

# Material Safety Data Sheet

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

EN

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## AMITRIPTYLINI HYDROCHLORIDUM

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

#### 1.1 Product identifier

Product name: Amitriptyline hydrochloride  
Amitriptylini hydrochloridum  
Amitriptyline hydrochloride  
Amitriptyline (chlorhydrate d')

N° CAS: 549-18-8

N° EC: 208-964-6

#### 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
Repr. 2	H361
STOT SE 1	H370
Aquatic Chronic 1	H410

#### 2.2 Label elements

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

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H301	Toxic if swallowed.
H361	Suspected of damaging fertility or the unborn child.

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H370	Causes damage to organs.
H410	Very toxic to aquatic life with long lasting effects.
Precautionary statements:	
P202	Do not handle until all safety precautions have been read and understood.
P273	Avoid release to the environment.
P281	Use personal protective equipment as required.
P391	Collect spillage.
P311	Call a POISON CENTER or doctor/physician.
Additional applicable label elements:	

### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Amitriptyline hydrochloride
IUPAC name:	3-(10,11-Dihydro-5H-dibenzo[a,d][7]annulen-5-ylidene)-N,N-dimethylpropan-1-amine hydrochloride
Synonyms:	Tryptizol Lentizol
N° CAS:	549-18-8
N° EC:	208-964-6
Molecular Formula:	C <sub>20</sub> H <sub>23</sub> N.HCl
Content:	99.0 per cent to 101.0 per cent (dried substance)

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.
After inhalation:	May cause irritation. Assure fresh air breathing. Rest. In case of being unwell, seek medical advice.
After skin contact:	May cause irritation. Remove affected clothing and wash all exposed skin with mild soap and water, followed by warm water rinse.
After eye contact:	Causes severe irritation. Avoid contact. Flush with copious quantities of warm water for at least 15 minutes. Obtain medical attention, if pain, blinking, tears persist.
After ingestion:	May cause irritation and toxicity. Rinse mouth, if swallowed. This material is rapidly and well absorbed following ingestion.

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

Adverse human health effects

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Adverse effects may include gastrointestinal disturbances, drowsiness, dizziness, headache, dry mouth, bloating, tiredness, weakness, unpleasant taste, excessive sweating, blurred vision or eye pain, confusion, hallucinations, difficult urination, change in heart rate, trembling, fainting, nervousness or restlessness, difficulty speaking or swallowing, mask-like face, impaired sexual function, weight gain, trouble sleeping, loss of balance, and stiff movements. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

### Overdose effects

Symptoms of overdose include confusion; convulsions; disturbed concentration; severe drowsiness; enlarged pupils; fever; troubled breathing; severe weakness; severe vomiting; respiratory, cardiac and CNS depression, including coma; and other signs of adverse effects.

### Acute

Possible eye, skin, gastrointestinal, and/or respiratory tract irritation.

### Chronic

Possible hyper sensitisation.

### Medical conditions aggravated by exposure

Hypersensitivity to material, pre-existing heart disease, narrow-angle glaucoma, active alcoholism, concurrent use of monoamine oxidase inhibitors and other antidepressants, asthma, schizophrenia, bipolar disorder, gastrointestinal disorders, hyperthyroidism, enlarged prostate, urinary retention, seizure disorders, blood disorders, and impaired liver or kidney function.

### Cross sensitivity

Persons sensitive to one tricyclic antidepressant, carbamazepine, maprotiline, or trazodone may be sensitive to this material also.

### Target organs

Heart and central nervous system.

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

Note to physicians:

Overdose treatment: Treatment of overdose is essentially symptomatic and supportive, and may include the following:

1. Perform gastric lavage.
2. Administer activated charcoal slurry repeatedly, followed by a stimulant cathartic.
3. Maintain respiratory and cardiac function and body temperature.
4. Monitor cardiovascular function (ECG) for not less than 5 days.
5. Digitalize cautiously for congestive heart failure.
6. Control cardiac arrhythmias with lidocaine or by alkalinizing blood to pH 7.4 to 7.5 with intravenous sodium bicarbonate. Arrhythmias refractory to sodium bicarbonate may be managed with slow intravenous infusion of phenytoin while monitoring ECG. Propranolol is also effective but should be used with caution because of its negative inotropic and hypotensive effects. Quinidine and procainamide should be avoided.
7. Administer physostigmine salicylate, 1 to 3 mg (adults) by slow intravenous infusion over 2 to 3 minutes, to help reverse severe anticholinergic effects (myoclonic seizures, severe hallucinations, hypertension, and ventricular arrhythmias). Because of the short duration of action of physostigmine, dosage may need to be repeated at 30 to 60 minute intervals, especially if life-threatening symptoms occur. However, routine administration of physostigmine is not recommended because of its toxicity. Physostigmine should be reserved for patients in coma with respiratory depression, uncontrollable seizures, severe hypertension, or serious cardiac arrhythmias.
8. Use standard measures to manage circulatory shock and metabolic acidosis.
9. Administer anticonvulsants such as diazepam, paraldehyde, phenytoin, and an inhalation anesthetic to control convulsions.

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10. Dialysis of tricyclic antidepressants has not been successful because of their high-protein binding. In case of reactions described in hazards identification / toxicological information or other severe, immediate or persisting symptoms, seek medical advice and call the nearest poison centre. Show the label and this safety data sheet.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable extinguishing media: Not available.

#### 5.2 Special hazards arising from the substance/mixture

Fire and explosion hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.

#### 5.3 Advice for firefighters

Surrounding fires: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Protection against fire: Not available.

