APOTEX
ADVANCING GENERICS

Material Safety Data Sheet

Section 1. Product Identification and Uses

Common/Trade name	**Risperidone Oral Solution, 1mg/mL**	**DSL#**	Not on the DSL list.
Synonyms	Not available.	**CAS#**	Mixture.
Chemical name	Not applicable.	**Molecular weight**	Not applicable.
Chemical family	Benzisoxazole derivative	**Chemical formula**	Not applicable.
Supplier	Apotex Corp. Weston, Florida 33326	**Chemical structure**	Not applicable.
Material uses	Pharmaceutical industry: Dosage form Therapeutic category: Antipsychotic agent.	**Manufacturer**	Apotex Inc. 150 Signet Drive Weston, Ontario M9L 1T9 416-749-9300
Emergency phone	**(416)-749-9300** ext. 5555 For general information call ext. 8483 (8 AM-4 PM)	**DIN**	Not available.

Section 2. Hazards Identification

Potential Acute Health Effects	Not expected to be hazardous under normal handling conditions.
Potential Chronic Health Effects	Possible hypersensitization.
WHMIS	Not controlled under WHMIS (Canada).
	Remark Covered by Food & Drug Act and therefore not regulated under WHMIS
Apotex Hazard Classification (For Apotex internal practices only)	This material has been assigned hazard class: **2**

Section 3. First Aid Measures

Eye contact	Flush with copious quantities of water. If irritation persists, obtain medical advice.
Skin contact	Not expected to result in hazardous effects.
Hazardous skin contact	Flush with copious amounts of water. Seek medical attention if irritation persist.
Slight inhalation	Not expected to result in hazardous effects.
Hazardous inhalation	Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration (use protective mask with one-way valve). If breathing is difficult give oxygen.
Slight ingestion	Flush out mouth with water. Seek medical attention if irritation persists.

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Hazardous ingestion Never give anything by mouth if victim is rapidly losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing has stopped, trained personnel should begin artificial respiration (use protective mask with one -way valve), or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
Treatment of overdose should be symptomatic and supportive and may include the following:
1. Do NOT induce vomiting.
2. Administer activated charcoal as a slurry.
3. For hypotension, infuse isotonic fluid.
4. Monitor vital signs, mental status, ECG, and electrolyte balance.
5. For ventricular tachydysrhythmias, treat with lidocaine or amiodarone. If patient is unstable, treat with cardioversion. For widening QRS complex, administer sodium bicarbonate. AVOID procainamide, quinidine, and disopyramide.
6. For neuroleptic malignant syndrome, treat with benzodiazepines, oral bromocriptine, or intravenous or oral dantrolene sodium, in conjunction with cooling and other supportive measures. Dantrolene is often ineffective as a sole agent and its efficacy is improved if given with a dopamine agonist. (Meditext 2006)

Section 4. Hazardous Ingredients

Name	CAS #	% (w/w)
Risperidone	106266-06-2	0.1
Sorbitol 70% FCC solution		10-30
Tartaric acid	87-69-4	<0.5
Benzoic acid	65-85-0	<0.5

Toxicity values of the hazardous ingredients

Refer to Sec. 11.

TLV Not established.

Section 5. Fire Fighting Measures

The product is: Not flammable.

Autoignition temperature Not applicable.

Fire degradation products Not available.

Flash points Not applicable.

Flammable limits Not applicable.

Fire extinguishing procedures Extinguisher media: Use extinguishing media suitable for surrounding materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Flammability Not flammable.

Remark

No additional remark.

Risks of explosion Risks of explosion of the product in presence of mechanical impact: No.
Risks of explosion of the product in presence of static discharge: No.

Remark

No additional remark.

Section 6. Accidental Release Measures

Spill and leak Absorb with an inert material and put the spilled material in an appropriate labeled waste disposal container. Follow appropriate Safe Work Practices.

Protective Clothing Pictograms in case of large spill and/or high exposure levels

Protective clothing in case of large spill Gloves. Covering uniform. Splash goggles. Half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridge.

