

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

**Product Code(s)** MM0369.04-0100

**Product Name** Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate

Hydrochloride (Ethylarticaine Hydrochloride)

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article

6(1) and not subject to the registration requirements according to REACH Title II

EC No -

**CAS No** 2602451-79-4

Pure substance/mixture Substance

Formula C12H18N2O3S HCI

Molecular weight 306.81

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

#### Supplier

LGC Limited Queens Road Teddington Middlesex TW11 0LY UNITED KINGDOM :+44 (0) 20 8943 7000 Fax :+44 (0) 20 8943 2767

eMail: gb@lgcstandards.com

Web: www.lgcstandards.com

For further information, please contact

E-mail address sds-request@lgcgroup.com

1.4. Emergency telephone number

EGHS / EN Page 1/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

# MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

Emergency Telephone For Hazardous Materials or Dangerous Goods Incident

Spill, Leak, Fire Exposure, or Accident

Call CHEMTREC:

USA & Canada 1-800-424-9300 Rest of the world +1 703-741-5970

Emergency Telephone - §45 - (EC)1272/2008				
Europe	112			
Austria	No information available			
Bulgaria				
Croatia				
Cyprus				
Czech Republic				
Denmark				
France				
Hungary				
Ireland				
Italy				
Lithuania				
Luxembourg	(+352) 8002 5500 Free telephone number with a 24/7 access in French, Dutch and English.			
Netherlands				
Norway				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden				
Switzerland				

## **SECTION 2: Hazards identification**

## 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

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

## 2.2. Label elements

Contains Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

EGHS / EN Page 2/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)



## Signal word Warning

#### **Hazard statements**

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

## Precautionary Statements - EU (§28, 1272/2008)

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P280 - Wear protective gloves and eye/face protection

P337 + P313 - If eye irritation persists: Get medical advice/attention

P501 - Dispose of contents/ container to an approved waste disposal plant

#### 2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Chemical name	EU - REACH (1907/2006) - Article 59(1) - Candidate List of Substances of Very	EU - REACH (1907/2006) - Endocrine Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	·
Methyl	-	-
3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-met		
hylthiophene-2-carboxylate Hydrochloride		
(Ethylarticaine Hydrochloride)		

## **SECTION 3: Composition/information on ingredients**

## 3.1 Substances

Chemical name	Weight-%	REACH registration	EC No	Classification	Specific	M-Factor	M-Factor
		number		according to	concentration		(long-term)
				Regulation (EC) No.	limit (SCL)		

EGHS / EN Page 3/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

# MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

				1272/2008 [CLP]		
Methyl	100	-	-	Acute Tox. 4 (H302)		
3-[[(2RS)-2-(Ethyla				Skin Irrit. 2 (H315)		
mino)propanoyl]ami				Eye Irrit. 2 (H319)		
no]-4-methylthiophe						
ne-2-carboxylate						
Hydrochloride						
(Ethylarticaine						
Hydrochloride)						
2602451-79-4						

### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

## **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur.

**Eye contact** Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and

persists.

**Skin contact** Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

**Ingestion** Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. Call a doctor.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

**Symptoms** May cause redness and tearing of the eyes. Burning sensation.

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

EGHS / EN Page 4/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

**Note to doctors**Treat symptomatically.

## **SECTION 5: Firefighting measures**

5.1. Extinguishing media

surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

## SECTION 6: Accidental release measures

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

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal

protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

EGHS / EN Page 5/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

## SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash it before reuse.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face

protection.

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

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

## SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

### **Biological occupational exposure limits**

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

**Derived No Effect Level (DNEL)**No information available.
Predicted No Effect Concentration
No information available.

EGHS / EN Page 6/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

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(PNEC)

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are

likely to occur, wear safety glasses with side-shields.

**Hand protection** Wear suitable gloves. Impervious gloves. The protective gloves to be used must comply

with the specifications of EC Directive 89/686/EEC and the related standard EN374. Wear

protective nitrile rubber gloves. Wear protective butyl rubber gloves.

Skin and body protection Wear suitable protective clothing. Long sleeved clothing.

exceeded or irritation is experienced, ventilation and evacuation may be required.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face

protection.

