1. Identification

Product identifier: Azaerythromycin A

Other means of identification
- Catalog number: 1045600
- Chemical name: 9-Deoxo-9a-aza-9a-homoerythromycin A

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
- Emergency phone number
  - CHEMTREC within US & Canada: 1-800-424-9300
  - CHEMTREC outside US & Canada: +1 703-527-3887
- E-mail: RSTECH@usp.org

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards: Not classified.

OSHA hazard(s): Not classified.

Label elements
- Signal word: Warning
- Hazard statement: Causes serious eye irritation.
- Precautionary statement:
  - Prevention: Wash thoroughly after handling. Wear eye/face protection.
  - Response: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
  - Storage: Not available.
  - Disposal: Not available.

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

3. Composition/information on ingredients

Substance: Azaerythromycin A

Hazardous components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azaerythromycin A</td>
<td></td>
<td>76801-85-9</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation: Remove to fresh air. 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: Causes irritation. Flush with copious quantities of water for at least 15 minutes. Get medical attention if irritation persists after washing.
Ingestion
Rinse mouth. Get medical attention if symptoms occur. Irritation of eyes and mucous membranes.

Most important symptoms/effects, acute and delayed

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

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
Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Cool containers exposed to flames with water until well after the fire is out.

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. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. 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. Wash spill site.

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. Use of a designated area is recommended for handling of potent materials.

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

Exposure limit values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azaerythromycin A (CAS 76801-85-9)</td>
<td>TWA</td>
<td>0.1 mg/m3</td>
</tr>
</tbody>
</table>

Biological limit values

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. This material is extremely potent. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

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 powder.

Physical state

Solid.

Form

Powder.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

131 °F (55 °C); also reported as approximately 138 °C

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

Slightly soluble.

Partition coefficient (n-octanol/water)

Not available.

Auto-ignition temperature

Not available.

Decomposition temperature

Not available.

Viscosity

Not available.

Other information

Chemical family

Synthesis intermediate.

Molecular formula

C37H70N2O12

Molecular weight

734.96

Solubility (other)

Soluble in ethanol and in acetone.

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
Oxidizing agents.

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

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

Inhalation
Due to lack of data the classification is not possible.

Skin contact
Due to lack of data the classification is not possible.

Eye contact
Causes serious eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics
Not available.

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

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Azaerythromycin A (CAS 76801-85-9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Rabbit</td>
<td></td>
<td>&gt; 200 mg/kg</td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td>&gt; 2000 mg/kg</td>
</tr>
</tbody>
</table>

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

Serious eye damage/eye irritation
Causes serious eye irritation.

Local effects

Irritation test
Result: Irritant.
Species: Rabbit
Organ: Eye
Severity: Severe

Irritation test
Result: Non-irritant.
Species: Rabbit
Organ: Skin

Respiratory sensitization
Due to lack of data the classification is not possible.

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

Sensitization

LLNA Sensitization test
Result: Non-sensitizing.
Species: Mouse

Germ cell mutagenicity
Due to lack of data the classification is not possible.

Carcinogenicity
This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity
Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure
Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure
Due to lack of data the classification is not possible.

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

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
This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.
Local disposal regulations
Not available.
Hazardous waste code
Not regulated.
Waste from residues / unused products
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.
One or more components are not listed on TSCA.
Superfund Amendments and Reauthorization Act of 1986 (SARA)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>Immediate Hazard</th>
<th>Delayed Hazard</th>
<th>Fire Hazard</th>
<th>Pressure Hazard</th>
<th>Reactivity Hazard</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 302 Extremely hazardous substance</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SARA 311/312 Hazardous chemical</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</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>No</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>No</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>No</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
10-13-2008
Revision date
11-16-2012
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.