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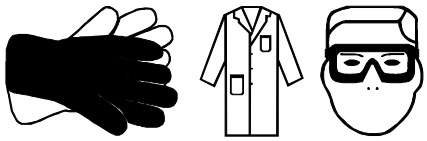

Section 7. Handling and Storage

Precautions	Avoid contact with eyes. Pregnant women should avoid exposure to this product.
Storage	Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and freezing.

Section 8. Exposure Controls/Personal Protection

Engineering Controls

Exposure to this material can be controlled in many ways. The measures appropriate for a particular worksite depend on how this material is used and on the extent of exposure. This general information can be used to help develop specific control measures. Ensure that control systems are properly designed and maintained. Comply with occupational, environmental, fire, and other applicable regulations.
Engineering methods to control hazardous conditions are preferred. Methods include mechanical (local exhaust) ventilation, process or personnel enclosure and control of process conditions. Administrative controls and personal protective equipment may also be required. Supply sufficient replacement air to make up for air removed by exhaust system.

Personal Protection

Covering uniform. Gloves. Safety glasses.

Protective Clothing (Pictograms)

PERSONAL PROTECTIVE EQUIPMENT/RESPIRATORY PROTECTION GUIDELINES: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. However major spills should require the use of designated personal protective equipment. If engineering controls and work practices are not effective in controlling exposure to this material, then wear suitable personal protective equipment including approved respiratory protection. Have appropriate equipment available for use in emergencies such as spills or fire.
EYE/FACE PROTECTION: Splash goggles/safety glasses.
SKIN PROTECTION: The use of nitrile gloves is required for Good Manufacturing Practices (GMP) compliance.
RESISTANCE OF MATERIALS FOR PROTECTIVE CLOTHING: Resistance of specific materials can vary from product to product. Evaluate resistance under conditions of use and maintain clothing carefully.
EXPOSURE CONTROLS/PERSONAL PROTECTION COMMENTS: In the event clothing becomes contaminated, remove promptly. Launder before use. Inform laundry personnel of contaminant's hazards. Do not eat, drink or smoke in work areas. Wash hands thoroughly after handling this material. Maintain good housekeeping.
PREGNANCY PRECAUTION:
Pregnant women should avoid exposure to this product unless:
True Barrier Technology or appropriate engineering controls exists or PPE as specified.

Section 9. Physical and Chemical Properties

Physical state and appearance	Solution.	**Odor**	Not available.
pH	Not available.	**Taste**	Not available.
Odor threshold	Not available.	**Color**	Clear, colorless.
Volatility	Not available.		
Melting point/ Freezing point	Not available.		
Boiling point	Not available.		
Specific gravity	Not available.		
Vapor density	Not available.		
Vapor pressure	Not available.		
Partition Coefficient:	Not available.		
Ionicity (surface active agent)	Not available.		

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Critical temperature	Not available.
Instability temperature	Not available.
Conditions of instability	No additional remark.
Dispersion properties	See solubility.
Evaporation rate	Not available.
Solubility	Not available.

Section 10. Stability and Reactivity

Stability	The product is stable.
Hazardous decomp. products	Emits toxic fumes under fire conditions.
Degradability	Not available.
Corrosivity	Not corrosive
	Remark No additional remark.
Reactivity/ Incompatibility	Protect from light and freezing.
	Remark No additional remark.

