



METAPHARMACEUTICAL IND SL

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FICHA SEGURIDAD de acuerdo el Reglamento (CE) No. 1907/2006

MEXILETINE HCl

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name : MEXILETINE HYDROCHLORIDE

Chemical Name: 1-methyl-2-(2,6-xylyloxy)ethylammonium chloride

CAS No. 5370-01-4

EINECS No. 226-362-1

REACH Registration No. Not applicable.

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

Identified use(s) Antiarrhythmic

Compañía distribuidora: **METAPHARMACEUTICAL IND. S. L.**

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URGENCIAS TOXICOLÓGICAS (24H)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

According to Regulation (EC) No. 1272/2008 (CLP)

Acute Tox. 4 , H302: Harmful if swallowed.

According to Directive 67/548/EEC & Directive 1999/45/EC

Xn , R22: Harmful if swallowed.

2.2 Label elements

Label elements

Hazard pictogram(s)



Signal word(s)	Warning
Hazard statement(s)	H302: Harmful if swallowed.
Precautionary statement(s)	P261: Avoid breathing dust/fume/gas/mist/vapours/spray. P301 + P312: IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell.
Label elements	
Xn	
Risk Phrases	R22: Harmful if swallowed.
Safety Phrases	S22: Do not breathe dust. S24/25: Avoid contact with skin and eyes. S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.

2.3 Information pertaining to special dangers for human and environment

Exposure to mexiletine hydrochloride may produce adverse events mainly in gastrointestinal, cardiac and nervous systems.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

According to Regulation (EC) No. 1272/2008 (CLP)

Hazardous ingredient(s)	CAS No.	Hazard pictogram(s)	Hazard statement(s)
1-methyl-2-(2,6-xylyloxy)ethylammonium chloride	5370-01-4	GHS07	H302

For full text of H/P phrases see section 16.

According to Directive 67/548/EEC & Directive 1999/45/EC

Hazardous ingredient(s)	CAS No.	Hazard Symbol	Risk Phrases
1-methyl-2-(2,6-xylyloxy)ethylammonium chloride	5370-01-4	Xn	R22

For full text of R phrases see section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

Inhalation	Remove persons affected by vapour to fresh air. If breathing becomes difficult, call a physician. Apply artificial respiration only if patient is not breathing or under medical supervision.
Skin Contact	Remove contaminated clothing immediately and drench affected skin with plenty of water, then wash with soap and water. Continue to wash the affected area for at least 15 minutes. If symptoms occur obtain medical attention. Contaminated clothing should be thoroughly cleaned.

Eye Contact	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes. If symptoms occur obtain medical attention.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). Do not give anything by mouth to an unconscious or convulsing person. Seek medical treatment.

4.2 Most important symptoms and effects, both acute and delayed

Mexiletine overdose may cause drowsiness, confusion, nausea, hypotension, sinus bradycardia, paresthesia, seizures, and cardiovascular adverse events.

4.3 First-aid equipment and medical advice for special treatment.

Symptomatic treatment and supportive therapy as indicated.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Extinguish with carbon dioxide, dry chemical, foam or waterspray.

5.2 Special hazards arising from the substance or mixture

Dike fire control water for later disposal. Disposal should be in accordance with local, state or national legislation. Contain effluent and prevent effluent from entering sewers and waterways. Contain the goods or any materials used in fire fighting.

5.3 Special protective equipment and precautions for fire fighters

A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear suitable respiratory protective equipment. Wear suitable protective clothing, gloves and eye/face protection. Contaminated clothing should be thoroughly cleaned.

6.2 Environmental precautions

Eliminate sources of ignition. Sweep up spilled substance but avoid making dust. Transfer to a container for disposal or recovery. Disposal should be in accordance with local, state or national legislation. Ventilate area and wash spill site after material pick up is complete.

6.3 Methods and materials for containment and cleaning up

Evacuate the area. Contain spillages. Do not allow to enter drains, sewers or watercourses. Transfer to a container for disposal or recovery.