**Environmental exposure controls** Do not allow into any sewer, on the ground or into any body of water.

## SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid Appearance Solid Colour white

OdourNo information available.Odour thresholdNo information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing point107 °CNone knownBoiling point / boiling rangeNo data availableNone knownFlammability (solid, gas)No data availableNone knownFlammability Limit in AirNone known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known

EGHS / EN Page 7/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 **Revision Number** 1

## MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate **Hydrochloride (Ethylarticaine Hydrochloride)**

No data available

**Autoignition temperature Decomposition temperature** 

No data available

None known None known

pH (as aqueous solution)

None known No data available

Kinematic viscosity **Dynamic viscosity** 

No information available None known

Water solubility Solubility(ies) **Partition coefficient** Vapour pressure

No data available No data available None known None known

Relative density No data available **Bulk density** No data available **Liquid Density** No data available

Relative vapour density

No data available None known

Particle characteristics

No information available **Particle Size Particle Size Distribution** No information available

9.2. Other information

Molecular weight 306.81

Molecular formula C12H18N2O3S HCI

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

## SECTION 10: Stability and reactivity

10.1. Reactivity

No information available. Reactivity

10.2. Chemical stability

Stability Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

EGHS / EN Page 8 / 16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

**Incompatible materials** Strong acids. Strong bases. Strong oxidising agents.

Hazardous decomposition products None known based on information supplied.

## SECTION 11: Toxicological information

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

#### Information on likely routes of exposure

#### **Product Information**

**Inhalation** Specific test data for the substance or mixture is not available.

**Eye contact** Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

**Ingestion** Specific test data for the substance or mixture is not available. Ingestion may cause

gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

No information available

**Acute toxicity** 

Delayed and immediate effects as well as chronic effects from short and long-term exposure

**Skin corrosion/irritation**Classification based on data available for ingredients. Irritating to skin.

EGHS / EN Page 9/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

**Respiratory or skin sensitisation** No information available.

Germ cell mutagenicity No information available.

**Carcinogenicity** No information available.

Reproductive toxicity No information available.

**STOT - single exposure** No information available.

**STOT - repeated exposure** No information available.

**Aspiration hazard** No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

11.2.2. Other information

Other adverse effects No information available.

## **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

EGHS / EN Page 10/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment This substance is not considered to be persistent, bioaccumulating nor toxic (PBT). This

substance is not considered to be very persistent nor very bioaccumulating (vPvB).

12.6. Endocrine disrupting properties

**Endocrine disrupting properties** No information available.

12.7. Other adverse effects

No information available.

## SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

## **SECTION 14: Transport information**

<u>IATA</u>

**14.1 UN number or ID number 14.2 UN proper shipping name**Not regulated Not regulated

14.3 Transport hazard class(es)14.4 Packing groupNot regulatedNot regulated

14.5 Environmental hazards Not applicable

14.6 Special precautions for user

Special Provisions None

EGHS / EN Page 11/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

**IMDG** 

14.1 UN number or ID number
14.2 UN proper shipping name
14.3 Transport hazard class(es)
14.4 Packing group
14.5 Marine pollutant
Not regulated
Not regulated
Not regulated
Not applicable

14.6 Special precautions for user

Special Provisions
None No information available
No information available

14.7 Maritime transport in bulk according to IMO instruments

RID

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

**ADR** 

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

## SECTION 15: Regulatory information

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

Water hazard class (WGK) slightly hazardous to water (WGK 1)

Poland SDS created according to the following Polish regulation: Act of February 25, 2011

on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as

EGHS / EN Page 12/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

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amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650). Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194, item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

## **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors Not applicable

Persistent Organic Pollutants Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

EGHS / EN Page 13/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

# MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

**TSCA** Contact supplier for inventory compliance status Contact supplier for inventory compliance status **DSL/NDSL** Contact supplier for inventory compliance status **EINECS/ELINCS** Contact supplier for inventory compliance status **ENCS IECSC** Contact supplier for inventory compliance status Contact supplier for inventory compliance status KECL Contact supplier for inventory compliance status **PICCS AICS** Contact supplier for inventory compliance status

#### Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

### 15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment has been carried out for this substance

## **SECTION 16: Other information**

## Key or legend to abbreviations and acronyms used in the safety data sheet

#### Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

#### Legend

SVHC: Substances of Very High Concern for Authorisation:

#### Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value \* Skin designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method

EGHS / EN Page 14/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

# MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

## Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 26-Jan-2022

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise

EGHS / EN Page 15/16



This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 26-Jan-2022 Revision Number 1

MM0369.04-0100 - Methyl 3-[[(2RS)-2-(Ethylamino)propanoyl]amino]-4-methylthiophene-2-carboxylate Hydrochloride (Ethylarticaine Hydrochloride)

when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. LGC makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**End of Safety Data Sheet** 

EGHS / EN Page 16/16