Section 11. Toxicological Information

Routes of entry	Eye contact. Skin contact
Toxicity data	Risperidone: RTECS: UV1164800 TDLo: 3428 µg/kg (oral-man) LD50: 56600 µg/kg (oral-rat) LD50: 63100 µg/oral-mouse)
Long-term effects	Possible hypersensitization. Target organs: Central nervous system. Carcinogenicity: Not listed by IARC, NTP, ACGIH, or OSHA. There were statistically significant increases in pituitary gland adenomas, endocrine pancreas adenomas, and mammary gland adenocarcinomas in mice and rats administered oral risperidone at doses of 0.63, 2.5, and 10 mg/kg for 18 months and 25 months, respectively. Reproductive Toxicity: Risperidone (0.16 to 5 mg/kg) was shown to impair mating, but not fertility in rats in reproductive studies. Teratogenicity: Pregnancy Category C. There are no adequate and well-controlled studies in pregnant women. However, there was one report of a case of agenesis of the corpus callosum in an infant exposed to Risperidone in utero . The causal relationship to Risperidone therapy is unknown. Risperidone should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Mutagenicity: Risperidone was not mutagenic in the Ames reverse mutation test, mouse lymphoma assay, in vitro rat hepatocyte DNA-repair assay, in vivo micronucleus test in mice, the sex-linked recessive lethal test in Drosophila, or the chromosomal aberration test in human lymphocytes or Chinese hamster cells.
	Remark Medical conditions aggravated by exposure: Hypersensitivity to material, active alcoholism, breast cancer, cardiovascular or cerebrovascular disease, dehydration or hypovolemia, dementia, diabetes or risk factors for diabetes, impaired liver or kidney function, Parkinson's disease, history of seizures, and risk factors for torsades de pointes.
Short-term effects and Signs & Symptoms of overexposure	The recommended dose of Risperidone is 2 to 16 mg/day. Adverse effects may include restlessness; mood or mental changes; changes in vision; decreased sexual performance or desire; dizziness; menstrual changes; muscle spasms of face, neck, or back; involuntary body movements or stiffness; inability to move eyes; unusual weakness or tiredness; loss of balance control or shuffling walk; trouble sleeping or increased duration of sleep; increased dream activity; problems with urination or increase in amount of urine; troubled breathing; fast or irregular heartbeat; skin rash, itching, or dryness; unusual secretion of milk; decreased salivation or dry mouth; constipation or diarrhea; cough; heartburn; headache; nausea; toothache; increased sweating; and increased sensitivity of skin to light or darkening of skin color. Possible allergic reaction to material if inhaled, ingested or in contact with skin. Overdose effects may include the adverse effects listed above, drowsiness, ECG abnormalities, electrolyte

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disturbances, low blood pressure, and seizures.

Remark

The above adverse effects are based on clinical studies.

Section 12. Ecological Information

Ecological Information

This material may cause long-term effects in the aquatic environment. Daphnia: EC50 (48 hr): 6 mg/L Bluegill fish: EC50 (96 hr): 5.8 mg/L Green algae: EC50 (72 hr): 26 mg/L

Section 13. Disposal Considerations

Waste Disposal

Collect in sealed containers and place in appropriate labeled pharmaceutical liquid waste class 261L (for Ontario).
Follow all appropriate safe work procedures and federal, provincial and local regulations for disposal. Use only licensed disposal and waste hauling companies.

Section 14. Transport Information TDG, IATA, IMDG

Not a TDG-controlled material.

UN

Not applicable.

Special Provisions for Transport

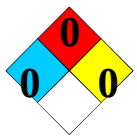
Not available.

Section 15. Other Regulatory Information and Pictograms

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) HAZARD INDEX

NFPA-HEALTH-blue :0-Materials that on short exposure under fire conditions would offer no hazard beyond that of ordinary combustible materials.
NFPA-FLAMMABILITY-red :0-Materials that will not burn.
NFPA-REACTIVITY-yellow :0-Normally stable.

National Fire Protection Association (U.S.A.)



Health

Fire Hazard

Reactivity

Specific Hazard

Hazardous Material Information System (U.S.A.)

Health Hazard	0
Fire Hazard	0
Reactivity	0
Personal Protection	X

* - Chronic hazard indicator
X - See Section 8

HCS (Hazardous Communication System) (OHSA, U.S.A.)

Not an HCS controlled material in USA.

DOT (Department of Transportation) (U.S.A) (Pictograms)

Not a DOT controlled material (United States).

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.
R47- May cause birth defect.

ADR (European Agreement of Dangerous goods by Road) (Pictograms)

Not controlled under European ADR.

Other Regulations

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This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

Section 16. Other Information

References The Merck Index, thirteenth edition
PDR Electronic Library
HSBD & RTECS Database

MSDS:	**Validation date: (year.month)**
U. S. Pharmacopeia	December 6, 2006

Revision date: 4/8/2011.

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Notice to Reader