1. Identification

**Product identifier** Artesunate

**Other means of identification**
- **Catalog number** 1042850
- **Chemical name** Butanedioic acid, mono[(3R,5aS,6R,8aS,9R,10S,12R,12aR)-decahydro-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j] ester
- **Synonym(s)** Artesunic acid

**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**
- Acute toxicity, oral Category 4
- Reproductive toxicity Category 2

**OSHA hazard(s)** Not classified.

**Label elements**

**Signal word** Warning

**Hazard statement** Harmful if swallowed. Suspected of damaging fertility or the unborn child.

**Precautionary statement**

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. Rinse mouth.

**Storage** Store locked up.

**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>Artesunate</td>
<td>Artesunic acid</td>
<td>88495-63-0</td>
<td>100</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**
Not available.

**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**
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**
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

**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  When using, do not eat, drink or smoke. Wash hands before breaks and immediately after handling the product. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance  Fine white or almost white crystalline powder.

Physical state  Solid.

Form  Powder.

Odor  Odorless.

Odor threshold  Not available.

pH  3.5 - 4.5

Melting point/freezing point  267.8 - 275 °F (131 - 135 °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.

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

Auto-ignition temperature  > 392 °F (> 200 °C)

Decomposition temperature  Not available.

Viscosity  Not available.

Other information

Chemical family  Sesquiterpene lactone (artemisinin derivative).

Molecular formula  C19H28O8

Molecular weight  384.42

Solubility (other)  Freely 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  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

- **Ingestion**: Harmful if swallowed.
- **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 other artemisinin derivatives may be sensitive to this material.

Medical conditions aggravated by exposure


Acute toxicity

- Harmful if swallowed.

### Test Results

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artesunate (CAS 88495-63-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50 Rat Oral</td>
<td>Rat</td>
<td>&gt; 825 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>600 - 900 mg/kg</td>
</tr>
</tbody>
</table>

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.

Carcinogenicity

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

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

Reproductive toxicity

- Suspected of damaging fertility or the unborn child. Administration of artemisinins early in gestation has caused embryotoxicity (death and birth defects) in animals. There is no evidence of adverse pregnancy outcomes with therapeutic use of artemisinins during the second and third trimesters and normal outcomes have been observed in a limited number of pregnancies known to be exposed during the first trimester.

Specific target organ toxicity - single exposure

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

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

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

12. Ecological information

Ecotoxicity

- There are no data on the ecotoxicity of this product.

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
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
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

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>
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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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<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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<td>New Zealand</td>
<td>New Zealand Inventory</td>
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<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
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<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          07-01-2009
Revision date        12-14-2012
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.