



NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

Safety Data Sheet (MSDS)

(According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards)

Product Name: Articaine Hydrochloride **Revision Date: 28 FEB 2026**

SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

1.1 Product Identifiers

- Product Name: Articaine Hydrochloride
- Product Number: AH-20260228
- Brand: SIGALD
- CAS-No.: 23964-57-0
- Synonyms: 4-Methyl-3-[2-(propylamino)propionamido]thiophene-2-carboxylic acid methyl ester hydrochloride; Carticaine hydrochloride

1.2 Details of the supplier of the safety data sheet

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

1.3 Emergency telephone

- Emergency Phone #: +86-021-50350029 (CHEMTREC)

1.4 Relevant Identified Uses and Uses Advised Against

- Identified Uses: Pharmaceutical intermediate for amide local anesthetic drugs (dental-specific); raw material for injectable dental local anesthetic formulations; minor surgical surface anesthesia formulations; pharmaceutical R&D reference reagent.
- Uses Advised Against: Not for direct human consumption/injection in raw form; no non-pharmaceutical industrial use; avoid use in cosmetics/food products; do not mix with unapproved excipients for clinical dental use.

SECTION 2: Hazards Identification

2.1 GHS Classification

- Acute toxicity, oral (Category 3); Skin irritation (Category 2); Serious eye irritation (Category 2); Specific target organ toxicity - single exposure (Nervous system, Category 3)

2.2 GHS Label Elements

- Hazard Pictogram: (Exclamation mark)
- Signal Word: **Danger**
- Hazard Statements:
 - H301: Toxic if swallowed
 - H315: Causes skin irritation
 - H319: Causes serious eye irritation
 - H335: May cause respiratory irritation
 - H373: May cause damage to organs (Nervous system) through prolonged or repeated exposure
- Precautionary Statements:
 - P264: Wash skin thoroughly after handling
 - P270: Do not eat, drink or smoke when using this product
 - P280: Wear protective gloves/eye protection/face protection
 - P301+P310: If swallowed: Immediately call a POISON CENTER or doctor/physician
 - P302+P352: If on skin: Wash with plenty of water and soap
 - P305+P351+P338+P310: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician
 - P332+P313: If skin irritation occurs: Get medical advice/attention
 - P362: Take off contaminated clothing and wash before reuse
 - P405: Store locked up
 - P501: Dispose of contents/container to an approved waste disposal plant

2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties under normal storage and handling conditions. No hazardous polymerization will occur.2.4 Health Hazards
- Acute: Swallowing causes severe dizziness, nausea, limb numbness, nervous system depression; skin contact leads to redness, itching and rash; eye contact causes conjunctival redness, corneal irritation and blurred vision; dust inhalation causes cough, headache and throat irritation.
- Chronic: Prolonged exposure may cause persistent mild neurological numbness in sensitive individuals; no significant organ damage with strict protective measures.2.5 Environmental Hazards
- Low acute toxicity to aquatic organisms (96h LC₅₀ = 250 mg/L for zebrafish); low bioaccumulation potential; biodegradable in natural environment with no persistent residues.2.6 Other Hazards
- No additional hazards identified under normal pharmaceutical use conditions with strict PPE.

SECTION 3: Composition/Information on Ingredients

- Substance / Mixture: **Pure Substance**
- Active Ingredient: Articaine Hydrochloride (100%)
- CAS-No.: 23964-57-0
- EC-No.: N/A
- Hazardous components: 100% (Articaine Hydrochloride, GHS Category 3/2/2/3)

SECTION 4: First Aid Measures

4.1 Description of First-Aid Measures

- If Inhaled: Move the victim to fresh air immediately, keep at rest in a position comfortable for breathing. Administer oxygen if breathing is difficult. Call a POISON CENTER/doctor at once.
- In Case of Skin Contact: Immediately remove all contaminated clothing and shoes. Rinse skin with plenty of running water and mild soap for 15-20 minutes. Seek medical advice if irritation/rash persists for more than 24 hours.
- In Case of Eye Contact: **IMMEDIATE MEDICAL ATTENTION REQUIRED.** Hold eyelids open and rinse thoroughly with plenty of running water for at least 20 minutes. Remove contact lenses if present and easy to do. Do not rub eyes. Call a POISON CENTER/ophthalmologist immediately.
- If Swallowed: **DO NOT INDUCE VOMITING.** Rinse mouth with water. Do not give anything by mouth to an unconscious person. Call a POISON CENTER/doctor immediately and provide product information.

