



MATERIAL SAFETY DATA SHEET

Revision date: 14-Jan-2010

Version: 2.0

Page 1 of 8

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

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Material Name: Ziprasidone hydrochloride oral suspension

Trade Name:	GEODON™ , ZELDOX®
Chemical Family:	Mixture
Intended Use:	Pharmaceutical product used as antipsychotic

2. HAZARDS IDENTIFICATION

Appearance: White to slightly yellow uniformly dispersed opaque suspension
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:
Short Term:

Ziprasidone belongs to a class of drugs which have been shown to cause electrocardiogram irregularities and arrhythmia. These effects 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. Adverse effects associated with therapeutic use include sleepiness (somnolence), tiredness, nausea, constipation, dizziness, restlessness, jerky muscle movement, diarrhea, and skin rash.

EU Indication of danger:

Irritant

EU Hazard Symbols:

Xi



EU Risk Phrases:

R43 - May cause sensitization by skin contact.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

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.

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 2 of 8
Version: 2.0

2. HAZARDS IDENTIFICATION

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Ziprasidone hydrochloride	138982-67-9	Not listed	Xn;R43-48/22	1
Colloidal silicon dioxide	7631-86-9	231-545-4	Not Listed	*
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Citric acid	77-92-9	201-069-1	Xi; R36	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Xylitol	87-99-0	201-788-0	Not Listed	*
Cherry flavor, artificial	NOT ASSIGNED	Not listed	Not Listed	*
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*
Sodium citrate, dihydrate	6132-04-3	Not listed	Not Listed	*
Xanthan gum	11138-66-2	234-394-2	Not Listed	*
Polysorbate 80	9005-65-6	Not listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

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.

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 3 of 8
Version: 2.0

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.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. 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. Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. Use process containment, local exhaust ventilation or perform work under fume hood/fume cupboard. Avoid inhalation and contact with skin, eye, 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. Prevent inhalation, contact with eye, 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

Refer to available public information for specific member state Occupational Exposure Limits.

Ziprasidone hydrochloride
Pfizer OEL TWA-8 Hr:

90µg/m³, Sensitizer

Colloidal silicon dioxide

Australia TWA

2 mg/m³

Austria OEL - MAKs

Listed

Czech Republic OEL - TWA

Listed

Estonia OEL - TWA

Listed

Germany - TRGS 900 - TWAs

4 mg/m³

Germany (DFG) - MAK

4 mg/m³ MAK

Ireland OEL - TWAs

Listed

Latvia OEL - TWA

Listed

OSHA - Final PELs - Table Z-3 Mineral D:

- (80)/(% SiO₂) mg/m³ TWA
TWA-20 mppcf

Slovenia OEL - TWA

Listed

Sodium chloride

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 4 of 8
Version: 2.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed

Analytical Method: Analytical method available for Ziprasidone. 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

Physical State:	Suspension	Color:	White to slightly yellow
Odor:	Cherry	Molecular Formula:	Mixture
Molecular Weight:	Mixture		

pH: 3.5 - 4.5

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 ziprasidone in free base, hydrochloride and/or mesylate forms. The remaining information describes the potential hazards of the individual ingredients.

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

Methylparaben

Mouse Oral LD50 > 8000 mg/kg
Rat Oral LD50 2280 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 5 of 8
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Polysorbate 80

Rat Oral LD50 25 g/kg

Xanthan gum

Rat Oral LD50 > 5000 mg/kg

Ziprasidone hydrochloride

Rat Oral LD50 > 2000 mg/kg
Rat IP LD50 > 2000 mg/kg
Mouse Oral LD50 > 2000 mg/kg
Mouse IP LD50 500-1000 mg/kg
Rabbit Dermal 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.

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

Citric acid

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Sodium chloride

Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Mild

Ziprasidone hydrochloride

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

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

Ziprasidone hydrochloride

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	Oral	10 mg/kg/day	NOAEL	Central Nervous System

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

Ziprasidone hydrochloride

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
Liver					Central nervous system

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

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 6 of 8
Version: 2.0

11. TOXICOLOGICAL INFORMATION

Ziprasidone hydrochloride

In Vitro Human Lymphocytes Negative
In Vivo Mouse Bone Marrow Negative
In Vitro Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vitro Mammalian Cell Mutagenicity Mouse Lymphoma Negative

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

Ziprasidone hydrochloride

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.

Colloidal silicon dioxide

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: This substance was not acutely toxic to aquatic organisms at its maximum solubility. See aquatic toxicity data below.

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

Ziprasidone hydrochloride

Daphnia magna (Water Flea) OECD EC50 48 Hours > 0.04 mg/L
Pseudokirchneriella subcapitata (Green Alga) TAD EC50 72 Hours 0.01 mg/L
Selenastrum capricornutum (Green Alga) OECD EC50 72 Hours > 0.76 mg/L
Pimephales promelas (Fathead Minnow) TAD EC50 96 Hours > 0.035 mg/L
Pimephales promelas (Fathead Minnow) OECD NOEC 32 Days 0.027 mg/L

Aquatic Toxicity Comments:

A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Ziprasidone hydrochloride

Activated sludge OECD EC50 3 Hours > 1000 mg/L

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.

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 7 of 8
Version: 2.0

15. REGULATORY INFORMATION

EU Symbol: Xi
EU Indication of danger: Irritant

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

EU Safety Phrases:
S24 - Avoid contact with skin.
S37 - Wear suitable gloves.

OSHA Label:
WARNING
May cause allergic skin reaction.

Canada - WHMIS: Classifications

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



Xylitol

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-788-0

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-785-7

Propylparaben

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	202-307-7

Sodium citrate, dihydrate

Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6

Xanthan gum

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	234-394-2

MATERIAL SAFETY DATA SHEET

Material Name: Ziprasidone hydrochloride oral suspension
Revision date: 14-Jan-2010

Page 8 of 8
Version: 2.0

15. REGULATORY INFORMATION

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed

Colloidal silicon dioxide

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-545-4

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-598-3

Citric acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	201-069-1

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. Safety data sheets for individual ingredients.

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 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. 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