

Amitriptyline hydrochloride

Safety Data Sheet

421642

Version: 3.1

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 21/02/2012 Revision date 13/11/2019
 Supersedes 27/03/2019

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

1.1. Product identifier

Product form : Substance
 Substance name : Amitriptyline hydrochloride
 IUPAC name : 3-(10,11-Dihydro-5H-dibenzo[a,d][7]annulen-5-ylidene)-N,N-dimethylpropan-1-amine hydrochloride
 EC-No. : 208-964-6
 CAS-No. : 549-18-8
 Product code : 421642
 Formula : C20H24ClN
 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 industry
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
 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 - The Netherlands
 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)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 3	H301
Serious eye damage/eye irritation, Category 2	H319
Hazardous to the aquatic environment — Acute Hazard, Category 1	H400
Hazardous to the aquatic environment — Chronic Hazard, Category 1	H410

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)



GHS06

GHS09

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed.
H319 - Causes serious eye irritation.
H410 - Very toxic to aquatic life with long lasting effects.

Precautionary statements (CLP)

: P273 - Avoid release to the environment.
P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor
P330 - Rinse mouth.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Amitriptyline hydrochloride	(CAS-No.) 549-18-8 (EC-No.) 208-964-6	99 - 101	Acute Tox. 3 (Oral), H301 Eye Irrit. 2, H319 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove victim to fresh air Seek medical advice.
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 If irritation persists, consult a doctor.
First-aid measures after eye contact	: Rinse immediately with plenty of water Seek medical advice.
First-aid measures after ingestion	: Rinse mouth. Seek medical attention immediately.

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

Symptoms/effects	: The most important known symptoms and effects are described in the labelling (see section 2.2) and/or section 11.
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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	: Carbon dioxide Dry powder Foam Water spray.
Unsuitable extinguishing media	: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Explosion hazard	: Product is not explosive.
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Hazardous decomposition products in case of fire : Toxic and irritating gases are released
hydrogen chloride
Nitrogen oxides
Carbon dioxide
Carbon monoxide.

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

6.1.1. For non-emergency personnel

Emergency procedures : Ensure adequate air ventilation. Avoid raising dust. Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear proper protective equipment.

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. Hose down area with water.

6.4. Reference to other sections

See Heading 13. See Heading 8.

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.

7.2. Conditions for safe storage, including any incompatibilities

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

Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

see chapter 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Gloves. Protective goggles. Dust/aerosol mask with filter type P3.

Hand protection:

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filtertype P3



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 313.9 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: ca. 196 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
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

Solubility	: Freely soluble in water Soluble in ethanol Soluble in methylene chloride.
Log Pow	: No data available
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.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Light (daylight)
Moisture
heat.

10.5. Incompatible materials

Strong oxidizers
Bases.

10.6. Hazardous decomposition products

Carbon dioxide
Carbon monoxide
Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Toxic if swallowed.

Amitriptyline hydrochloride (549-18-8)	
LD50 oral rat	240 mg/kg
LD50 oral	140 mg/kg mouse

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Rabbit result: Eye irritation
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Amitriptyline hydrochloride (549-18-8)	
LC50 fish 1	0.25 mg/l 96 hour
EC50 Daphnia 1	0.39 mg/l 24 hour
ErC50 (algae)	0.16 mg/l 72 hour

12.2. Persistence and degradability

Amitriptyline hydrochloride (549-18-8)	
Persistence and degradability	Product is practically not biodegradable.

12.3. Bioaccumulative potential

Amitriptyline hydrochloride (549-18-8)	
Bioaccumulative potential	No bioaccumulation data available.

12.4. Mobility in soil

Amitriptyline hydrochloride (549-18-8)	
Ecology - soil	There are no available data for a classification.

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

Waste treatment methods	: Avoid release to the environment.
Product/Packaging disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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



ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.

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ADR	IATA
14.3. Transport hazard class(es)	
6.1	6.1
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : Yes	Dangerous for the environment : Yes
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Classification code (ADR) : T2
Special provisions (ADR) : 274, 614
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P002, IBC08, LP02, R001
Special packing provisions (ADR) : B3
Mixed packing provisions (ADR) : MP10
Portable tank and bulk container instructions (ADR) : T1
Portable tank and bulk container special provisions (ADR) : TP33
Tank code (ADR) : SGAH, L4BH
Tank special provisions (ADR) : TU15, TE19
Vehicle for tank carriage : AT
Transport category (ADR) : 2
Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7
Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28
Special provisions for carriage - Operation (ADR) : S9
Hazard identification number (Kemler No.) : 60
Orange plates : 
Tunnel restriction code (ADR) : E
EAC code : 2X

- Air transport

PCA Excepted quantities (IATA) : E1
PCA Limited quantities (IATA) : Y645

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PCA limited quantity max net : 10kg
quantity (IATA)
PCA packing instructions (IATA) : 670
PCA max net quantity (IATA) : 100kg
CAO packing instructions (IATA) : 677
CAO max net quantity (IATA) : 200kg
Special provisions (IATA) : A3, A5
ERG code (IATA) : 6L

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

Amitriptyline hydrochloride is not on the REACH Candidate List

Amitriptyline 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			Duchefa logo change
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : EP. Supplier. EDQM.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1

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Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

SDS EU (REACH Annex II) duchefa nieuwe logo

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.