-1790
  US
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number:
  - CHEMTREC within US & Canada: 1-800-424-9300
  - CHEMTREC outside US & Canada: +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Sensitization, respiratory

OSHA hazard(s): Not classified.

Label elements

- Signal word: Danger
- Hazard statement: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- Precautionary statement:
  - Prevention: In case of inadequate ventilation wear respiratory protection.
  - Response: If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor.
  - Storage: Not available.
  - Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC): Not classified.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Hazardous components</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactase</td>
<td></td>
<td>Tilactase * Beta-D-galactoside galactohydrolase</td>
<td>9031-11-2</td>
<td>100</td>
</tr>
</tbody>
</table>

Material name: Lactase

Version #: 02   Revision date: 01-27-2014   Issue date: 07-01-2007
4. First-aid measures

Inhalation
If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Skin contact
Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact
Rinse with water. Get medical attention if irritation develops and persists.

Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
May cause allergic respiratory reaction.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO2.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire-fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.

Conditions for safe storage, including any incompatibilities
Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values
No biological exposure limits noted for the ingredient(s).

Exposure guidelines
No exposure standards allocated.

Appropriate engineering controls
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment
Eye/face protection
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection
Hand protection
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Thermal hazards
Not available.

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
White to light tan powder.

Physical state
Solid.

Form
Powder.

Odor
Slight odor.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
Not available.

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility in water
Soluble.

Partition coefficient (n-octanol/water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Chemical family
Enzyme.

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Stable at normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials
Strong oxidizing agents.
Hazardous decomposition products
Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information
Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Symptoms related to</td>
<td>Runny nose. Red eyes. Difficulty breathing. Skin rash.</td>
</tr>
<tr>
<td>the physical,</td>
<td></td>
</tr>
<tr>
<td>chemical, and</td>
<td></td>
</tr>
<tr>
<td>toxicological</td>
<td></td>
</tr>
<tr>
<td>characteristics</td>
<td></td>
</tr>
<tr>
<td>Medical conditions</td>
<td>Respiratory disorders. Allergies.</td>
</tr>
<tr>
<td>aggravated by</td>
<td></td>
</tr>
<tr>
<td>exposure</td>
<td></td>
</tr>
<tr>
<td>Acute toxicity</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactase (CAS 9031-11-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 10000 mg/day</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 10000 mg/kg</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>May cause allergy or asthma symptoms or breathing difficulties if inhaled.</td>
<td></td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Sensitization</td>
<td>Allergic rhinitis, conjunctivitis, asthma, and skin reactions have been reported in some workers occupationally exposed to lactase.</td>
<td></td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.</td>
<td></td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - single exposure</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Due to lack of data the classification is not possible.</td>
<td></td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Based on available data, the classification criteria are not met.</td>
<td></td>
</tr>
</tbody>
</table>

12. Ecological information

| Ecotoxicity                  | No ecotoxicity data noted for the ingredient(s).                  |
| Persistence and degradability| No data is available on the degradability of this product.       |
| Bioaccumulative potential    | Not available.                                                   |
| Mobility in soil             | Not available.                                                   |
| Other adverse effects        | Not available.                                                   |

13. Disposal considerations

| Disposal instructions          | Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. |
| Local disposal regulations     | Not available.                                                   |
| Hazardous waste code           | Not available.                                                   |
| Waste from residues / unused products | Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). |
| Contaminated packaging         | Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied. |
14. Transport information

DOT
Not regulated as a hazardous material by DOT.

IATA
Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
No information available.

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.
All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 07-01-2007
Revision date 01-27-2014
Version # 02
Further information Not available.
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Revision Information

This document has undergone significant changes and should be reviewed in its entirety.