4.2 Most Important Symptoms and Effects

- Acute: Severe gastrointestinal discomfort, limb numbness, dizziness (swallowed); skin erythema, pruritus (contact); severe eye irritation, blurred vision (contact); cough, throat tightness (inhalation).
 - Delayed: Mild neurological numbness may occur 1-2 hours after excessive exposure; no other known delayed toxic effects with proper treatment.
- #### 4.3 Indication of Immediate Medical Attention
- All exposure scenarios (swallowing, eye contact, heavy inhalation) require **immediate professional medical attention**; symptomatic treatment in a hospital is recommended for severe exposure.

SECTION 5: Firefighting Measures

5.1 Extinguishing Media

- Suitable Extinguishing Media: Water spray, foam, carbon dioxide (CO₂), dry chemical powder.
 - Unsuitable Extinguishing Media: No limitations of extinguishing agents.
- #### 5.2 Special Hazards Arising from the Substance

- Non-combustible; slight decomposition at high temperature (>220°C) produces low-toxic amine, thiophene and hydrochloride fumes; no toxic/explosive gases released under normal fire conditions.
- #### 5.3 Advice for Firefighters
- Wear self-contained breathing apparatus (SCBA) and full chemical-resistant fire-fighting protective gear if decomposition fumes occur during fire.
 - Keep a safe distance from the fire scene; prevent fire-extinguishing water from entering municipal sewers or natural water bodies.

SECTION 6: Accidental Release Measures

6.1 Personal Precautions

- Wear N95 dust mask, chemical-resistant nitrile gloves, full face shield and impermeable lab coat. Ensure good ventilation at the spill site and evacuate all non-essential personnel.
- Do not touch the spilled powder with bare hands; avoid inhaling dust during the cleanup process.

6.2 Environmental Precautions

- Prevent spilled powder from entering sewers, rivers, lakes or soil. Cover the spill with inert material (sand/vermiculite) to avoid dust spreading and environmental contamination.

6.3 Methods and Materials for Containment and Cleaning Up

- Small Spill: Gently sweep up with a clean dry brush, collect into a sealed HDPE plastic container for professional hazardous waste disposal. Do not blow or vacuum the powder.
- Large Spill: Contain the spill with sandbags/dikes, transfer to a sealed HDPE drum with clear hazard labels, and hand over to a licensed hazardous waste treatment company. Do not wash the spill into drains or water bodies.

6.4 Reference to Other Sections

For waste disposal, see Section 13.

SECTION 7: Handling and Storage

7.1 Precautions for Safe Handling

- Operate in a well-ventilated dust-free negative pressure fume hood; use dust-free operation tools to avoid generating dust during weighing and mixing.
- Wear the specified full PPE for all handling operations; no eating, drinking, smoking or phone use in the work area.
- Wash hands, face and exposed skin thoroughly with soap and water after handling; take a shower if necessary.
- Avoid contact with strong acids, strong bases, oxidizing agents, heavy metal salts and high-temperature environments; do not mix with other pharmaceutical raw materials without professional guidance.

7.2 Conditions for Safe Storage

- Storage Conditions: Store in a **cool, dry, dark and locked** pharmaceutical warehouse. Temperature $\leq 25^{\circ}\text{C}$, relative humidity $\leq 60\%$. Keep the container tightly sealed with aluminum foil to prevent hygroscopy, light degradation and contamination.
- Incompatibilities: Strong acids (HCl, H_2SO_4), strong bases (NaOH, KOH), oxidizing agents (H_2O_2 , KMnO_4), heavy metal salts, alkaline pharmaceutical excipients, esterase-containing substances.
- Storage Class (TRGS 510): 6 (Toxic Solids with Irritant Properties)
- Shelf Life: 36 months (unopened, under the specified storage conditions).
- Segregation: Store separately from all other pharmaceutical raw materials, food, feed and cosmetics; place in a dedicated toxic substance storage area with warning signs.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters

- Occupational Exposure Limit (OEL): No official national/international OEL; internal strict control limit: 0.10 mg/m^3 (8-hour TWA, dust).

- Biological Limit Value (BLV): N/A.

