



# SAFETY DATA SHEET

## SECTION 1: IDENTIFICATION OF THE PRODUCT & THE COMPANY

- a) **Material Name** : Ziprasidone mesylate for injection  
b) **Common/ trade Name** : Ziprasidone mesylate for injection  
c) **Chemical Family:** : Mixture  
d) **Product Use** : Finished pharmaceutical product  
**Product type** : Regulated prescription drug  
**Container Information** : Vial

### **Relevant Identified Uses of the Substance or Mixture and Uses Advised Against**

**Intended Use:** Pharmaceutical product used as antipsychotic

- e) **Manufacture Name** : **Gland pharma Limited**  
**Address** : Unit-I, Plot No: 54, 55, 64 to 68, Sy.No:172 & 177  
Phase-III, TSIIC, Pashamylaram Village  
Patancheru Mandal, Sangareddy District-  
502307, Telangana, India.

**Telephone Number for Info** : +91-40-30510999

## SECTION 2: HAZARDS IDENTIFICATION

### **Classification of the Substance or Mixture**

#### **GHS – Classification**

Skin Sensitization: Category 1

#### **US OSHA Specific – Classification**

**Physical Hazard:** Combustible Dust

#### **EU Classification:**

EU Indication of danger: Irritant

EU Risk Phrases: R43 - May cause sensitization by skin contact

### **Label Elements**

**Signal Word:** Warning

**Hazard Statements:** H317 - May cause an allergic skin reaction  
May form combustible dust concentrations in air

**Precautionary Statements:** P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
P272 - Contaminated work clothing should not be allowed out of the workplace  
P280 - Wear protective gloves/protective clothing/eye protection/face protection



# SAFETY DATA SHEET

P302+ P352 - IF ON SKIN: Wash with plenty of soap and water

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P321 - Specific treatment (see supplemental first aid instructions on this label)

P363 - Wash contaminated clothing before reuse



**Other Hazards**

No data available

**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 precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SECTION 3 – COMPOSITION AND INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	GHS Classification	%
Sulfobutylether b-cyclodextrin sodium (SBECD)	7585-39-9	231-493-2	Xi;43	Skin Sens. 1 (H317)	*
Ziprasidone mesylate trihydrate	185021-64-1	Not Listed	Xn;R48/22	STOT RE.2 (H373)	8.5

**Additional Information:**

\* Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

**For the full text of the R phrases and CLP/GHS abbreviations mentioned in this Section, see Section 16**

## SECTION 4 - FIRST AID MEASURES



# SAFETY DATA SHEET

## Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 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:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

## Most Important Symptoms and Effects, Both Acute and Delayed

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

### Medical Conditions

- Aggravated by Exposure:** None Know

## Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

## SECTION 5: FIRE-FIGHTING MEASURES

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

### Special Hazards Arising from the Substance or Mixture

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

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

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8).  
Minimize exposure.

### Environmental Precautions



# SAFETY DATA SHEET

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

## Methods and Material for Containment and Cleaning Up

### 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.

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

## SECTION 7: HANDLING AND STORAGE

**Precautions for Safe 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. Releases 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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control Parameters

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

**Pfizer OEL TWA-8 Hr:** 3000µg/m<sup>3</sup>

#### Ziprasidone mesylate trihydrate

**Pfizer OEL TWA-8 Hr:** 90µg/m<sup>3</sup>, (as free base)

### Exposure Controls

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

**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.

### Personal Protective



# SAFETY DATA SHEET

**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.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Lyophilized powder	<b>Color:</b>	White to off-white
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**Solubility:** Soluble: Water

**pH:** 3.5 - 4.6

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Sulfobutylether b-cyclodextrin sodium (SBECD)**

No data available

**Ziprasidone mesylate trihydrate**

No data available

**Decomposition Temperature (°C):** No data available.

**Evaporation Rate (Gram/s):** No data available

**Vapor Pressure (kPa):** No data available

**Vapor Density (g/ml):** No data available

**Relative Density:** No data available

**Viscosity:** No data available

**Flammability:**

**Autoignition Temperature (Solid) (°C):** No data available



# SAFETY DATA SHEET

**Flammability (Solids):** No data available  
**Flash Point (Liquid) (°C):** No data available  
**Upper Explosive Limits (Liquid) (% by Vol.):** No data available  
**Lower Explosive Limits (Liquid) (% by Vol.):** No data available

