SAFETY DATA SHEETS

This SDS packet was issued with item:

078437012

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078547617 078906678 078914399 078914400

Material Safety Data Sheet

LORAZEPAM TABLETS
(0.5/1.0/2.0 mg)

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING	
Material	Lorazepam
Empirical Chemical Formula	$C_{15}H_{10}C_{l2}N_2O_2$
Synonyms	-
Manufacturer	Ohm Laboratories, Inc., 1385 Livingston Ave. North Brunswick, NJ, 08907, USA.
Distributor	Ranbaxy Pharmaceuticals Inc., 9431, Florida Mining Blvd. East, Jacksonville, FL, 32257

2. COMPOSITION / INFORMATION ON INGREDIENTS		
Ingredients	CAS Number	Percentage
Lorazepam	846-49-1	0.5 mg=1.00% 1.0 mg=1.00% 2.0 mg=1.60%
Non-Hazardous Ingredients	–	0.5 mg=99.00% 1.0 mg=99.00% 2.0 mg=98.40%

3. HAZARDS IDENTIFICATION	
Fire and Explosion	Expected to be non-combustible.
Health	Adverse effects most commonly reported in clinical use include sedation, dizziness, weakness, clumsy motion of limbs/trunk (ataxia), in coordination, fatigue, drowsiness, amnesia, confusion, state of intense good feeling (euphoria), and suicidal behavior. Benzodiazepines may cause fetal damage when administered during pregnancy. Secreted in human breast milk.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES	
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.

Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
NOTES TO PHYSICIANS / HEALTH PROFESSIONALS	
Medical Treatment	Treat according to locally accepted protocol. For additional guidance, refer to the current prescribing information or to the local poison control information center. Treatment of benzodiazepine overdose should be symptomatic and supportive and may include the following: 1. Do not induce vomiting. 2. Administer activated charcoal as slurry. 3. Monitor vital signs, manage airway, and provide assisted ventilation if needed. 4. Infuse 10 - 20 mL/kg isotonic fluid to control hypotension. If persistent, treat with intravenous administration of a vasopressor such as dopamine or norepinephrine. 5. Flumazenil, a benzodiazepine agonist/antagonist, has been administered intravenously to reverse coma and respiratory depression in cases of severe poisoning. Flumazenil use is not recommended in cases where seizures are likely or there is serious cyclic antidepressant poisoning. 6. Forced diuresis and hemodialysis are ineffective. 7. Manage withdrawal symptoms initially with phenobarbital or the benzodiazepine, then decrease dose by about 10% per day for ten days.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detail description of medical conditions caused by or aggravated by overexposure to this product. Hypersensitivity to material, alcohol or drug abuse, glaucoma, myasthenia gravis, lung disease, sleep apnea, kidney or liver impairment, seizure disorders, and mental disorders such as depression.
Antidotes	Flumazenil, antidote for a benzodiazepine.

5. FIRE-FIGHTING MEASURES	
Fire and Explosion Hazards	High sensitivity of a dust cloud to ignition, based on minimum ignition energy. Strong dust explosion characteristic.
Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Special Firefighting Procedures	Self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other chlorine-containing compounds.

6. ACCIDENTAL RELEASE MEASURES	
Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.
Decontamination Procedure	No specific decontamination procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

7. HANDLING AND STORAGE	
Safe Handling and Use	Minimize dust generation and accumulation. If tablets are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing.
Storage	No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION	
PERSONAL PROTECTIVE EQUIPMENT	
Eye Protection	None required for consumer use of this product. Avoid eye contact.
Respirators	None required for consumer use of this product. If respiratory protective equipment (RPE) is used, the type of RPE will depend upon air concentrations present, required protection factor as well as hazards, physical properties and warning properties of substances present.
Other Equipment or Procedures	None required for consumer use of this product.
Work / Hygienic Practices	Follow good Industrial & Personal Hygiene practices. Wash hands thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES	
Physical Form (Appearance)	Color & Shape: 0.5 mg - White, round, flat face, beveled edge tablets, debossed with RX 7 on one

	side and plain on the other side. 1.0 mg - White, round, flat face, beveled edge tablets, debossed with RX above the bisect and 773 below the bisect on one side and plain on the other side. 2.0 mg – White to off white round, flat face, beveled edge tablets, debossed with RX above the bisect and 774 below the bisect on one side and plain on the other side.