8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency particulate air (HEPA) filter for all dust-generating operations; dust collection system with emission concentration $\leq 0.05 \text{ mg/m}^3$.
- Personal Protective Equipment (PPE):
 - Eye/Face Protection: Chemical-resistant full face shield (mandatory for all operations); safety goggles as secondary protection.
 - Skin Protection: Chemical-resistant nitrile rubber gloves (thickness $\geq 0.20 \text{ mm}$), impermeable anti-chemical lab coat, protective shoe covers and disposable arm covers.
 - Respiratory Protection: N95 dust mask for routine small-scale operations; powered air-purifying respirator (PAPR) for large-scale weighing/mixing.
 - Hand Protection: Replace gloves immediately if damaged, punctured or contaminated; change gloves every 2 hours for continuous operation.

SECTION 9: Physical and Chemical Properties

9.1 Basic Physical and Chemical Properties a) Physical State: Solid (white crystalline powder) b) Color: White to off-white c) Odor: Practically odorless d) Melting Point/Freezing Point: 174-178°C e) Boiling Point: Not applicable (decomposes before boiling) f) Flammability: Non-combustible g) Flammability Limits: Not applicable h) Flash Point: Not applicable i) Autoignition Temperature: > 450°C j) Decomposition Temperature: $\geq 220^{\circ}\text{C}$ (mild decomposition, produces low-toxic fumes) k) pH Value: 4.0-6.0 (1% aqueous solution, 25°C) l) Viscosity: Not applicable (solid) m) Water Solubility: Freely soluble in water (≈ 80 g/L, 25°C); freely soluble in ethanol, methanol; slightly soluble in acetone, ethern) Partition Coefficient (log P, n-octanol/water): 2.5 (25°C) o) Vapor Pressure (25°C): < 0.0001 hPa p) Density (25°C): 1.30-1.34 g/cm³ (bulk density) q) Particle Size: 95% passing 80 mesh r) Explosive Properties: Not explosives) Oxidizing Properties: None t) Hygroscopy: Slightly hygroscopic, slightly sensitive to light

SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under the recommended storage conditions ($\leq 25^{\circ}\text{C}$, dry, dark, sealed); stable under standard pharmaceutical processing temperature ($\leq 60^{\circ}\text{C}$) with light protection. 10.2 Possibility of Hazardous Reactions: No hazardous reactions under normal pharmaceutical use and processing conditions; mild hydrolysis may occur in moist and alkaline environment to produce non-toxic metabolites. 10.3 Conditions to Avoid: High temperature ($> 220^{\circ}\text{C}$), direct sunlight/ultraviolet light, high humidity, contact with incompatible materials, strong mechanical shock, alkaline environment. 10.4 Incompatible Materials: Strong acids, strong bases, oxidizing agents, heavy metal salts, reducing agents, alkaline pharmaceutical excipients, water with high pH value. 10.5 Hazardous Decomposition Products: Carbon dioxide, water vapor, low-toxic amine fumes, thiophene derivatives and hydrochloride fumes (at high temperature complete combustion/decomposition); non-toxic carboxylic acid derivatives produced by alkaline hydrolysis.

SECTION 11: Toxicological Information

11.1 Toxicological Effects

- Acute Toxicity:
 - Oral (Rat, LD₅₀): 38 mg/kg (Toxic)
 - Dermal (Rabbit, LD₅₀): 650 mg/kg (Harmful)
 - Inhalation (Rat, LC₅₀): 4 mg/m³ (4-hour exposure, Toxic)
- Skin Corrosion/Irritation: Rabbit 4-hour closed patch test - moderate redness, edema and rash (Category 2), reversible within 7 days with treatment.
- Eye Irritation/Damage: Rabbit eye test - severe conjunctival redness, mild corneal opacity (Category 2), reversible with treatment within 48 hours.
- Respiratory Irritation: Rat inhalation test - moderate bronchial spasm, cough and lung irritation at low dust concentrations (≥ 0.4 mg/m³).
- Mutagenicity: Ames test, chromosome aberration test - negative; no mutagenic effects.
- Carcinogenicity: IARC Classification - Group 3 (not classifiable as to carcinogenicity to humans).
- Reproductive Toxicity: High doses (≥ 15 mg/kg) in animal tests cause mild fetal developmental retardation; no adverse effects at low clinical dental doses.
- Specific Target Organ Toxicity: Nervous system is the main target organ; high dose causes nerve block, dizziness, limb numbness and mild central nervous system depression.

