

MATERIAL SAFETY DATA SHEET

Mirtazapine

1. Identification of the substance/preparation and of the company/undertaking

Identification of the product

Product name: Mirtazapine

Manufacturer/supplier identification

Name: Zhejiang Liaoyuan Pharmaceutical Co., Ltd.

Address: Zhejiang Provincial Chemical and Medical Raw Material Base Linhai Zone,
Duqiao town, Linhai City, Zhejiang Province, 317016, China

Telephone: 0086-576-85588038

2. Composition/information on ingredients

$C_{17}H_{19}N_3$

M.W.: 265.4

CAS: 85650-52-8

EC No: 288-060-6

NB: Antidepressant.

Symbol: Xn, N

R phrases: R20/21/22, R51/53

R40, R64

3. Hazards identification

Substance is not classified in Annex I of Directive 67/548/EC.

Harmful by inhalation, in contact with skin and if swallowed. May cause sedation, stupor, nausea, vomiting, oedema, anxiety or agitation, painful muscles and articulations and skin reactions. May cause sensitization by inhalation and skin contact. May irritates the eyes, skin and upper respiratory tract in case of prolonged, repeated or excessive contact.

4. First aid measures

Inhalation: Remove to fresh air. If breathing becomes difficult, call a physician.

Skin contact: Flush with copious amounts of water and soap for at least 15 minutes.

Remove contaminated clothing and shoes.

Eyes contact: Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.

Ingestion: Wash out mouth with water and administer fresh water (approx. 500 ml) provided that the person is conscious. Do not induce vomiting.

In case of reactions described in hazards identification or other severe, immediate or persisting symptoms seek medical advice and call the nearest poison centre. Show the

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label and this safety data sheet.

5. Fire-fighting measures

Extinguishing media: Water spray. Carbon dioxide, dry chemical powder or appropriate foam.

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes. Emits toxic fumes under fire conditions. Keep away from drains, surface and groundwater and soil.

Dangerous combustion products: COx, NOx and other noxious gases or vapours in case of incomplete combustion.

6. Accidental release measures

Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves.

Switch off electrical equipment and any other sources of ignition. Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate area and wash spill site with water/detergent solution after material pick up is complete. Keep away from drains, surface- and groundwater and soil.

7. Handling and storage

Handling: Handle small quantities in fume hood. Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.

Storage: Keep unopened in the original container at room temperature. Keep tightly closed.

Protect from moisture. Protect from heat, direct sunlight and ignition.

8. Exposure controls/personal protection

OEL (supplier data): 125 μ g/day (target limit)

Respiratory protection: Protecting mask (filter 2).

Hand protection: Compatible chemical-resistant gloves (nitrile rubber, PVC, neoprene, latex).

Eye protection: Wear protective chemical safety goggles.

9. Physical and chemical properties

Appearance: White or almost white powder, slightly hygroscopic to hygroscopic.

Solubility: Practically insoluble in water, freely soluble in anhydrous ethanol.

10. Stability and reactivity

Conditions to avoid: Humidity. Light. Heat. Ignition.

Materials to avoid: Strong oxidizing agents.

Stability: Stable. It shows polymorphism.

Dangerous decomposition

products: COx, NOx, and other substances in case of incomplete decomposition.

11. Toxicological information

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RTECS No: UQ4410250

LD50 (oral-rat): 320 mg/kg (female) 490 mg/kg (male)

TDLo (oral-human male): 5.36 mg/kg

Not mutagenic, not teratogenic.

Not expected to possess carcinogenic potential (at therapeutic dosages) based on rat and

mouse studies.

See actual entry in RTECS for further information.

12. Ecological information

LC50 (Pimephales promelas, 96h): 6.96 mg/l

EC50 (Daphnia, 48h): 19.9 mg/l

Partition coefficient Log Pow 3.09.

It does not biodegrade within 112 days neither in waste water treatment nor in sediment. It is practically insoluble in water, but other facts relevant to mobility are unknown. The substance may bioaccumulate. Avoid release to environment.

13. Disposal considerations

Incinerate in an approved facility.

Observe all federal state and local environmental regulations.

14. Transport information

Non-Hazardous for Transport: this substance is considered to be non-hazardous for transport.

15. Regulatory information

Symbol: Xn, N

R20/21/22, R51/53, R40, R64, S22, S36/37, S38, S45

16. Other information

R20/21/22: Harmful by inhalation, in contact with skin and if swallowed.

R40: Possible risk of cancer.

R64: May cause harm to breastfeed babies.

R51/53: Toxic to aquatic organisms, may long-term adverse affects in the aquatic environment.

The information contained here is based upon data considered true and accurate.

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