10. STABILITY AND REACTIVITY	
Stability	Stable
Conditions to Avoid	Avoid exposure to heat and light.

11. TOXICOLOGICAL INFORMATION	
This material contains active pharmaceutical ingredient Lorazepam, the specific information on which is provided below.	
Oral Toxicity	Oral Rat : LD50: 4500 mg/kg Oral Mouse : LD50: 1850 mg/kg Oral Dog : LD50: >2 grams/kg
Inhalation Toxicity	n/k
Skin Effects	n/k
Eye Effects	n/k
Target Organ Effects	n/k
Sensitisation	n/k
Genetic Toxicity	n/k
Carcinogenicity	In an 18-month study in rats, Lorazepam showed no evidence of carcinogenic potential.
Reproductive Effects	Results were mixed in a meta-analysis of studies that tracked the occurrence of major malformations in infants of mothers who used a benzodiazepine in early pregnancy. There have been reports of newborns exhibiting flaccidity, breathing and feeding problems, and hypothermia after maternal use of benzodiazepines in late pregnancy, and withdrawal symptoms, e.g. tremor and irritability, have been seen in newborns exposed to benzodiazepines in utero. Studies in rabbits have shown that Lorazepam caused anomalies, fetal resorption, and increased fetal loss at oral doses of 40 mg/kg and intravenous doses of 4 mg/kg and higher. The administration of Lorazepam to mice and rats during

	gestation was not associated with an increased incidence of birth defects, except at extremely high doses which caused cleft palate in one study. Some reduction of fetal weight, but no birth defects, occurred in mice and rats when administered up to 4 mg/kg/day during pregnancy.
Gastrointestinal Reactions	n/k
Hypersensitivity Reactions	n/k
Pharmacological Effects	Studies in healthy volunteers show that in single high doses Lorazepam has a tranquilizing action on the central nervous system with no appreciable effect on the respiratory or cardiovascular systems. Lorazepam is readily absorbed with an absolute bioavailability of 90 percent. Peak concentrations in plasma occur approximately 2 hours following administration. The peak plasma level of Lorazepam from a 2 mg dose is approx. 20 mg/mL. The mean half-life of un-conjugated Lorazepam in human plasma is about 12 hours and for its major metabolite, Lorazepam glucuronide, about 18 hours. At clinically relevant concentrations, Lorazepam is approximately 85% bound to plasma proteins. Lorazepam is rapidly conjugated at its 3-hydroxy group into Lorazepam glucuronide which is then excreted in the urine. Lorazepam glucuronide has no demonstrable CNS activity in animals. The plasma levels of Lorazepam are proportional to the dose given. There is no evidence of accumulation of Lorazepam on administration up to six months. Studies comparing young and elderly subjects have shown that advancing age does not have a significant effect on the pharmacokinetics of Lorazepam. However, in one study involving single intravenous doses of 1.5 to 3 mg of Lorazepam Injection mean total body clearance of Lorazepam decreased by 20% in 15 elderly subjects of 60 to 84 years of age compared to that in 15 younger subjects of 19 to 38 years of age.
Over Dosage	Overdosage of benzodiazepines is usually manifested by varying degrees of central nervous system depression ranging from drowsiness to coma. In mild cases, symptoms include drowsiness, mental confusion, paradoxical reactions, dysarthria and lethargy. In more serious cases, and especially when other drugs or alcohol were ingested, symptoms may include ataxia, hypotonia, hypotension, cardiovascular depression, respiratory depression, hypnotic state, coma, and death.
Contraindications	Lorazepam is contraindicated in patients with hypersensitivity to benzodiazepines or to any components of the formulation. Acute narrow-angle glaucoma.
Other Information	Principal routes of exposure are by accidental skin and eye contact and inhalation of generated dusts. Premature infants of mothers receiving Lorazepam had a high

	incidence of depressed respiration, hypothermia and feeding problems. Prolonged use of benzodiazepines can lead to alcoholism-like dependence. Tolerance and withdrawal symptoms are seen in long-term treatment in high doses. Benzodiazepines can cause involuntary movements and difficulties in moving the muscles of the face. Arteriosclerosis, kidney, liver and respiratory conditions can be aggravated. They also cause an increased risk of some birth defects such as cleft palate. Benzodiazepines may be associated with some cancers.