SECTION 12: Ecological Information

12.1 Toxicity

- Fish (Zebrafish, 96h LC₅₀): 250 mg/L
 - Daphnia (48h EC₅₀): 230 mg/L
 - Freshwater Algae (72h EC₅₀): 270 mg/L
- 12.2 Persistence and Degradability: Biodegradable (BOD₅/COD = 0.55); degraded by microorganisms in aquatic and soil environments within 25-30 days, no persistent residues. 12.3 Bioaccumulative Potential: Low (log P = 2.5); no significant bioaccumulation in aquatic organisms and food chain. 12.4 Mobility in Soil: Low mobility; strongly adsorbs to soil organic matter (K_{oc} = 580), no leaching risk to groundwater. 12.5

PBT/vPvB Assessment: Not classified as PBT/vPvB substances. 12.6 Other Adverse Effects: No known adverse effects on soil microorganisms and terrestrial plants at low concentrations; high concentration may cause mild inhibition of aquatic algae growth.

SECTION 13: Disposal Considerations

13.1 Waste Treatment Methods

- Product Waste: Contaminated/expired product is classified as **toxic hazardous waste**; must be disposed of by licensed hazardous waste treatment facilities via high-temperature incineration ($\geq 800^{\circ}\text{C}$) with flue gas treatment.
- Packaging Waste: Rinse packaging with ethanol and acidified water to remove residual powder, then dispose of as toxic hazardous waste; do not recycle or reuse any contaminated packaging.
- Unused Product: Do not discharge to the environment; incinerate with professional waste treatment companies in accordance with local national and international toxic waste regulations.
- Disposal Compliance: Comply with national and local hazardous waste disposal regulations (e.g., China HW02, EU EWC 080102, US RCRA Subtitle C).

SECTION 14: Transport Information

14.1 UN Number: ADR/RID: 2811; IMDG: 2811; IATA-DGR: 2811

14.2 UN Proper Shipping Name: Toxic solid, organic, n.o.s. (Articaine Hydrochloride)

14.3 Transport Hazard Class: 6.1 (Toxic substances)

14.4 Packaging Group: II (Moderate hazard)

14.5 Environmental Hazards: IMDG Marine Pollutant: **No**

14.6 Special Precautions for Transport

- Transport in sealed HDPE pharmaceutical-grade drums with aluminum foil inner lining and locked cover; affix standard Class 6.1 toxic hazard labels and product identification labels.
- Transport temperature $\leq 30^{\circ}\text{C}$; avoid direct sunlight, rain, collision, extrusion and rough handling during transport.
- Do not transport with food, feed, cosmetics, aquatic products and other pharmaceutical raw materials; transport in a dedicated compartment of specialized hazardous chemical vehicles.
- Comply with ADR/RID, IMDG Code and IATA-DGR transport regulations for Class 6.1 toxic substances; provide MSDS and transport approval documents for customs clearance.

SECTION 15: Regulatory Information

15.1 National/International Regulations

- China: Hazardous Chemicals Safety Management Regulation (Class 6.1 toxic chemical); Pharmaceutical Raw Material Registration Requirements for medical intermediates; Chinese Pharmacopoeia (CP) 2025 edition compliance; Special Control of Toxic Chemicals Regulations.
- EU: REACH (Annex XVII compliant; not in SVHC Candidate List); CLP (GHS classification as Danger); European Pharmacopoeia (EP) 10.0 compliance; ADR/RID Class 6.1 transport regulations.
- US: TSCA (listed on the TSCA Inventory); DOT Class 6.1 toxic material; FDA (compliant with pharmaceutical intermediate quality standards); United States Pharmacopoeia (USP) 47 compliance; RCRA toxic waste regulations.
- Japan: JP 17 compliance; Japanese Pharmaceutical Affairs Law; Japanese Poisonous and Deleterious Substances Control Law.
- Other: Comply with local pharmaceutical raw material import/export registration, toxic chemical control and hazardous chemical transport regulations of the destination country.

15.2 Additional Regulatory Requirements

- Provide English MSDS, COA and toxic chemical transport approval documents for customs clearance; apply for a special hazardous chemical storage license for on-site storage; provide product quality test reports and pharmacopoeia compliance certificates for pharmaceutical production use.

SECTION 16: Other Information

- Further Information: This MSDS is based on current scientific and regulatory knowledge, complying with GB/T 16483, GB/T 17519 and GHS Rev.9 standards. It is for professional



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occupational health and safety use only for trained operators, transport personnel and storage managers.

- Revision Date: 28 FEB 2026
- Disclaimer: The supplier is not liable for any damage, injury or environmental pollution caused by improper use, storage, transport or disposal of this product beyond the scope of the specified standards and national/international regulations. All operations must be conducted by trained professional personnel with strict compliance with relevant safety regulations.

