

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form	: Substance
Trade name	: ARTICAINE HYDROCHLORIDE
Chemical name	: methyl 4-methyl-3-[[2-(propylamino)propanoyl]amino]thiophene-2-carboxylate hydrochloride
IUPAC name	: Methyl 4-methyl-3-[(N-propylalanyl)amino]-2-thiophenecarboxylate hydrochloride (1:1)
EC-No.	: 245-957-7
CAS-No.	: 23964-57-0
Type of product	: Active Ingredient for Medicinal / Pharmaceutical Use
Formula	: C13H21ClN2O3S
Synonyms	: 2-thiophenecarboxylic acid, 4-methyl-3-[[1-oxo-2-(propylamino)propyl]amino]-, methyl ester, monohydrochloride; 4-Methyl-3-[[1-oxo-2-(propylamino)propyl]amino]-2-thiophenecarboxylic acid methyl ester hydrochloride; methyl 4-methyl-3-[(N-propylalanyl)amino]thiophene-2-carboxylate hydrochloride
Product group	: Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	: SMILES: CCCNC(C(=O)Nc1c(csc1C(=O)OC)C.Cl

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Main use category	: Industrial use
Industrial/Professional use spec	: Industrial For professional use only
Use of the substance/mixture	: Amide-type local anesthetic. Articaine hydrochloride is used for relief of pain in minor
Function or use category	: Pharmaceuticals

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet****Supplier**

MOEHS IBÉRICA, S.L.  
Roma, 8 - P.I. Cova Solera  
08191 Rubi  
Spain  
T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

MOEHS CATALANA, S.L.  
Cesar Martinell i Brunet, 12 A P.I. Rubi Sud  
08191 Rubi  
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T +34 93 586 05 20 - F +34 93 699 8350  
[hse@moehs.es](mailto:hse@moehs.es) - [www.moehs.com](http://www.moehs.com)

**Manufacturer**

BENECHIM S.R.L.  
rue René Magritte 163 (North Zoning)  
B-7860 Lessines  
Belgium  
T + 32 68 33 49 13

**1.4. Emergency telephone number**

Emergency number : +34 93 586 05 20 // +32(0) 70 245 245  
(9:00 - 17:00)

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Acute toxicity (oral), Category 4	H302
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 2	H319

# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation H335  
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412  
Full text of H- and EUH-statements: see section 16

### Adverse physicochemical, human health and environmental effects

No additional information available

## 2.2. Label elements

### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed.  
H315 - Causes skin irritation.  
H319 - Causes serious eye irritation.  
H335 - May cause respiratory irritation.  
H412 - Harmful to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.  
P264 - Wash hands, forearms and face thoroughly after handling.  
P270 - Do not eat, drink or smoke when using this product.  
P271 - Use only outdoors or in a well-ventilated area.  
P273 - Avoid release to the environment.  
P280 - Wear eye protection, face protection, protective gloves, protective clothing.  
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P312 - Call doctor if you feel unwell.  
P330 - Rinse mouth.  
P332+P313 - If skin irritation occurs: Get medical advice/attention.  
P337+P313 - If eye irritation persists: Get medical advice/attention.  
P403+P233 - Store in a well-ventilated place. Keep container tightly closed.  
P501 - Dispose of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

## 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type

: Mono-constituent

Name	Product identifier	%
ARTICAINE HYDROCHLORIDE	CAS-No.: 23964-57-0 EC-No.: 245-957-7	100

### 3.2. Mixtures

Not applicable

# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.
First-aid measures after skin contact	: Wash with plenty of water/.... Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion	: Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: May cause respiratory irritation.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Swallowing a small quantity of this material will result in serious health hazard.

#### 4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Foam. Dry powder. Carbon dioxide. Water spray. Sand.
Unsuitable extinguishing media	: Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard	: Dust may form explosive mixture in air.
Hazardous decomposition products in case of fire	: Carbon dioxide. fume. Carbon monoxide. Toxic fumes may be released.

#### 5.3. Advice for firefighters

Firefighting instructions	: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Evacuate unnecessary personnel.
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##### 6.1.2. For emergency responders

Protective equipment	: Equip cleanup crew with proper protection.
Emergency procedures	: Ventilate area.

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters. Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
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# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust. Use only outdoors or in a well-ventilated area.

Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in original container. Store at room temperature. Store in a well-ventilated place. Keep container tightly closed.

Incompatible products : Strong bases. Strong acids.

Incompatible materials : Sources of ignition. Direct sunlight.

### 7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 2 (0.1 - 1 mg/m<sup>3</sup>)

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

No additional information available

#### 8.2.2. Personal protection equipment

**Personal protective equipment:**

Avoid all unnecessary exposure.

**Personal protective equipment symbol(s):**



##### 8.2.2.1. Eye and face protection

**Eye protection:**

Chemical goggles or safety glasses

# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 8.2.2.2. Skin protection

#### Skin and body protection:

Wear suitable protective clothing

#### Hand protection:

Wear protective gloves.

