



MATERIAL SAFETY DATA SHEET

Revision date: 14-Jan-2010

Version: 2.0

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Ziprasidone mesylate for injection

Trade Name:	GEODON IM; ZELDOX IM
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antipsychotic

2. HAZARDS IDENTIFICATION

Appearance: White to off-white sterile lyophilized powder
Signal Word: WARNING

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 Hazard Symbols:
Xn



EU Risk Phrases: R43 - May cause sensitization by skin contact.
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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2. HAZARDS IDENTIFICATION

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Sulfobutylether b-cyclodextrin sodium (SBECD)	7585-39-9	231-493-2	Xi;43	*
Ziprasidone mesylate trihydrate	185021-64-1	Not listed	Xn;R48/22	8.5

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the R phrases mentioned in this Section, see Section 16

4. 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.

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 (see Section 8). Minimize exposure.

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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.

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. 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.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sulfobutylether b-cyclodextrin sodium (SBECD)
Pfizer OEL TWA-8 Hr:

3000µg/m³

Ziprasidone mesylate trihydrate
Pfizer OEL TWA-8 Hr:

90µg/m³, (as free base)

Analytical Method: Analytical method available for Ziprasidone; Sulfobutylether b-cyclodextrin sodium (SBECD)

Engineering Controls:

. Contact Pfizer Inc for further information.
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

Physical State:

Lyophilized powder

Color:

White to off-white

Molecular Formula:

Mixture

Molecular Weight:

Mixture

Solubility:

Soluble: Water

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9. PHYSICAL AND CHEMICAL PROPERTIES

pH: 3.5 - 4.6

Polymerization: Will not occur

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)

Sulfobutylether b-cyclodextrin sodium (SBECD)

Rat Oral LD50 > 2000 mg/kg
Rat/Mouse IV LD50 > 2000 mg/kg

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)

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

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11. TOXICOLOGICAL INFORMATION

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))

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
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.

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

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

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

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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 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.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Symbol: Xn
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.

EU Safety Phrases:
S22 - Do not breathe dust.
S24 - Avoid contact with skin.
S53 - Avoid exposure - obtain special instructions before use.

OSHA Label:
WARNING
May cause allergic reaction.
May cause damage to liver through prolonged or repeated exposure.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B



Sulfobutylether b-cyclodextrin sodium (SBECD)	
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-493-2

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15. REGULATORY INFORMATION

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R43 - May cause sensitization by skin contact.

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

Data Sources: Pfizer proprietary drug development information. Publicly available toxicity information.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet