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

1.1 Product identifiers
Product name: Amitriptyline Hydrochloride
CAS-No.: 549-18-8

1.2 Relevant identified uses of the substance or mixture and uses advised against
Identified uses: Laboratory chemicals, Industrial & for professional use only.

1.3 Details of the supplier of the safety data sheet
Company: Central Drug House (P) Ltd
7/28 Vardaan House
New Delhi-10002
INDIA
Telephone: +91 11 49404040
Email: care@cdhfinechemical.com

1.4 Emergency telephone number
Emergency Phone #: +91 11 49404040 (9:00am - 6:00 pm) [Office hours]

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification according to Regulation (EC) No 1272/2008
Acute toxicity, Oral (Category 3), H301
Eye irritation (Category 2), H319
Acute aquatic toxicity (Category 1), H400
Chronic aquatic toxicity (Category 1), H410

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements
Labelling according Regulation (EC) No 1272/2008
Pictogram

Signal word: Danger
Hazard statement(s)
H301 Toxic if swallowed.
H319 Causes serious eye irritation.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statement(s)
P273 Avoid release to the environment.
P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P501 Dispose of contents/container to an approved waste disposal plant.

Supplemental Hazard Statements

2.3 Other hazards - none

SECTION 3: Composition/information on ingredients

3.1 Substances

Formula: C20H23N · HCl
Molecular weight: 313.86 g/mol
CAS-No.: 549-18-8
EC-No.: 208-964-6

Hazardous ingredients according to Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Component</th>
<th>Classification</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amitriptyline hydrochloride</td>
<td>Acute Tox. 3; Eye Irrit. 2;</td>
<td>&lt;= 100 %</td>
</tr>
<tr>
<td>CAS-No.</td>
<td>549-18-8</td>
<td></td>
</tr>
<tr>
<td>EC-No.</td>
<td>208-964-6</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Aquatic Acute 1; Aquatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Chronic 1; H301, H319, H400,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td>M-Factor - Aquatic Acute: 1</td>
<td></td>
</tr>
</tbody>
</table>

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance.

If inhaled
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact
Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If swallowed
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed
The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed
No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
5.2 **Special hazards arising from the substance or mixture**
Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas

5.3 **Advice for firefighters**
Wear self-contained breathing apparatus for firefighting if necessary.

5.4 **Further information**
No data available

SECTION 6: Accidental release measures

6.1 **Personal precautions, protective equipment and emergency procedures**
Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 **Environmental precautions**
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 **Methods and materials for containment and cleaning up**
Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 **Reference to other sections**
For disposal see section 13.

SECTION 7: Handling and storage

7.1 **Precautions for safe handling**
Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 **Conditions for safe storage, including any incompatibilities**
Store in cool place. Keep container tightly closed in a dry and well-ventilated place.
Recommended storage temperature 2 - 8 °C
Keep in a dry place.
Storage class (TRGS 510): Combustible Solids

7.3 **Specific end use(s)**
Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 **Control parameters**

8.2 **Exposure controls**

**Appropriate engineering controls**
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

**Personal protective equipment**

**Eye/face protection**
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

**Skin protection**
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
Body Protection
Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection
Where risk assessment shows air-purifying respirators are appropriate use (EN 143) respirator cartridges as a backup to engineering controls. If full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
a) Appearance
   Form: powder
   Colour: white
b) Odour
   No data available
c) Odour Threshold
   No data available
d) pH
   5.0 - 6.0 at 10 g/l
e) Melting point/freezing point
   Melting point/range: 198 - 200 °C
f) Initial boiling point and boiling range
   No data available
g) Flash point
   No data available
h) Evaporation rate
   No data available
i) Flammability (solid, gas)
   No data available
j) Upper/lower flammability or explosive limits
   No data available
k) Vapour pressure
   No data available
l) Vapour density
   No data available
m) Relative density
   No data available
n) Water solubility
   Soluble
o) Partition coefficient: n-octanol/water
   log Pow: 5.0
p) Auto-ignition temperature
   No data available
q) Decomposition temperature
   No data available
r) Viscosity
   No data available
s) Explosive properties
   No data available
t) Oxidizing properties
   No data available

9.2 Other safety information
   No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
   No data available
10.2 Chemical stability
Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions
No data available

10.4 Conditions to avoid
No data available

10.5 Incompatible materials
Strong oxidizing agents

10.6 Hazardous decomposition products
Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride gas
Other decomposition products - No data available
In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity
LD50 Oral - Rat - 240 mg/kg(Amitriptyline hydrochloride)
LDLO Oral - Human - female - 19 mg/kg(Amitriptyline hydrochloride)

Skin corrosion/irritation
No data available(Amitriptyline hydrochloride)

Serious eye damage/eye irritation
Eyes - Rabbit(Amitriptyline hydrochloride)
Result: Irritating to eyes.

Respiratory or skin sensitisation
No data available(Amitriptyline hydrochloride)

Germ cell mutagenicity
No data available(Amitriptyline hydrochloride)

Carcinogenicity
IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity
May cause congenital malformation in the fetus.(Amitriptyline hydrochloride)

Specific target organ toxicity - single exposure
No data available(Amitriptyline hydrochloride)

Specific target organ toxicity - repeated exposure
No data available

Aspiration hazard
No data available(Amitriptyline hydrochloride)

Additional Information
RTECS: HO9450000

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SECTION 12: Ecological information

12.1 Toxicity

Toxicity to fish
LC50 - Oncorhynchus mykiss (rainbow trout) - 0.25 mg/l - 96 h(Amitriptyline hydrochloride)  
(OECD Test Guideline 203)

Toxicity to daphnia and other aquatic invertebrates
EC50 - Daphnia magna (Water flea) - 0.39 mg/l - 24 h(Amitriptyline hydrochloride)

Toxicity to algae
ErC50 - Selenastrum capricornutum (green algae) - 0.16 mg/l - 72 h(Amitriptyline hydrochloride)

12.2 Persistence and degradability
According to the results of tests of biodegradability this product is not readily biodegradable.

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available(Amitriptyline hydrochloride)

12.5 Results of PBT and vPvB assessment
PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects
Very toxic to aquatic life with long lasting effects.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product
Offer surplus and non-recyclable solutions to a licensed disposal company. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

Contaminated packaging
Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADR/RID: 2811  
IMDG: 2811  
IATA: 2811

14.2 UN proper shipping name

ADR/RID: TOXIC SOLID, ORGANIC, N.O.S. (Amitriptyline hydrochloride)  
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (Amitriptyline hydrochloride)  
IATA: Toxic solid, organic, n.o.s. (Amitriptyline hydrochloride)
14.3 Transport hazard class(es)
ADR/RID: 6.1  
IMDG: 6.1  
IATA: 6.1

14.4 Packaging group
ADR/RID: III  
IMDG: III  
IATA: III

14.5 Environmental hazards
ADR/RID: no  
IMDG Marine pollutant: no  
IATA: no

14.6 Special precautions for user
No data available

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical safety assessment
For this product a chemical safety assessment was not carried out

SECTION 16: Other information

Full text of H-Statements referred to under sections 2 and 3.

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.

Further information
The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Central Drug House (P) Ltd and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.cdhfinechemical.com for additional terms and conditions of sale.