

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



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

#### 1.1 Product identifier

Product name:	Lidocaine Lidocainum Lidocaïne Lidocaine Lidocain
N° CAS:	137-58-6
N° EC:	205-302-8

#### 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:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk 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 toxicity (category 4)	H302
-----------------------------	------

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

P264 Wash thoroughly after handling.

# 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: 23/11/2022

Revision: 23/08/2024

Version: 01

## LIDOCAINUM



P270	Do not eat, drink or smoke when using this product.
P330	Rinse mouth.
P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P501	Dispose of contents/container in accordance with local/national/international regulations.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Lidocaine
IUPAC name:	2-(diethylamino)-N-(2,6-dimethylphenyl)acetamide
Synonyms:	Lignocaine Xylocaine Duncaine Esracaine Alphacaine
N° CAS:	137-58-6
N° EC:	205-302-8
Molecular Formula:	C <sub>14</sub> H <sub>22</sub> N <sub>2</sub> O
Content:	99.0 % to 101.0 % (anhydrous substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Consult a physician. 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.
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, also under 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.
Self-protection of the first aider:	Not applicable.

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



### 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 hazard.

### 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 if 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 avoid product decomposition and the development of potential health hazards. Always use complete fire protection. Collect water that should not enter sewage system. Dispose of contaminated water used to extinguish and the remains of the second in accordance with current regulations.
Protection against fire:	Helmet with visor, flame retardant clothing (jacket and pants with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or the car (self-protector) in the 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 the area and evacuate unnecessary personnel.

#### For emergency responders

Not available.

### 6.2 Environmental precautions

Avoid penetration of product into sewers, surface and ground water. If product reaches sewers, notify authorities.

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

Store away from other materials. If on the ground, collect avoiding the formation of dust and dispose of in suitable containers. Disposal of contaminated material should be carried out according to section 13.

### 6.4 Reference to other sections

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



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:	Store only in the original container. Keep container closed, in a well-ventilated place, away from direct sunlight.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	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 bear the CE marking attesting to compliance with applicable regulations. Provide an emergency shower with a visco-elastic 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 glasses according to EN166.
Skin protection:	Choose body protection according to the amount 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

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



approved under appropriate governmental standards such as NIOSH (USA) 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:	Not available.
Melting/freezing point:	66 – 70 °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:	(25 °C): 0.500 g/mL
Solubility:	Practically insoluble in water, very soluble in ethanol (96 %) and in methylene chloride.
Solubility in water:	Practically insoluble in water.
Partition coefficient (n-octanol/water):	Not available.
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: 234.34 g/mol

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



No special conditions. Stable under 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

Decomposition by heat may produce toxic fumes of CO, CO<sub>2</sub> and NO<sub>x</sub>. The product has no possibility of hazardous polymerization.

### 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<sub>x</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD <sub>50</sub> , rat): 317 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.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	N° RTECS: AN7525000

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	May cause eye irritation.
Skin contact:	Harmful if absorbed through the skin. May cause skin irritation.
Inhalation:	Harmful if inhaled. May cause respiratory tract irritation.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



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 to dispose 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 as unused product.

## SECTION 14: TRANSPORT INFORMATION

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

#### 14.1 UN Number

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

#### 14.2 UN proper shipping name

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

#### 14.3 Transport hazard class(es)

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

#### 14.4 Packing group

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

#### 14.5 Environmental hazards

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

#### 14.6 Special precautions for user

Not available.

# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



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

Not available.

### 14.8 Additional transport information

Not available.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

### 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

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



# Material Safety Data Sheet

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

## LIDOCAINUM

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 23/11/2022

Revision: 23/08/2024

Version: 01



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

FAC SECUNDUM ARTEM NV

info@magis-pharma.be