6.4 Reference to other sections

Collect mechanically and dispose of according to Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use only in well-ventilated areas.
Do not breathe dust. Control dust formation.
Avoid contact with skin and eyes.
When using do not eat, drink or smoke.
Wash hands and exposed skin after use.
Contaminated clothing should be thoroughly cleaned.

7.2 Conditions for safe storage, including any incompatibilities
Keep container tightly closed.

7.3 Specific end use(s)
Antiarrhythmic

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational Exposure Limits

No Occupational Exposure Limit assigned.

8.2 Exposure controls

Engineering Controls

Provide adequate ventilation when using the material and follow the principles of good occupational hygiene to control personal exposures.

Personal protection equipment

Eye/face protection

Safety spectacles.

Skin protection

Wear suitable gloves.

Respiratory protection

Where engineering controls are not fitted or inadequate wear suitable respiratory protective equipment.

Environmental exposure controls

Consideration should be given to the work procedures involved and the potential extent of exposure as they may determine whether a higher level of protection is required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Form	Crystalline powder.
Colour	White. Off-white.
Odour	Odourless.
Odour Threshold (ppm)	Not applicable.
pH (Value)	Not applicable.
Melting Point (°C)	203-205 °C
Boiling Point (°C)	Not applicable.
Flash Point (°C)	Not applicable.
Flammability (solid, gas)	Not available.
Vapour Pressure (mm Hg)	Not applicable.
Vapour Density (Air=1)	Not applicable.
Density (g/ml)	Not applicable.
Solubility (Water)	Freely soluble in water.
Partition Coefficient	Not available.
Auto Ignition Temperature (°C)	Not available.
Decomposition Temperature (°C)	Not available.
Viscosity (mPa.s)	Not applicable.
Explosive Properties	Not available.
Oxidising Properties	Not available.

9.2 Additional Information

As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material in order to dissipate the potential build-up of static electricity.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical Stability

Stable under normal conditions.

10.3 Hazardous Reactions

None known.

10.4 Conditions to avoid

Keep away from heat, sources of ignition and direct sunlight.

10.5 Incompatible materials:

Keep away from strong acids, strong bases and oxidizing agents.

10.6 Hazardous Decomposition Product(s)

Combustion or thermal decomposition will evolve toxic vapours.

11. TOXICOLOGICAL INFORMATION

11.1 General information

See Section: 2

11.2 Information on toxicological effects

Acute toxicity

Ingestion

Oral Median Lethal Dose (rat) = 330 mg/kg
TDL0 (oral, woman) = 360 mg/kg. Adverse effects:
convulsions or effect on seizure threshold, coma, dyspnea.

Inhalation

No information available. May be harmful if inhaled.

Skin Contact

No information available. May be harmful in contact with skin.

Eye Contact

No information available.

skin corrosion/irritation

May cause irritation.

Eyes corrosion/irritation

May cause irritation.

Respiratory/skin sensitization

No information available.

Mutagenicity

There is no evidence of mutagenic potential.

Carcinogenicity

There is no evidence that this product represents a carcinogenic risk under normal conditions of handling and use.

Reproductive toxicity

No evidence of teratogenic potential or impaired fertility have been observed in animal studies, but an increase in fetal resorption has been observed.
Avoid contact during pregnancy/while nursing.

STOT-single exposure

May cause respiratory irritation.

STOT-repeated exposure

No information available.

Aspiration hazard

Not known.

12. ECOLOGICAL INFORMATION

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Bury on an authorised landfill site or incinerate under approved controlled conditions, using incinerators suitable for the disposal of noxious chemical waste.

Additional Information

Disposal should be in accordance with local, state or national legislation.

14. TRANSPORT INFORMATION

Not classified as dangerous for transport.

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

Self classification:

Acute Tox. 4 , H302: Harmful if swallowed.

15.2 Chemical Safety Assessment

Not applicable.

16. OTHER INFORMATION**16.1 The following sections contain revisions or new statements:**

The whole document: According to Regulation (EC) No. 1272/2008 (CLP)

16.2 GLOSSARY

H-statements:

H302: Harmful if swallowed.

Risk Phrases :

R22: Harmful if swallowed.

16.3 References:

None.

16.4 Additional Information

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