12. ECOLOGICAL INFORMATION
This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.
Do not allow product to enter drinking water supplies, waste water or soil.

13. DISPOSAL CONSIDERATIONS	
Disposal Recommendations	Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.
Regulatory Requirements	Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION	
The MSDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.	
Transport Information	Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION	
EU Classification and Labelling	n/k
US OSHA Standard (29 CFR Part	n/k

1910.1200)	
OTHER US REGULATIONS	
	n/k

16. OTHER INFORMATION
The above information and recommendations are believed to be correct as on date but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose. Ranbaxy shall not be held liable for any damage resulting from handling or from contact with the above product. Ranbaxy reserves the right to revise this MSDS.

MATERIAL SAFETY DATA SHEET

Prepared to U.S. OSHA, CMA, ANSI, Canadian WHMIS Standards, European Union CLP EC 1272/2008 and the Global Harmonization Standard

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

TRADE/MATERIAL NAME: LORAZEPAM TABLETS

Lorazepam Tablets 0.5 mg CIV 100, Lorazepam Tablets 0.5 mg CIV 500, Lorazepam Tablets 0.5 mg CIV 1000, Lorazepam Tablets 1 mg CIV 100, Lorazepam Tablets 1 mg CIV 500, Lorazepam Tablets 1 mg CIV 1000, Lorazepam Tablets 2 mg CIV 100, Lorazepam Tablets 2 mg CIV 500, Lorazepam Tablets 2 mg CIV 1000,

DESCRIPTION: Lorazepam Tablets

OTHER DESIGNATIONS: NDC# 00591-0240-01, 00591-0240-05, 00591-0240-10, 00591-0241-01, 00591-0241-05, 00591-0241-10, 00591-0242-01, 00591-0242-05, 00591-0242-10

CHEMICAL NAME: (±)-7-Chloro-5-(*o*-chlorophenyl)-1,3-dihydro-3-hydroxy-2*H*-1,4-benzodiazepin-2-one

CHEMICAL FAMILY: Benzodiazepine

HOW SUPPLIED: 0.5, 1 and 2 mg tablets

FORMULA: $C_{15}H_{10}C_{12}N_2O_2$

SUPPLIER OF THE SAFETY DATA SHEET

RESPONSIBLE PARTY U.S.:	**WATSON PHARMACEUTICALS, INC.**
U.S. ADDRESS:	400 Interpace Parkway, Parsippany, NJ 07054, USA
U.S. BUSINESS PHONE/GENERAL MSDS INFORMATION:	1-800-272-5525
RESPONSIBLE PARTY EUROPE:	
EUROPEAN ADDRESS:	
Email: Robert.McCafferty@Watson.com	
EUROPEAN BUSINESS PHONE:	
EMERGENCY PHONE (U.S./NORTH AMERICA):	CHEMTREC: 1-800-424-9300 (24 hours) U.S., Canada, Puerto Rico
EMERGENCY PHONE (OUTSIDE U.S.):	CHEMTREC: +1-703-527-3887 (24 hours) Outside North America

NOTE: ALL United States Occupational Safety and Health Administration Standard (29 CFR 1910.1200), U.S. State equivalent Standards, Canadian WHMIS [Controlled Products Regulations], EU Directives through EC 1907: 2006, and European Union CLP EC 1272/2008, required information is included in appropriate sections based on the U.S. ANSI Z400.1-2010 format. This product has been classified in accordance with the hazard criteria of the countries listed above.