Hand protection		
Type	Material	Standard
Disposable gloves	Nitrile rubber (NBR), Natural rubber, Polyvinylchloride (PVC), Polyvinylalcohol (PVA), Butyl rubber	EN ISO 374

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

Wear appropriate mask

Respiratory protection		
Device	Filter type	Standard
Dust mask	Type P3	EN 143

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: Local powder.
Molecular mass	: 320.87 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 177 – 178 °C
Freezing point	: Not available
Boiling point	: 340 – 441
Flammability	: Dust could form explosive mixtures with air
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: 220 – 251
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 4.2 – 4.9
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in water. Water: 0.002 – 0.007 mol/l
Partition coefficient n-octanol/water (Log Kow)	: -0.523 – 1.93
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: 1.18 – 1.25

# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Additional information	: Minimum ignition energy : 30-40 mJ. Dust Cloud minimum Flammability Temperature : 420 °C. Layer Minimum flammability Temperature : >400°C. Explosion Severity Factor Kmax (bar.m/s) : 225. Explosion Class : St2
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## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable in use and storage conditions as recommended in item 7.

### 10.3. Possibility of hazardous reactions

Stable under normal conditions of use.

### 10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

### 10.5. Incompatible materials

Strong acids. Strong bases.

### 10.6. Hazardous decomposition products

fume. Carbon monoxide. Carbon dioxide.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Harmful if swallowed.
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

### ARTICAINE HYDROCHLORIDE (23964-57-0)

LD50 oral rat	978 mg/kg
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Skin corrosion/irritation	: Causes skin irritation. pH: 4.2 – 4.9
Serious eye damage/irritation	: Causes serious eye irritation. pH: 4.2 – 4.9
Respiratory or skin sensitisation	: Not classified
Additional information	: Based on available data, the classification criteria are not met

# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Germ cell mutagenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Carcinogenicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Reproductive toxicity	: Not classified
Additional information	: Based on available data, the classification criteria are not met
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Additional information	: Based on available data, the classification criteria are not met
Aspiration hazard	: Not classified
Additional information	: Based on available data, the classification criteria are not met

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	: The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605
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#### 11.2.2. Other information

Potential adverse human health effects and symptoms	: Harmful if swallowed.
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## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - water	: Harmful to aquatic life with long lasting effects.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Harmful to aquatic life with long lasting effects.

#### ARTICAINE HYDROCHLORIDE (23964-57-0)

LC50 - Fish [1]	70.7 mg/l
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### 12.2. Persistence and degradability

#### ARTICAINE HYDROCHLORIDE (23964-57-0)

Persistence and degradability	May cause long-term adverse effects in the environment.
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### 12.3. Bioaccumulative potential

#### ARTICAINE HYDROCHLORIDE (23964-57-0)

Partition coefficient n-octanol/water (Log Kow)	-0.523 – 1.93
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### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties	: The substance/mixture has no endocrine disrupting properties.
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# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 12.7. Other adverse effects

Additional information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials : Avoid release to the environment.

## SECTION 14: Transport information

In accordance with / ADR / IMDG / IATA / ADN / RID

### 14.1. UN number or ID number

UN-No. (ADR) : Not applicable  
UN-No. (IMDG) : Not applicable  
UN-No. (IATA) : Not applicable  
UN-No. (ADN) : Not applicable  
UN-No. (RID) : Not applicable

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable  
Proper Shipping Name (IMDG) : Not applicable  
Proper Shipping Name (IATA) : Not applicable  
Proper Shipping Name (ADN) : Not applicable  
Proper Shipping Name (RID) : Not applicable

### 14.3. Transport hazard class(es)

**ADR**  
Transport hazard class(es) (ADR) : Not applicable

**IMDG**  
Transport hazard class(es) (IMDG) : Not applicable

**IATA**  
Transport hazard class(es) (IATA) : Not applicable

**ADN**  
Transport hazard class(es) (ADN) : Not applicable

**RID**  
Transport hazard class(es) (RID) : Not applicable

### 14.4. Packing group

Packing group (ADR) : Not applicable  
Packing group (IMDG) : Not applicable  
Packing group (IATA) : Not applicable  
Packing group (ADN) : Not applicable  
Packing group (RID) : Not applicable

### 14.5. Environmental hazards

Dangerous for the environment : No  
Marine pollutant : No  
Other information : No supplementary information available



# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

#### Inland waterway transport

Not applicable

#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

##### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

##### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

##### POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

##### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

##### Germany

- Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).  
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
- Water hazard class (WGK) : WGK 2, Significantly hazardous to water (Classification according to AwSV; ID No. 9533).
- Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

##### Netherlands

- SZW-lijst van kankerverwekkende stoffen : The substance is not listed
- SZW-lijst van mutagene stoffen : The substance is not listed

# ARTICAINE HYDROCHLORIDE

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed  
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

### Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

### Switzerland

Storage class (LK) : LK 11/13 - Solids

## 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
EC50	Median effective concentration
LC50	Median lethal concentration
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
LD50	Median lethal dose
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : None.

### Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H412	Harmful to aquatic life with long lasting effects.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.