

**Product Name** Ziprasidone mesylate for injection 20 mg/mL**1. Product Information****Product Name :** Ziprasidone mesylate for injection 20 mg/mL**Chemical Family:** Mixture**Intended use:** Pharmaceutical product used as antipsychotic**Details of the manufacturer:**

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200**2. Hazards Identification****Statement of Hazard :** May cause allergic reaction.

May cause damage to liver through prolonged or repeated exposure.

Additional Hazard Information:**Short Term:** Drugs of this class have been associated with rare, but potentially serious cardiac events.

These events have not been observed from occupational exposures, however, those with preexisting cardiovascular illnesses may be at increased risk from exposure.

Known Clinical Effects: This drug is prescribed for antipsychotic therapy and can depress central nervous system function. Common adverse effects include sleepiness (somnolence), tiredness, dizziness, restlessness, nausea, constipation, jerky muscle movement, diarrhea, and skin rash.

Sulfobutylether b-cyclodextrin sodium (SBECD) has been associated with toxic effects in the kidney.

EU Indication of danger: Harmful

Irritant

EU Risk Phrases:

R43 - May cause sensitization by skin contact.

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.

Australian Hazard Classification (NOHSC): Hazardous Substance. Non-Dangerous Goods**Note:** This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The

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precautionary statements and warnings included may not apply in all cases.

Your needs may vary depending upon the potential for exposure in your workplace

3. Composition/Information on Ingredients

C.A.S. No : 199191-69-0
 Molecular Formula : $C_{21}H_{21}ClN_4OS \cdot CH_3SO_3H \cdot 3H_2O$
 Molecular Weight : 563.09
 Chemical Name : 5-[2-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]ethyl]-6-chloro-1,3-dihydro-2H-indol-2-one methanesulfonate trihydrate

4. First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap.

Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water.

Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately

Inhalation: If inhaled, remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure : For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

5. Fire Fighting Measures

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (Such as dust and mists) may fuel fires/explosions.

6. Accidental Release Measures

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. Handling and Storage

General Handling: Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Release to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Stored at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature] in dry form. Protect from light.

8. Exposure Controls/Personal Protection

Ziprasidone mesylate trihydrate Pfizer OEL TWA-8Hr : 90µg/m³, (as free base)

Analytical Method : Analytical method available for Ziprasidone; Sulfobutylether b-cyclodextrin sodium (SBECD) Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE)

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. Physical and Chemical Properties

Appearance: Off white pale pink lyophilized powder.



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10. Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. Toxicological Information

General Information : The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Ziprasidone mesylate trihydrate

Rat Dermal LD50 > 2,000 mg/kg

Rat Oral LD50 > 2000 mg/kg

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Acute Toxicity Comments C : Ziprasidone hydrochloride tested negative for phototoxicity in mice and for anaphylaxis/antigenicity in guinea pigs.

Irritation / Sensitization: (Study Type, Species, Severity)

Ziprasidone mesylate trihydrate

Skin Irritation Rabbit Non-irritating

Eye Irritation Rabbit Non-irritating

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

6 Month(s) Rat Oral 40 mg/kg/day LOAEL Central nervous system, Liver

6 Month(s) Dog Oral 40 mg/kg/day LOAEL Central Nervous System Liver

1 Month(s) Rat Oral 160 mg/kg/day NOAEL Central Nervous System

12 Month(s) Dog 10 mg/kg/day NOAEL Central Nervous System

Ziprasidone hydrochloride was evaluated orally in dogs at doses up to 20 mg/kg/day for 12 months with only slight body weight effects in the high dose males.

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Reproductive & Fertility Rat Oral 40 mg/kg/day NOAEL Negative

Peri-/Postnatal Development Rat 5 mg/kg/day NOAEL Embryotoxicity, Fetotoxicity

Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Oral 30 mg/kg/day NOAEL Not Teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

In Vitro Human Lymphocytes Negative

In Vivo Mouse Bone Marrow Negative

Bacterial Mutagenicity (Ames) Salmonella Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

2 Year(s) Rat Oral 12 mg/kg/day Not carcinogenic

2 Year(s) Mouse Oral 200 mg/kg/day Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Environmental Overview: The environmental characteristics of this mixture have

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not been fully evaluated. No harmful effects to aquatic organisms are expected based on the effects of the individual ingredients

12. Ecological Information

Persistence and degradability: No data available

Toxicity: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

PBT and vPvB assessment: No data available

Other adverse effects: No data available

13. Disposal Considerations

Disposal Procedures : Dispose of waste in accordance with all applicable laws and regulations. Member state specific and community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposures and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and waste water.

14. Transport Information

DOT (US): Not dangerous goods.

IMDG: Not dangerous goods.

IATA: Not dangerous goods.

15. Regulatory Information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Hazard categories Immediate Hazard - Yes

Delayed Hazard - No

Fire Hazard - No

Pressure Hazard - No

Reactivity Hazard - No

16. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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