Material Safety Data Sheet

Section 1. Product Identification and Uses

Common/Trade name	**Oxcarbazepine Tablets, 150 mg, 300 mg and 600 mg**	**DSL#**	Not on the DSL/NDSL list.
Synonyms	Not available.	**CAS#**	Mixture.
Chemical name	Not applicable.	**Molecular weight**	Not applicable.
Chemical family	Carbamazepine derivative	**Chemical formula**	Not applicable.
Supplier	Apotex Corp. Weston, Florida 33326	**Chemical structure**	Not applicable.
Material uses	Pharmaceutical industryDosage form Therapeutic category: Anticonvulsant.	**Manufacturer**	Apotex Inc. 150 Signet Drive Weston, Ontario M9L 1T9 416-749-9300
Emergency phone	FOR EMERGENCIES INVOLVING DANGEROUS GOODS Call CANUTEC's 24-hr Number 613-996-6666 For general information call: 1-(416)-749-9300 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

WHMIS CLASS D-2A: Material causing other toxic effects (VERY TOXIC).

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	May cause irritation. Flush out mouth with water.

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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. Administer activated charcoal as a slurry
2. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, consider phenobarbital.
Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. [Meditext 2008]

Section 4. Hazardous Ingredients

Name	CAS #	% (w/w)
Oxcarbazepine	28721-07-5	70 - 90
Crospovidone	9003-39-8	10 - 30
Methyl cellulose 15 CPS	9004-67-5	1 - 10

Toxicity values of the hazardous ingredients

Refer to Sec. 11.

TLV Not established.

Section 5. Fire Fighting Measures

The product is: May be combustible at high temperature.

Autoignition temperature Not available.

Fire degradation products Decomposition products may include the following materials: carbon oxides (CO, CO_2), nitrogen oxides (NO, NO_2 etc.).

Flash points Not applicable.

Flammable limits Not available.

Fire extinguishing procedures Extinguisher media: water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and 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 available

Remark

No additional remark.

Risks of explosion Risks of explosion of the product in presence of mechanical impact: Not available.
Risks of explosion of the product in presence of static discharge: Not available.

Remark

No additional remark.

Section 6. Accidental Release Measures

Spill and leak Vacuum or sweep up spillage. Avoid dust. Place spillage into an appropriate labeled waste disposal container. Wash contaminated clothing before reuse. Ventilate area and wash spill site. 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 Covering uniform. Gloves. Half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridge. Splash goggles.

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Section 7. Handling and Storage

Precautions	In case of insufficient ventilation, wear suitable respiratory equipment. Avoid breathing dust. Wash thoroughly after handling. Pregnant women should avoid exposure to this product.
Storage	Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Section 8. Exposure Controls/Personal Protection

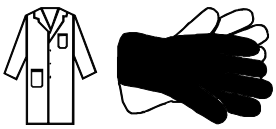
Engineering Controls

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.

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. Have appropriate equipment available for use in emergencies such as spills or fire.
If the physical state of the finished product is altered by crushing, grinding or breakage, appropriate PPE may be required including half facepiece Air Purifying Respirator with combination particulate/organic vapour cartridges.
The respirator use limitations specified by the approving agency and the manufacturer must be observed.
EYE/FACE PROTECTION : Not required under normal working conditions.
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

150 mg: yellow, oval, biconvex, film-coated tablets, scored and engraved “OXC 150” on one side, “APO” on the other side.
300 mg: yellow, oval, biconvex, film-coated tablets, scored and engraved “OXC 300” on one side, “APO” on the other side.
600 mg: yellow, oval, biconvex, film-coated tablets, scored and engraved “OXC 600” on one side, “APO” on the other side.

pH	Not available.	**Taste**	Not available.
Odor threshold	Not available.	**Odor**	Not available.

Volatility	Not available.
Melting point/ Freezing point	Not available.
Boiling point	Not available.
Specific gravity	Not available.
Vapor density	Not available.
Vapor pressure	Not applicable.
Partition Coefficient:	Not available.

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Ionicity (surface active agent)	Not available.
Critical temperature	Not available.
Instability temperature	Not available.
Conditions of instability	No additional remark.
Dispersion properties	Not available.
Evaporation rate	Not available.
Solubility	Not available.

Section 10. Stability and Reactivity

Stability	The product is stable.
Hazardous decomp. products	Not available.
Degradability	Not available.
Corrosivity	Not corrosive
	Remark No additional remark.
Reactivity/ Incompatibility	Not available
	Remark No additional remark.