DATE OF PREPARATION: February 22, 2005 **DATE OF REVISION:** June 19, 2012

2. HAZARDS IDENTIFICATION

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

Classification: Not Applicable Signal Word: Not Applicable Hazard Statement Codes: Not Applicable

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

Classification: Not Applicable Risk Phrases: Not Applicable Safety Phrases: Not Applicable

See Section 16 for full EU classification information of product and components and full text of hazard and precautionary statements

EMERGENCY OVERVIEW:

Product Description: This product is supplied as round white tablets.

Health Hazards: The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin. **Health Hazards (continued):** Individuals who have had allergic reactions to products containing Lorazepam, Starch, or any of the other ingredients in this product, may experience allergic reactions after exposure to this product. Therapeutic use of Lorazepam can cause adverse symptoms on the cardiovascular system and central nervous system. Lorazepam is a reproductive toxin by ingestion and causes fetal developmental abnormalities.

Flammability Hazards: If heated to high temperatures for a prolonged period, the product may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides, nitrogen oxides, hydrogen chloride, and sodium oxides).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.

Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.

3. COMPOSITION and INFORMATION ON INGREDIENTS

CHEMICAL NAME	CAS #	EINECS #	% w/w	EU Classification (67/548/EEC) GHS & EU Classification (1272/2008 EC) Risk Phrases/Hazard Statements/Symbol
Lorazepam	846-49-1	212-687-6	Proprietary	SELF CLASSIFICATION EU 67/548 Classification: Harmful Risk Phrases: R62+R63 Hazard Symbol:  EU/GHS 1272/2008 Signal word: Danger Classification: Reproductive Toxicity Cat. 2 Hazard Statement Codes: H361 Hazard Symbol/Pictogram: 
Lactose	63-42-3	200-559-2	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Magnesium Stearate	557-04-0	209-150-3	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Microcrystalline Cellulose	9004-34-6	232-674-9	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable
Polacrillin Potassium	39394-76-5	Mixture	Proprietary	EU 67/548 Hazard Classification: Not Applicable EU/GHS 1272/2008 Classification: Not Applicable

See Section 16 for full EU classification information of product and components.

4 FIRST-AID MEASURES

Persons developing hypersensitivity reactions should receive medical attention. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Take a copy of label and MSDS to physician or health professional with the contaminated individual.

SKIN EXPOSURE: Basic hygiene should prevent any problems. If the product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes. Victims must seek immediate medical attention, especially if an adverse reaction occurs.

EYE EXPOSURE: If airborne dusts generated by this product enter the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids and then "roll" while flushing eyes. Minimum flushing is for 15 minutes if the exposure has resulted in an adverse effect. The contaminated individual must seek medical attention if any adverse effect continues after rinsing.

INHALATION: If airborne dusts generated by this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Seek medical attention if adverse effect continues after removal to fresh air.

INGESTION: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain immediate medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Pre-existing allergies, upper G.I. disease, blood disease caused by an allergy or reaction to any other medicine, drug abuse or dependence, or history of, kidney disease or, liver disease, porphyria, cardiovascular conditions, conditions causing urinary retention, angle-closed glaucoma and increased intra-ocular pressure in eyes may be aggravated by chronic overexposures to this product.

RECOMMENDATIONS TO PHYSICIANS: This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. Treatment is symptomatic and supportive. Empty the stomach as quickly as possible by emesis, followed by gastric lavage. Should respiration or blood pressure become compromised, respiratory assistance, central nervous system stimulants, and pressor agents should be administered cautiously as indicated. Since overdosage is often deliberate, patients may attempt suicide by other means during the recovery phase. Deaths by deliberate or accidental overdosage have occurred with this class of drugs. Manifestations of Lorazepam overdosage include somnolence, confusion, and coma. Induced vomiting and/or gastric lavage should be undertaken, followed by general supportive care, monitoring of vital signs, and close observation of the patient. Hypotension, though unlikely, usually may be controlled with norepinephrine bitartrate injection. The usefulness of dialysis has not been determined. Flumazenil, a specific benzodiazepine receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines and may be used in situations when an overdose with a benzodiazepine is known or suspected. Prior to the administration of flumazenil, necessary measures should be instituted to secure airway, ventilation, and intravenous access. Flumazenil is intended as an adjunct to, not as a substitute for, proper management of benzodiazepine overdose. Patients treated with flumazenil should be monitored for re-sedation, respiratory depression, and other residual benzodiazepine effects for an appropriate period after treatment. **The prescriber should be aware of a risk of seizure in association with flumazenil treatment, particularly in long-term benzodiazepine users and in cyclic antidepressant overdose.**

5. FIRE-FIGHTING MEASURES

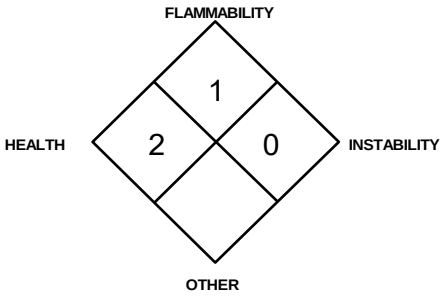
FLASH POINT: Not established.

AUTOIGNITION TEMPERATURE: Not established.

FLAMMABLE LIMITS (in air by volume, %):

Lower (LEL): Not applicable.
Upper (UEL): Not applicable.

NFPA RATING



Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate **3** = Serious **4** = Severe

FIRE EXTINGUISHING MATERIALS: Use extinguishing media appropriate for surrounding fire.

Water Spray: OK	Carbon Dioxide: OK
Dry Chemical: OK	Halon: OK
Foam: OK	Other: Any "ABC" Class

UNUSUAL FIRE AND EXPLOSION HAZARDS: Under emergency conditions, this product can cause temporary incapacitation or residual injury. This product may ignite if highly heated for a prolonged period of time. When involved in a fire, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, hydrogen chloride and sodium oxides).

Explosion Sensitivity to Mechanical Impact: Not sensitive.
Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL FIRE-FIGHTING PROCEDURES: Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment. If protective equipment is contaminated by this product, it should be thoroughly washed with running water prior to removal of SCBA respiratory protection. Firefighters whose protective equipment becomes contaminated should thoroughly shower with warm, soapy water and should receive medical evaluation if they experience any adverse effects.

6. ACCIDENTAL RELEASE MEASURES

SPILL RESPONSE: For small releases of this compound (1 bottle), take basic hygiene precautions. Lightweight gloves, a lab coat, and eye protection should be worn. Pick up or sweep up spilled tablets, place in a bag, and hold for waste disposal. Avoid generating airborne dusts of this product during cleanup. In case of a large spill, clear the affected area and protect people. Large or uncontrolled releases (a case of bottles) should be responded to by trained personnel using pre-planned procedures. Proper protective equipment should be used, including lab gloves, full body gown, boots, and splash goggles. Respiratory protection should not be necessary. Pick up or sweep up spilled tablets. Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces.

7. HANDLING and USE

WORK PRACTICES AND HYGIENE PRACTICES: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke, or apply cosmetics while handling this product. Wash hands thoroughly after handling this product or equipment and containers that contain this product. Follow SPECIFIC USE INSTRUCTIONS supplied with this product. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this compound, and during patient administration. Use of this product should meet the provisions outlined as follows:

- Work should be performed in an appropriate, designated area,
- Contaminated waste must be properly handled, and,
- If necessary, work areas must be regularly decontaminated.

STORAGE AND HANDLING PRACTICES: Employees must be trained to properly use this product. Use of this product should be performed in a designated area for working with drugs. Ensure product is properly labeled. Store this product away from incompatible materials. Store this product in original container. Inspect bottles containing this product for leaks or damage. As a listed Controlled Substance under DEA regulations, this product must be kept in a secure area with access only to authorized persons.

PRODUCT PREPARATION INSTRUCTIONS FOR MEDICAL PERSONNEL: Handle this material following standard medical practices and following the recommendations presented on the Package Insert.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear latex or butyl rubber gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. Wipe equipment down with damp sponge or polypad.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION

VENTILATION AND ENGINEERING CONTROLS: Use with adequate ventilation. Follow standard medical product handling procedures. During decontamination of work surfaces, workers should wear the same equipment recommended in Section 6 (Accidental Release Measures) of this MSDS.

