1. Identification

Product identifier: Orlistat Related Compound E

Catalog number: 1478855

Chemical name: L-Isoleucine, N-formyl-, (1S)-1-[(2S,3S)-3-hexyl-4-oxo-2-oxetanyl]methyl)dodecyl ester

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

Manufacturer: U. S. Pharmacopeia

Address: 12601 Twinbrook Parkway

Rockville

MD 20852-1790

United States

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: Not classified.

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Hazard symbol: None.

Signal word: None.

Hazard statement: Not available.

Precautionary statement

Prevention: Not available.

Response: Not available.

Storage: Not available.

Disposal: Not available.

Hazard(s) not otherwise classified (HNOC): None known.

Supplemental information: None.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orlistat Related Compound E</td>
<td>1072902-75-0</td>
<td>100</td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

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

Provide general supportive measures and treat symptomatically.

Indication of immediate medical attention and special treatment needed

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

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

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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

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

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

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

Occupational exposure limits

No exposure limits noted for ingredient(s).

Biological limit values

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

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

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.
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.

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).

Wear appropriate thermal protective clothing, when necessary.

Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

**Appearance**
- **Physical state**: Solid.
- **Form**: Powder.
- **Color**: White.
- **Odor**: Not available.
- **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 available.

**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(ies)**
- **Solubility (water)**: Not available.

**Auto-ignition temperature**: Not available.
- **Decomposition temperature**: Not available.
- **Viscosity**: Not available.

**Other information**
- **Molecular formula**: C29H53NO5
- **Molecular weight**: 495.75

10. Stability and reactivity

**Reactivity**
- The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability**
- Material is stable under normal conditions.

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

**Conditions to avoid**
- Contact with incompatible materials.

**Incompatible materials**
- None known.

**Hazardous decomposition products**
- NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

**Information on likely routes of exposure**
- **Inhalation**: Knowledge about health hazard is incomplete.
- **Skin contact**: Knowledge about health hazard is incomplete.
- **Eye contact**: Knowledge about health hazard is incomplete.
Ingestion

Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical, and toxicological characteristics

Not available.

Information on toxicological effects

Acute toxicity

Not available.

Skin corrosion/irritation

Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation

Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization

Knowledge about health hazard is incomplete.

Skin sensitization

Knowledge about health hazard is incomplete.

Germ cell mutagenicity

Knowledge about mutagenicity is incomplete.

Carcinogenicity

Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Knowledge about health hazard is incomplete.

Specific target organ toxicity - single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure

Knowledge about health hazard is incomplete.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

No data available.

Mobility in soil

No data available.

Other adverse effects

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.
15. Regulatory information

US federal regulations
This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)
Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)
Not listed.

US. Massachusetts RTK - Substance List
Not regulated.

US. New Jersey Worker and Community Right-to-Know Act
Not listed.

US. Pennsylvania RTK - Hazardous Substances
Not regulated.

US. Pennsylvania Worker and Community Right-to-Know Law
Not listed.

US. Rhode Island RTK
Not regulated.

US. California Proposition 65
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>
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<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
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<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
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<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
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<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
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<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
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<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
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<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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Material name: Orlistat Related Compound E
1478855    Version #: 02    Revision date: 10-27-2016    Issue date: 03-12-2008
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<tbody>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
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<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
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</tbody>
</table>

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
*A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

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

- Issue date: 03-12-2008
- Revision date: 10-27-2016
- Version #: 02

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