**Polymerization:**

## SECTION 10: STABILITY AND REACTIVITY

**Reactivity:** No data available

**Chemical Stability:** Stable under normal conditions of use.

### **Possibility of Hazardous Reactions**

**Oxidizing Properties:** No data available

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

## SECTION 10: STABILITY AND REACTIVITY

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

**Hazardous Decomposition** No data available

**Products:**

## SECTION 11: TOXICOLOGICAL INFORMATION

### **Information on Toxicological Effects**

#### **General Information:**

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

#### **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.

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

#### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

Rat Oral LD50 > 2000 mg/kg

Rat/Mouse IV LD50 > 2000mg/kg

#### **Ziprasidone mesylate trihydrate**



# SAFETY DATA SHEET

Rat Dermal LD50 > 2,000 mg/kg  
Rat Oral LD50 > 2000mg/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)**

### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

Eye Irritation Rabbit Non-irritating  
Skin Irritation Rabbit Non-irritating  
Skin Sensitization - GPMT Guinea Pig Positive

### **Ziprasidone mesylate trihydrate**

Skin Irritation Rabbit Non-irritating  
Eye Irritation Rabbit Non-irritating

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

### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

6 Month(s) Rat Intravenous 600 mg/kg/day NOAEL Kidney, Liver  
1 Month(s) Rat Intravenous 160 mg/kg/day NOAEL Kidney  
6 Month(s) Dog Intravenous 600 mg/kg/day NOAEL Kidney  
1 Month(s) Dog Intravenous 120 mg/kg/day NOAEL Kidney

### **Ziprasidone mesylate trihydrate**

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

## **SECTION 11: TOXICOLOGICAL INFORMATION**

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

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

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

### **Sulfobutylether b-cyclodextrin sodium (SBECD)**

Fertility and Embryonic Development Rat Intravenous 1500 mg/kg/day NOAEL No effects at maximum dose  
Embryo / Fetal Development Rabbit Intravenous 1500 mg/kg/day NOAEL Not Teratogenic



# SAFETY DATA SHEET

Prenatal & Postnatal Development Rat Intravenous 600 mg/kg/day NOAEL Maternal Toxicity

## Ziprasidone mesylate trihydrate

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)

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

Bacterial Mutagenicity (Ames)	Salmonella, E. coli	Negative
In Vitro Chromosome Aberration	Human Lymphocytes	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	HGPRT Negative
In Vivo Micronucleus	Mouse Bone Marrow	Negative

#### Ziprasidone mesylate trihydrate

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))

#### Ziprasidone mesylate trihydrate

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.

## SECTION 12: ECOLOGICAL INFORMATION

**Environmental Overview:** The environmental characteristics of this mixture have not been fully evaluated. No harmful effects to aquatic organisms are expected based on the effects of the individual ingredients

### Toxicity:

#### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### Sulfobutylether b-cyclodextrin sodium (SBECD)

Oncorhynchus mykiss (Rainbow Trout)	OECD LC50	96 Hours	> 220 mg/L
Daphnia magna (Water Flea)	OECD EC-50	48 Hours	> 96 mg/L
Green algae	OECD IC50	72 Hours	> 100 mg/L





# SAFETY DATA SHEET

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

## SECTION 13: DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** 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 exposure 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 wastewater.

## SECTION 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## SECTION 15: REGULATORY INFORMATION

**Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture**

**Canada - WHMIS: Classifications**

**WHMIS hazard class:**

Class D, Division 2, Subdivision B



**Sulfobutylether b-cyclodextrin sodium (SBECD)**

**CERCLA/SARA 313 Emission reporting**

Not Listed

**California Proposition 65**

Not Listed



# SAFETY DATA SHEET

## SECTION 15: REGULATORY INFORMATION

**Inventory - United States TSCA - Sect. 8(b)** Present

**Australia (AICS):** Present

**EU EINECS/ELINCS List** 231-493-2

### **Ziprasidone mesylate trihydrate**

**CERCLA/SARA 313 Emission reporting** Not Listed

**California Proposition 65** Not Listed

**EU EINECS/ELINCS List** Not Listed

## SECTION 16: OTHER INFORMATION:

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary terms will apply to this SDS.

AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable,
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute



## **SAFETY DATA SHEET**

NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
IOEL	International Occupational Exposure Limit
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations