

Pilocarpine hydrochloride

Safety Data Sheet

258504

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Date of issue: 10/11/2011 Revision date: 06/01/2017

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

1.1. Product identifier

Product form : Substance
Substance name : Pilocarpine hydrochloride
IUPAC name : (3S,4R)-3-Ethyl-4-[(1-methyl-1H-imidazol-5-yl)methyl]-dihydrofuran-2(3H)-one hydrochloride
EC index no : 614-017-00-1
EC no : 200-212-5
CAS No : 54-71-7
Product code : 258504
Formula : C₁₁H₁₇CIN₂O₂
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity (inhal.), Category 2 H330
Acute toxicity (oral), Category 2 H300

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Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

Nervous system disorder. Damage to kidneys. Depression of the central nervous system. Reduced blood pressure. Exposure may produce an allergic reaction. May produce irregular heart beat and nervous symptoms. Gastrointestinal complaints. Muscle weakness.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)

:



GHS06

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H330 - Fatal if inhaled
H300 - Fatal if swallowed

Precautionary statements (CLP)

: P260 - Do not breathe dust
P264 - Wash hands, forearms and face thoroughly after handling
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P284 - [In case of inadequate ventilation] wear respiratory protection
P301+P310 - IF SWALLOWED: immediately call a POISON CENTER or doctor/physician

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substance

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Pilocarpine hydrochloride	(CAS No) 54-71-7 (EC no) 200-212-5 (EC index no) 614-017-00-1	99 - 101	Acute Tox. 2 (Inhalation), H330 Acute Tox. 2 (Oral), H300

Full text of H-statements: see section 16

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove victim to fresh air. If not breathing, give artificial respiration. Seek medical attention immediately.

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- First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse. Seek medical attention if ill effect or irritation develops.
- First-aid measures after eye contact : Rinse immediately with plenty of water. Seek medical advice.
- First-aid measures after ingestion : Rinse mouth. Induce vomiting. Give water to drink. Seek medical attention immediately.

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

- Symptoms/injuries : Dilated pupils. Cramps. Sweating. Breathing difficulties. Gastrointestinal complaints. Cardiac and blood circulation effects. Nervous system disorder. Damage to kidneys.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Chlorine. Nitrogen oxides.
- Explosion hazard : Large amounts: Risk of dust explosion.

5.3. Advice for firefighters

- Firefighting instructions : Prevent fire fighting water from entering the environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Evacuate area.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. Wear respiratory protection.
- Emergency procedures : Ensure adequate air ventilation. Avoid raising powdered materials into airborne dust.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.
Material should be handled in a laboratory hood whenever possible.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from moisture. Protect from sunlight.

Maximum storage period : 5 year

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

Respiratory protection:

Dust production: dust mask with filter type P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
 Appearance : Crystalline powder. Crystalline solid.
 Molecular mass : 244.7 g/mol
 Colour : white.
 Odour : weak.
 Odour threshold : No data available
 pH : 3.5 - 4.5
 pH solution : 5 %
 Relative evaporation rate (butylacetate=1) : No data available
 Melting point : 202 - 205 °C
 Freezing point : No data available
 Boiling point : No data available
 Flash point : No data available

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Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 400 - 550 kg/m ³
Solubility	: Soluble in ethanol. Water: 1000 g/l
Log Pow	: -3.03
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions. May decompose under the influence of light.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

heat. Moisture. Light (daylight).

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

No additional information available

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Inhalation: Fatal if inhaled. Oral: Fatal if swallowed.

Pilocarpine hydrochloride (54-71-7)	
LD50 oral rat	200 mg/kg

Skin corrosion/irritation	: Not classified pH: 3.5 - 4.5
Serious eye damage/irritation	: Not classified pH: 3.5 - 4.5
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified

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Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Pilocarpine hydrochloride (54-71-7)	
Log Pow	-3.03

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available


SECTION 13: Disposal considerations

13.1. Waste treatment methods

No additional information available

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IATA
14.1. UN number	
1544	1544
14.2. UN proper shipping name	
ALKALOIDS, SOLID, N.O.S. / ALKALOID SALTS, SOLID, N.O.S.	Not applicable
14.3. Transport hazard class(es)	
6.1	6.1
	Not applicable
14.4. Packing group	
II	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

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14.6. Special precautions for user

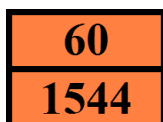
- Overland transport

Classification code (ADR) : T2

Excepted quantities (ADR) : E4

Hazard identification number (Kemler No.) : 60

Orange plates :



Tunnel restriction code (ADR) : D/E

EAC code : 2X

- Air transport

No data available

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Pilocarpine hydrochloride is not on the REACH Candidate List

Pilocarpine hydrochloride is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.4	Emergency telephone	Modified	Added additional information
2	R-phrases	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves
8.2	Skin and body protection	Modified	Added additional information (type of clothing related to concentration levels)

Full text of H- and EUH-statements:

Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
H300	Fatal if swallowed
H330	Fatal if inhaled

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product