

SAFETY DATA SHEET

Section 1 - Identification of Substance or Mixture and Company

Product identify:

Product name: (R)-Duloxetine HCl
Synonyms: (R)-(-)-N-Methyl-3-(1-naphthalenyloxy)-3-(2-thienyl)-propanamine HCl
Catalog number: PI-32658

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

Identified uses: Laboratory chemicals, Manufacture of substances

Details of the supplier of the safety data sheet

Company identification: PI Chemicals Ltd.
633 Eshan Road,
Pudong New Area, Shanghai China, 201203

Telephone number: +86-21-58953700

Fax number: +86-21-58953701

E-mail address: info@pipharm.com

Emergency telephone number

Emergency number: +86-21-58953706

Section 2 - Hazards Identification

Classification of the substance or mixture:

Regulation (EC) No 1272/2008

Skin irritation Category 2

Eye irritation Category 2

Acute toxicity, Oral Category 4

Label elements

Classification according to (EC) No 1272/2008



Signal word: Warning

Hazard statement(s):

H302: Harmful if swallowed

H315: Causes skin irritation

H320: Causes eye irritation

Precautionary statement(s)

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Accroding to EU Directive 67/548/EEC or 1999/45/EC.

Symbol(s): Xn Harmful

Risk phrases:

R 22: Harmful if swallowed

R 36/38: Irritating to eyes and skin

Safety phrases:

S 26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S 36/37: Wear suitable protective clothing and gloves.

HMIS classification:

Health hazard: 0

Chronic health hazard: *

Flammability: 0

Physical hazards : 0

NFPA rating:

Health hazard: 0

Fire: 0

Reactivity hazard: 0

Section 3: Composition & Information on Ingredients

Molecular formula: C18H19NOS.HCl

Molecular weight: 333.88

| Component | Concentration |
|-------------------------------------|----------------------|
| CAS Number: 910138-96-4 | 98% |
| EC Number: No data available | |

Section 4 - First Aid Measures

Eye: Flush eyes with plenty of water for at least 15 minutes. Get medical aid if symptoms appear.

Skin: Wash skin with plenty of water at least 15 minutes while removing contaminated clothing and shoes. Get medical aid if irritation develops and persists.

Ingestion: Wash mouth out with water. Get medical aid immediately.

Inhalation: Remove from exposure and move to fresh air immediately. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical aid.

Section 5 – Fire-Fighting Measures

Extinguishing media: Use water spray, dry chemical, carbon dioxide, or appropriate foam.

Special hazards arising from the substance or mixture: Carbon oxides, Nitrogen oxides, Sulphur oxides, Hydrogen chloride gas

Advice for firefighters: Wear a self-contained breathing apparatus for fire fighting if necessary

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:

Use proper personal protective equipment as indicated in Section 8.

Environmental precautions: Prevent further spillage or leakage when safe and capable

Methods and materials for containment and cleaning up:

Vacuum or sweep up material and keep in a suitable closed container for disposal. Do not flush with water.

Section 7 - Handling and Storage

Precautions for safe handling:

Provide appropriate exhaust ventilation at places where dust is formed. Avoid contact with skin, eyes and clothes. Avoid inhalation of vapors and spray mist.

Conditions for safe storage, including any incompatibilities:

Store in a dry, well-ventilated place. Keep tightly closed.

Recommended long term storage temperature: 2 - 8 °C

Section 8 - Exposure Controls/Personal Protection

Control parameters:

Contains no materials with occupational exposure limits.

Exposure controls:

Ensure well ventilation, good industrial hygiene and safety practice.

Personal protective equipment

Eye/Face protection:

Wear appropriate protective eyeglasses under the standards such as EN166(EU) or type ABEK(EN14387).

Skin/Body protection:

Wear appropriate protective gloves which have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN374 derived from it to prevent skin exposure. Dispose of contaminated gloves in accordance with applicable laws. Wash and dry hands.

Wear appropriate protective clothing to prevent skin exposure.

Respiratory protection:

Use an approved respirator and components under appropriate government standards such as NIOSH(US) or CEN(EU) if exposure limits are exceeded or if irritation or other symptoms are experienced.

Section 9- Physical and Chemical Properties

| | |
|--|------------------------|
| Physical state: | Powder |
| Color: | White to off-white |
| Odour: | No data available |
| Melting point/freezing point: | 160-165°C |
| Initial boiling point and boiling range: | 466.2°C at 760mmHg |
| Flash point: | 235.7°C |
| Evaporation rate: | No data available |
| Flammability(solid, gas): | No data available |
| Upper/lower flammability or explosive limits: | No data available |
| Vapour pressure: | No data available |
| Vapour density: | No data available |
| Relative density: | 1.158g/cm ³ |
| Solubility: | No data available |
| Partition coefficient: n-octanol/water: | No data available |
| Auto-ignition temperature: | No data available |
| Decomposition temperature: | No data available |
| Viscosity: | No data available |

Section 10-Stability and Reactivity

| | |
|--|---|
| Reactivity: | No data available |
| Chemical stability: | Stable under recommended temperatures and pressures. |
| Possibility of hazardous reactions: | No data available |
| Conditions to avoid: | No data available |
| Incompatible materials: | Strong oxidizing agents |
| Hazard Decomposition products: | Carbon oxides, Nitrogen oxides, Sulphur oxides, Hydrogen chloride gas |

Section 11 - Toxicological Information

| | |
|--|--|
| Acute toxicity: | No data available |
| Component: (R)-Duloxetine HCl | |
| Skin corrosion/irritation: | No data available |
| Serious eye damage/eye irritation: | No data available |
| Respiratory or skin sensitization: | No data available |
| Germ cell mutagenicity: | No data available |
| Carcinogenicity: | Not listed as a carcinogen by ACGIH, IARC, NTP, or CA Prop 65. |
| Reproductive toxicity: | No data available |
| Specific target organ toxicity(STOT)-single exposure: | No data available |

Specific target organ toxicity (STOT)-repeated exposure: No data available

Aspiration hazard: No data available

Additional information: RTECS#: not available

Section 12 – Ecological Information

Toxicity: No data available

Component: Di-N-Propyl oxalate

Persistence and degradability: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

Results of PBT and vPvB assessment: No data available

Other adverse effects: No data available

Section 13 - Disposal Consideration

Waste treatment methods

Product: Dispose of in accordance with federal, state and local environmental regulations

Contaminated packaging: Dispose of as unused product

Section 14 - Transport Information

IATA

Not dangerous goods.

IMDG

Not dangerous goods.

RID/ADR

Not dangerous goods.

DOT(US)

Not dangerous goods.

Section 15 - Regulatory Information

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

No data available

Chemical safety assessment: No data available

Section 16 – Other Information

SDS creation date: May 6, 2013

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The above information is believed to be accurate and represents the best knowledge available to us currently. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no way shall PI Chemicals, be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, even if PI Chemicals has been advised of the possibility of such damages.