Section 11. Toxicological Information

Routes of entry	As the product is a solid dosage form, the major route of entry is ingestion. Other routes of entry, including inhalation, skin and eye contact may occur only under certain circumstances.
Toxicity data	Oxcarbazepine: LD50: Not available. Sensitization Data: Rare cases of anaphylaxis and angioedema have been reported after therapeutic use of oxcarbazepine. Crospovidone: LD50: 100 000 mg/kg (oral-rat) Methyl cellulose 15 CPS: LD50: Not available
Long-term effects	Possible hypersensitization. Carcinogenicity: Not listed by IARC, NTP, ACGIH, or OSHA. In mice, oral doses of 70 mg/kg/day and higher increased the incidence of hepatocellular adenomas, and in female rats, doses of 25 mg/kg/day and higher increased the incidence of hepatocellular carcinomas. There was an increase in the incidence of benign testicular interstitial cell tumors in rats at 250 mg/kg/day. In mice, oral doses of 70 mg/kg/day and higher increased the incidence of hepatocellular adenomas, and in female rats, doses of 25 mg/kg/day and higher increased the incidence of hepatocellular carcinomas. There was an increase in the incidence of benign testicular interstitial cell tumors in rats at 250 mg/kg/day. Reproductive and Developmental Effects: Pregnancy Category C. This material is closely related to carbamazepine, which causes birth defects in humans. Rats given 300 mg/kg orally during pregnancy had offspring with an increased incidence of birth defects, and doses of 1000 mg/kg caused embryofetal death and decreased body weight. Pregnant rats given oral doses of 150 mg/kg had offspring with a persistent reduction in body weight and altered behavior. An increased incidence of malformations occurred in the offspring of pregnant mice given oxcarbazepine doses of 1100 mg/kg/day. Mutagenicity: Oxcarbazepine was positive in the Ames test in vitro in one of five bacterial strains without activation, and it increased chromosomal aberrations and polyploidy in Chinese hamster ovary cells in vitro without activation. There was no mutagenic or clastogenic activity with oxcarbazepine in V79 Chinese hamster cells in vitro, and it did not cause micronucleus formation in rat bone marrow in vivo.
	Remark Contraindications: Oxcarbazepine should not be used in patients with a known hypersensitivity to oxcarbazepine or to any of its components.

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Short-term effects and Signs & Symptoms of overexposure

Adverse effects may include clumsiness or unsteadiness, vision problems, abnormal or uncontrolled body movements, behavioral or emotional changes, dizziness, drowsiness, headache, cough, fever, sneezing, sore throat, nausea, vomiting, diarrhea, vertigo, confusion, troubled breathing, wheezing, bruising, acne, back or chest pain, constipation, dry mouth, heartburn, bloody nose, hot flashes, coma, convulsions, fast or irregular heartbeat, increased thirst, muscle cramps, faintness or lightheadedness, trembling, memory loss, skin rash, bloody or cloudy urine, change in urination, vaginal itching or discharge, difficulty speaking, change in sense of taste, sleepiness, and upper respiratory disorders. Oxcarbazepine may decrease the effectiveness of oral contraceptives. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.
Overdose effects may include low blood sodium which may lead to seizures and coma, slow heart rate, low blood pressure, ringing in ears, vertigo, and abnormal drowsiness.

Remark

The above adverse effects are based on clinical studies.

Section 12. Ecological Information

Ecological Information Not available.

Section 13. Disposal Considerations

Waste Disposal For internal Apotex waste disposal: Collect in sealed containers and place in appropriate labeled pharmaceutical solid waste class 261A.
For external waste disposal: 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 controlled under TDG (Canada).

UN Not applicable (PIN and PG).

Special Provisions for Transport Not applicable.

Section 15. Other Regulatory Information and Pictograms

NATIONAL FIRE PROTECTION ASSOCIATION (NFPA) HAZARD INDEX

NFPA-HEALTH-blue :1-Slightly hazardous to health.
NFPA-FLAMMABILITY-red :1-Materials that must be preheated before ignition can occur.
NFPA-REACTIVITY-yellow :0-Normally stable.

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

Fire Hazard
Reactivity
Health
Specific Hazard

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

Health Hazard	*	1
Fire Hazard		1
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. R40- Possible risks of irreversible effects. R42/43- May cause sensitization by inhalation and skin contact. R63- May cause harm to the unborn child.

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

Not controlled under ADR (Europe).

Other Regulations

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

HSBD & RTECS Database
The Merck Index
PDR Electronic Library

MSDS:

U. S. Pharmacopeia

Validation date: (year.month)

November 8, 2008

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Notice to Reader