SAFETY DATA SHEET



1. Identification

Product identifier Articaine Hydrochloride

Other means of identification

Catalog number 1042918 **CAS** number 23964-57-0

Synonyms Carticaine hydrochloride

Chemical name 2-Thiophenecarboxylic acid, 4-methyl-3-[[1-oxo-2-(propylamino)propyl]amino]-, methyl ester,

monohydrochloride

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 Company name **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

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

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Not classified. Physical hazards

Acute toxicity, oral Category 4 **Health hazards**

Environmental hazards Not classified. **OSHA** defined hazards Not classified.

Label elements



Signal word Warning

Harmful if swallowed. **Hazard statement**

Precautionary statement

Prevention Wash thoroughly after handling.

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

Not available. **Storage**

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

Hazard(s) not otherwise

This product is supplied in a small quantity which does not constitute a combustible dust hazard. classified (HNOC) The physical properties of this material indicate that in large quantities accumulated dust may be

hazardous.

Supplemental information Pharmacologically active material.

3. Composition/information on ingredients

Substance

Material name: Articaine Hydrochloride USP SDS US

% **CAS** number **Chemical name** Common name and synonyms Articaine Hydrochloride Carticaine hydrochloride 23964-57-0 100

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.

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

Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head

low so that stomach content doesn't get into the lungs.

Most important symptoms/effects, acute and delayed

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Treat symptomatically. Treatment of local anesthetic overdose may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. For circulatory depression, administer a vasopressor or intravenous fluids. For seizures, administer an intravenous benzodiazepine, followed by phenobarbital or propofol if seizures recur. Avoid the use of phenytoin which may worsen or precipitate cardiac arrhythmias. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Lipid infusion may be useful for reversing severe cardiac toxicity. For coma and respiratory depression, protect airway with an endotracheal tube and assist ventilation as necessary. For bradycardia and bradyarrhythmias with heart rates less than 60, administer intravenous, intramuscular, or subcutaneous atropine. For hypotension, infuse isotonic fluid. If persistent, administer dopamine. For severe metabolic acidosis, correct with intravenous sodium bicarbonate. For respiratory acidosis, treat with assisted ventilation. For methemoglobinemia in symptomatic patients, administer intravenous methylene blue. Enhanced elimination with hemodialysis, exchange transfusion, AV hemofiltration, and forced diuresis has not been shown to increase clearance substantially. Urinary acidification is not recommended. Cardiac bypass support should be considered for cardiovascular collapse.

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

materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

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.

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

Environmental precautions

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

1042918 Version #: 03 Revision date: 09-23-2020 Issue date: 04-01-2009

2/7

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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material	Туре	Value
Articaine Hydrochloride (CAS 23964-57-0)	TWA	0.02 mg/m3

Biological limit values

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

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.FormPowder.ColorWhite.

Odor Faint odor. Characteristic.

Odor threshold Not available. pH Not available.

Melting point/freezing point 334.4 - 338 °F (168 - 170 °C)

350.6 - 352.4 °F (177 - 178 °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
Not available.
Vapor density
Not available.
Not available.

Solubility(ies)

Solubility (water) Freely soluble.

Solubility (other) Alcohol: Freely soluble.

Partition coefficient -1.41

(n-octanol/water)

Auto-ignition temperature698 °F (370 °C)Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical family Amino amide.

Dust explosion properties

Minimum ignition energy (MIE) - dust

6 - 13 mJ DTA

cloud

Molecular formula C13H20N2O3S . HCl

Molecular weight 320.83 g/mol

pH in aqueous solution 4.2 - 5.2 to 5 Solution: 1% Potential for dust Capable of dust explosions.

explosion

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 avoidContact with incompatible materials.

Incompatible materials None known.

Hazardous decomposition

products

NOx. SOx. CI-. 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.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Local anesthetics: Headache. Numbness. Neck or back pain. Chest pain. Change in vision. Slurred speech. Dizziness. Drowsiness. Weakness. Feeling hot or cold. Ringing in ears. Anxiety. Nervousness. Excitement. Confusion. Difficulty in breathing. Gastrointestinal disturbances.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

1042918 Version #: 03 Revision date: 09-23-2020 Issue date: 04-01-2009

Product Species Test Results

Articaine Hydrochloride (CAS 23964-57-0)

Oral

LD50 Rat 980 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye Knowledge about health hazard is incomplete.

irritation

Respiratory or skin sensitization

Respiratory sensitization Knowledge about sensitization hazard is incomplete.

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

Sensitization test Result: Non-sensitizing. Species: Guinea pig Organ: Skin

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

In vitro Ames test Result: Negative.

In vitro Chinese hamster ovary chomosomal aberration test

Result: Negative.

In vitro mammalian gene mutation test

Result: Negative.

In vivo mouse micronucleus test

Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Knowledge about health hazard is incomplete.

Adverse fetal effects were not seen in animal studies.

Reproductivity studies in animals administered the base of this material have yielded mixed

results. Adverse fetal effects occurred at high, maternally toxic doses in animals.

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

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 product.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

-1.41

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 instructionsDispose 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.

1042918 Version #: 03 Revision date: 09-23-2020 Issue date: 04-01-2009

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 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 dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Not applicable.

Annex II of MARPOL 73/78 and

the IBC Code

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

One or more components are not listed on TSCA.

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard

Acute toxicity (any route of exposure)

categories 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 regulationsCalifornia 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

Country(s) or region	Inventory name	On inventory (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

6/7

Country(s) or region Inventory name On inventory (yes/no)* Europe European Inventory of Existing Commercial Chemical

Substances (EINECS)

European List of Notified Chemical Substances (ELINCS) Europe No

Japan Inventory of Existing and New Chemical Substances (ENCS) No Korea Existing Chemicals List (ECL) No

Philippines Philippine Inventory of Chemicals and Chemical Substances Nο

(PICCS)

Taiwan Taiwan Chemical Substance Inventory (TCSI) Yes United States & Puerto Rico Toxic Substances Control Act (TSCA) Inventory No

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

New Zealand Inventory

Issue date 04-01-2009 09-23-2020 **Revision date**

Version #

New Zealand

Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the **Further information**

Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

USP Reference Standards are sold for chemical test and assay purposes only, and NOT for **Disclaimer**

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

1042918 Version #: 03 Revision date: 09-23-2020 Issue date: 04-01-2009

No

^{*}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).