

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

LIDOCAINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Lidocaine hydrochloride Lidocaini hydrochloridum Lidocaïne hydrochloride Lidocaïne (chlorhydrate de) Lidocainhydrochlorid
N° CAS:	6108-05-0
N° EC:	200-803-8

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
------------------	--

1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 3	H301
Skin Irrit. 2	H315
Eye Irrit. 2	H319
Resp. Sens. 1	H334
STOT SE 3	H335

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

Toxic
Harmful

Hazard statements:

H301	Toxic if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

Precautionary statements:

P264	Wash thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P330	Rinse mouth.
P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P501	Dispose of contents/container in accordance with local/national/international regulations.

Additional applicable label elements:



2.3 Other hazards

None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Lidocaine hydrochloride
IUPAC name:	2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide;hydrate;hydrochloride
Synonyms:	Lidocaine hydrochloride monohydrate Lignocaine hydrochloride Dalcaine
N° CAS:	6108-05-0
N° EC:	200-803-8
Molecular Formula:	C ₁₄ H ₂₃ ClN ₂ O, H ₂ O
Content:	99.0 per cent to 101.0 per cent (anhydrous substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. Show the safety data sheet to the doctor on duty.
After inhalation:	Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial respiration if breathing stops or under medical supervision.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all contaminated clothing immediately. Get medical attention if irritation develops and persists.
After eye contact:	Remove contact lenses and rinse immediately with plenty of water, including under the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

Ingestion of even a small amount of this product can produce a serious health risk.

4.3 Indication of any immediate medical attention and special treatment needed

Do not administer anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Foam, dry powder, carbon dioxide, sand, water mist. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, fumes harmful to health may be produced.

5.3 Advice for firefighters

Surrounding fires:	Cool containers with water to prevent decomposition of product and development of potential health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and trousers with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of smoke, a self-contained breathing apparatus (EN 137).
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

For exposure control and personal protective measures, see section 8.

Equip clean-up personnel with appropriate protective equipment. Ventilate area and evacuate unnecessary personnel.

For emergency responders

For exposure control and personal protective measures, see section 8.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

Equip clean-up personnel with appropriate protective equipment. Ventilate area and evacuate unnecessary personnel.

6.2 Environmental precautions

Avoid penetration of the product into sewers, surface and ground water.

If product enters drains, notify authorities.

6.3 Methods and material for containment and cleaning up

Store away from other materials.

If on the ground, collect avoiding dust formation and dispose of in suitable containers.

Disposal of contaminated material should be carried out according to section 13.

6.4 Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:

Handle the product after consulting all other sections of this safety data sheet. Avoid dispersing product into the environment. Do not eat, drink or smoke during use. Remove contaminated clothing and protective equipment before entering eating areas.

Personal protection:

Not available.

Technical protective measures:

Not available.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Store only in original container. Keep container closed, in a well ventilated place.

Storage – away from:

Store protected from light. Store containers away from incompatible materials, see section 10.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction.

When choosing personal protective equipment, ask your chemical suppliers if this is necessary.

Personal protective equipment must be CE-marked for compliance with applicable regulations.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

Provide an emergency shower with a viscoelastic tray.

Hygiene measures: Handle with appropriate industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

Individual protection measures

Eye/face protection: Protective face shields and safety goggles according to EN166.

Skin protection: Choose body protection according to the quantity and concentration of the hazardous substance in the workplace.

Hand protection: Handle with gloves.

The selected protective gloves must comply with the specifications of EU Directive 89/686/EEC and the derived EN 374 standard.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143).

Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder.

Odour: Characteristic.

Odour threshold: Not available.

pH: 4.0 - 5.5 (0.5 %)

Melting/freezing point: 74 – 79 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

Evaporation rate: Not available.

Flammability (solid/gas): Not available.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: Not available.

Vapour density: Not available.

Relative density: Not available.

Solubility: Freely soluble in ethanol (96 per cent).

Solubility in water: Very soluble in water.

Partition coefficient (n-octanol/water): Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

Auto-ignition temperature: Not available.

Decomposition temperature: Not available.

Viscosity: Not available.

Explosive properties: Not available.

Oxidising properties: Not available.

9.2 Other information

Molecular weight: 288.80 g/mol

Density (25 °C): 0.353 g/mL

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No special conditions.

Stable under the recommended handling and storage conditions (see section 7).

10.2 Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3 Possibility of hazardous reactions

Heat decomposition may produce toxic fumes of CO, CO₂ and NO_x.

The product has no possibility of hazardous polymerisation.

10.4 Conditions to avoid

Avoid any type of incorrect handling: high pressures and/or temperatures.

Direct sunlight.

10.5 Incompatible materials

Strong acids and bases.

10.6 Hazardous decomposition products

Toxic fumes of carbon oxides (CO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Acute oral toxicity (LD₅₀, rat): 292 mg/kg

Skin corrosion/irritation: Not available.

Serious eye damage/irritation: Not available.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the

CMR properties:

Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Signs and Symptoms of Exposure: Central nervous system depression, dizziness, blurred vision, tremors, drowsiness, convulsions, unconsciousness. N° RTECS: AN7700000 Behaviour: Seizure or collapse threshold effects.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	Harmful if absorbed through skin. May cause skin irritation.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Ingestion:	Harmful if swallowed. Toxic if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.
Contaminated container: Dispose of as unused product.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

LIDOCAINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not available.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not available.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not available.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not available.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not available.

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (IATA).

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Toxic



Harmful

Risk phrases:

R25 Toxic if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

R42 May cause sensitisation by inhalation.

Safety phrases:

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

15.2 Chemical safety assessment

A chemical safety assessment of the product has not been carried out.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



LIDOCAINI HYDROCHLORIDUM

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available.

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending 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, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information has been compiled from sources considered to be dependable and is accurate to the best of the FSA NV's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. FSA NV cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

16.8 Department issuing MSDS

Quality Department

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

LIDOCAINI HYDROCHLORIDUM

EN

FORM-06-14-01 (V00)

Page 10/9

Publication: 29/09/2022

Revision: XX/XX/XXXX

Version: 00



FAC SECUNDUM ARTEM NV

info@magis-pharma.be