Hazardous combustion products: Incomplete combustion will generate poisonous carbon monoxide, carbon dioxide and other toxic gases.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

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

##### For non-emergency personnel

Remove ignition sources. Evacuate area. Avoid breathing dust. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

##### For emergency responders

Remove ignition sources. Evacuate area. Avoid breathing dust. Spill should be handled by trained cleaning personnel properly equipped with respiratory and eye protection.

#### 6.2 Environmental precautions

Prevent entry to sewers and public waters.

Notify authorities if product enters sewers or public waters.

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

Clean spills promptly using a high efficiency vacuum cleaner.

To clean the floor and all objects contaminated by this material, use: sodium hypochlorite solution.

Ensure adequate ventilation.

#### 6.4 Reference to other sections

Not available.

### SECTION 7: HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Precautions for safe handling: Not available.

Personal protection: Avoid all unnecessary exposure. Ensure prompt removal from eyes, skin and clothing.

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Technical protective measures:

Material should be handled in laboratory hood whenever possible.

Handling:

Handle in accordance with good industrial hygiene and safety procedures. Avoid all contact and inhalation of dust, mist and/or vapours associated with the material. Wash thoroughly after handling.

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

Storage:

This is not intended for long-term storage.

Conditions for safe storage, including any incompatibilities:

Keep container tightly closed in a cool, well-ventilated place.

Storage – away from:

Protected from light. All heat sources, including direct sunlight. Open flame. Sources of ignition. Sparks. 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

Provide local exhaust or general room ventilation.

Material should be handled in a laboratory hood whenever possible.

#### Individual protection measures

Eye/face protection: Chemical goggles or safety glasses.

Skin protection: Wear suitable protective clothing.

Hand protection: Wear suitable gloves resistant to chemical penetration.

Respiratory protection: Wear approved mask. (P2)

In case of insufficient ventilation, wear suitable respiratory equipment.

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 powder or colourless crystals.

Odour: Odorless or nearly odorless .

Odour threshold: n/f

pH: 5.0 – 6.0 (1% aqueous solution)

Melting/freezing point: 196 °C – 197 °C

Initial boiling point: n/f

Boiling range: Not available.

Flash point: n/f

Evaporation rate: n/f

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Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	n/f
Vapour pressure:	< 1 mm Hg (20 °C)
Vapour density:	n/f
Relative density:	n/f
Solubility:	Freely soluble in ethanol (96 per cent), chloroform and in methylene chloride.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	n/f
Auto-ignition temperature:	n/f
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	n/f
Oxidising properties:	n/f

### 9.2 Other information

Molecular weight: 313.9

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

Stable under normal conditions of use.

### 10.3 Possibility of hazardous reactions

None under normal conditions.

Hazardous polymerization: Will not occur.

### 10.4 Conditions to avoid

Moisture. Direct sunlight. Heat. Sparks.

### 10.5 Incompatible materials

Strong oxidizers.

Bases.

### 10.6 Hazardous decomposition products

When heated to decomposition, emits dangerous fumes.

Nitrogen oxides.

Carbon dioxide.

Carbon monoxide.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (rat): 240 mg/kg
	Oral LD <sub>50</sub> (mouse): 140 mg/kg
	Oral LD <sub>50</sub> (cat): 37 mg/kg

Skin corrosion/irritation:	Rabbit: slight irritation.
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Serious eye damage/irritation:	Rabbit: severe irritation.
Respiratory/skin sensitisation:	n/f
Germ cell mutagenicity:	Negative in Ames test.
Carcinogenicity:	Not listed as a carcinogen by NTP, IARC and OSHA.
Reproductive toxicity:	Adequate and well-controlled pregnancy studies in humans have not been done. However, animal studies have shown that amitriptyline causes birth defects when used in doses many times the human dose. Withdrawal symptoms have been observed in infants whose mothers received tricyclic antidepressants immediately prior to delivery.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Not available.

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

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Toxic if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

LC<sub>50</sub> – 96 h – fish: 0.31 mg/L

### 12.2 Persistence and degradability

Not available.

### 12.3 Bioaccumulative potential

Not available.

### 12.4 Mobility in soil

Log P octanol/water at 20 °C: 4.9

### 12.5 Results of PBT and vPvB assessment

Not available.

### 12.6 Other adverse effects

Environmental precautions: Avoid release to the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

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General: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.

Special precautions: This product contains hazardous components for the environment. Avoid release to the environment.

### SECTION 14: TRANSPORT INFORMATION

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

##### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), 3077  
IATA/ICAO (Air) :

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Environmentally Hazardous Substance, Solid, N.O.S. (Amitriptyline hydrochloride)  
IATA/ICAO (Air) :

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), 9  
IATA/ICAO (Air) :

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), III  
IATA/ICAO (Air) :

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IMDG – Marine pollution: Yes.  
IATA/ICAO (Air) :

##### 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

Not available.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

Toxic Harmful Harmful to the environment

R20/21/22 Harmful by inhalation, in contact with skin and if swallowed.

R25 Toxic if swallowed.

R39 Danger of very serious irreversible effects.

R41 Risk of serious damage to eyes.

R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R62 Possible risk of impaired fertility.

R63 Possible risk of harm to the unborn child.



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### Safety phrases:

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

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

S53 Avoid exposure - obtain special instructions before use.

S61 Avoid release to the environment. Refer to special instructions/Safety data sheets.

### 15.2 Chemical safety assessment

Not available.

## 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

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.

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### 16.8 Department issuing MSDS

Quality Department

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