# USO

# SAFETY DATA SHEET

## 1. Identification

Product identifier Artemisinin

Other means of identification

 Catalog number
 1042747

 CAS number
 63968-64-9

Chemical name (3R,5aS,6R,8aS,9R,12S,12aR)-Octahydro-3,6,9-trimethyl-3,12-epoxy-12H-pyrano[4,3-j]-1,2-benzo

dioxepin-10(3H)-one

**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

Company name
U. S. Pharmacopeia

Address 12601 Twinbrook Parkway

Rockville MD

20852-1790 United States

**Telephone** RS Technical Services 301

301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Reproductive toxicity

Reproductive toxicity Category 2

Not classified.

Label elements

**Environmental hazards** 

**OSHA** defined hazards



Not classified.

Signal word Warning

**Hazard statement** 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. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If exposed or concerned: Get medical advice/attention.

Storage Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

**Supplemental information** Pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Artemisinin USP SDS US

1042747 Version #: 02 Revision date: 10-18-2019 Issue date: 08-30-2013

**Chemical name CAS** number % Common name and synonyms Artemisinin 63968-64-9 100

## 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.

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

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

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

Most important

symptoms/effects, acute and

delayed

Provide general supportive measures and treat symptomatically.

Indication of immediate medical attention and special treatment needed

**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.

Pharmacologically active material. Occupational exposure may cause physiological effects.

## 5. Fire-fighting measures

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

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.

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

General fire hazards No unusual fire or explosion hazards noted.

#### 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 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. For waste disposal, see section 13 of the SDS.

**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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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).

Material name: Artemisinin USP SDS US Appropriate engineering

controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

**Hand protection** Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved

or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of

skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Respirators are generally not required for laboratory operations. Use a tight-fitting full-face

respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task

and the level of existing engineering controls.

**Thermal hazards** Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards.

Procedures for any other uses or quantities should be determined after an appropriate

assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical stateSolid.FormSolid.ColorWhite.

Odor Not available.
Odor threshold Not available.
pH Not available.

Melting point/freezing point 309.2 - 312.8 °F (154 - 156 °C)

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 0.0000003 kPa at 25 °C

Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Poorly soluble.

**Solubility (other)** Dimethylsulfoxide: Soluble.

Methanol: Soluble. Oils: Poorly soluble.

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

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Other information

Chemical family Artemisinin.

Molecular formula C15H22O5

Molecular weight 282.33

## 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 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

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.Eye contactKnowledge about health hazard is incomplete.IngestionKnowledge about health hazard is incomplete.

Species

Symptoms related to the physical, chemical, and

toxicological characteristics

Gastrointestinal disturbances. Rash. Dizziness. Itching. Headache. Ringing in ears. Hearing

Test Results

problems. Bleeding. Dark urine.

## Information on toxicological effects

#### **Acute toxicity**

Product

Fiduuci	Species	rest Results
Artemisinin (CAS 63968-64-9)		
Oral		
LD50	Mouse	4228 mg/kg
	Rat	5576 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization	n	
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.	
1400 14		

## IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

# US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

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 in humans 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

Knowledge about health hazard is incomplete.

Material name: Artemisinin USP SDS US

Specific target organ toxicity -

repeated exposure

Knowledge about health hazard is incomplete.

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

**Further information** Pharmacologically active material. Occupational exposure may cause physiological effects.

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 substance.

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

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the **Disposal instructions** 

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

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

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.

# 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

the IBC Code

Not applicable. Annex II of MARPOL 73/78 and

**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 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 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

**Classified hazard** 

Reproductive toxicity

categories

SARA 313 (TRI reporting)

Not regulated.

Material name: Artemisinin USP SDS US

## 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

Not regulated.

Inventory name

(SDWA)

#### US state regulations

#### **California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

#### **International Inventories**

Country(s) or region

obuiltiy(3) or region	inventory name	On miveritory (yes/no)
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
	Australia Canada Canada China Europe  Europe Japan Korea New Zealand Philippines	Australia Australian Inventory of Chemical Substances (AICS) Canada Domestic Substances List (DSL) Canada Non-Domestic Substances List (NDSL) China Inventory of Existing Chemical Substances in China (IECSC) Europe European Inventory of Existing Commercial Chemical Substances (EINECS) Europe European List of Notified Chemical Substances (ELINCS) Japan Inventory of Existing and New Chemical Substances (ENCS) Korea Existing Chemicals List (ECL) New Zealand New Zealand Inventory Philippines Philippine Inventory of Chemicals and Chemical Substances (PICCS)

<sup>\*</sup>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
 08-30-2013

 Revision date
 10-18-2019

Version # 02

United States & Puerto Rico

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Toxic Substances Control Act (TSCA) Inventory

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.

Material name: Artemisinin USP SDS US

No

On inventory (yes/no)\*