1. Identification

Product identifier  Clarithromycin Related Compound A

Other means of identification

- Catalog number  1134380
- Chemical name  6,11-Di-O-Methyl Erythromycin 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
- 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.

OSHA hazard(s)  Not classified.

Label elements

- Hazard symbol  No symbol.
- Signal word  Not available.
- Hazard statement  Not available.

Precautionary statement

- Prevention  Not available.
- Response  Not available.
- Storage  Not available.
- Disposal  Not available.

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

3. Composition/information on ingredients

Substance Non-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>Clarithromycin Related</td>
<td></td>
<td>81103-14-2</td>
<td>100</td>
</tr>
<tr>
<td>Compound A</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation  Move 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  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  Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed

General information

Treat symptomatically.

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.
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  
485.6 - 494.6 °F (252 - 257 °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  
Soluble in hot water.

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

Auto-ignition temperature  
Not available.

Decomposition temperature  
Not available.

Viscosity  
Not available.

Other information

Molecular formula  
C39H71NO13

Molecular weight  
762

Solubility (other)  
Soluble in methanol, in dimethylacetamide, and in hot dimethylformamide.

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  
Due to lack of data the classification is not possible.

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  
Due to lack of data the classification is not possible.

Symptoms related to the physical, chemical, and toxicological characteristics  
Cross sensitivity
Persons sensitive to erythromycin or other macrolides may be sensitive to this material also.

Medical conditions aggravated by exposure
Related material: Gastrointestinal ulcers. Liver impairment. It is not known if this material causes the same effects.

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

Skin corrosion/irritation
Due to lack of data the classification is not possible.

Serious eye damage/eye irritation
Due to lack of data the classification is not possible.

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

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

Germ cell mutagenicity
Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Carcinogenicity
Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, 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
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.

One or more components are not listed on TSCA.

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
No
SARA 311/312 Hazardous chemical: No

Other federal regulations:
- 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: 04-14-2010
- Revision date: 06-01-2015
- Version #: 02
- Further information: Not available.

Disclaimer:
USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.

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