8. EXPOSURE CONTROLS - PERSONAL PROTECTION (Continued)

EXPOSURE LIMITS/GUIDELINES:

CHEMICAL NAME	CAS #	EXPOSURE LIMITS IN AIR									
		ACGIH-TLVs		OSHA-PELs		NIOSH-RELs		NIOSH	AIHA WEELs		OTHER
		TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	TWA mg/m^3	STEL mg/m^3	IDLH mg/m^3	TWA mg/m^3	STEL mg/m^3	$\mu g/m^3$
Lorazepam	846-49-1	NE	NE	NE	NE	NE	NE	NE	NE	NE	1
Lactose	63-42-3	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE
Magnesium Stearate Limits are for Stearates	557-04-0	10	NE	NE	NE	NE	NE	NE	NE	NE	NE
Microcrystalline Cellulose	9004-34-6	10	NE	10 (total dust) 5 (resp. frac.)	NE	10 (total dust) 5 (resp. frac.)	NE	NE	NE	NE	NE
Polacrillin Potassium	39394-76-5	NE	NE	NE	NE	NE	NE	NE	NE	NE	NE

NE = Not Established. See Section 16 for Definitions of Terms Used.

INTERNATIONAL OCCUPATIONAL EXPOSURE LIMITS: Currently, there are international exposure limits for components of this product as follows:

CELLULOSE:
Australia: TWA = 10 mg/m^3, JAN 1993
Belgium: TWA = 10 mg/m^3, JAN 1993
France: VME = 10 mg/m^3, JAN 1999
The Netherlands: MAC-TGG = 10 mg/m^3, JAN 1999
Russia: TWA = 2 mg/m^3, STEL = 4 mg/m^3, Skin, JAN 1993
Switzerland: MAK-W = 6 mg/m^3, JAN 1999

CELLULOSE (continued):
United Kingdom: TWA 10 mg/m^3, STEL = 20 mg/m^3, Total Dust, SEP 2000
United Kingdom: TWA 4 mg/m3, Respirable Dust, SEO 2000
In Argentina, Bulgaria, Colombia, Jordan, New Zealand, Singapore, Vietnam check ACGIH TLV

RESPIRATORY PROTECTION: A respirator is not required for routine conditions of use of this product. Airborne contaminant concentrations must be maintained below guidelines listed in Section 2 (Composition and Information on Ingredients). A dust mask is recommended for use during operations generating excessive dusts.

EYE PROTECTION: Not normally needed during normal use..

HAND PROTECTION: For situations in which prolonged skin contact is anticipated, double glove, using latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before putting on gloves and after removing gloves. Gloves should cover the gown cuff.

BODY PROTECTION: Use appropriate protective clothing for the task (e.g., lab coat, etc.)

9. PHYSICAL and CHEMICAL PROPERTIES

BOILING POINT: Not applicable for product.
FREEZING/MELTING POINT Not established.
EVAPORATION RATE (nBuAc = 1): Not established.
SOLUBILITY IN WATER: Not soluble.
VAPOR PRESSURE (air = 1): Not applicable for product.
SPECIFIC GRAVITY (water = 1): Not applicable.
ODOR THRESHOLD: Not established.
pH: Not established.
COEFFICIENT WATER/OIL DISTRIBUTION: Not established.
APPEARANCE AND COLOR: This product is supplied as round white tablets.
HOW TO DETECT THIS SUBSTANCE (warning properties): The appearance of this product is a distinguishing characteristic.

10. STABILITY and REACTIVITY

STABILITY: This product is stable.

DECOMPOSITION PRODUCTS: If exposed to extremely high temperatures, the products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides, hydrogen chloride and sodium oxides).

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: This product is generally compatible with other common materials in a medical facility. Acids, caustics, and other chemicals that could affect its performance should be avoided.

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Avoid heat, light, and contact with incompatible chemicals.

11. TOXICOLOGICAL INFORMATION

GENERAL TOXICITY INFORMATION: Individuals who have had allergic reactions to products containing Lorazepam and Starch or any of the other ingredients in this product may experience allergic reactions to this product. Symptoms described in patients given therapeutic doses of this substance include the following.

11. TOXICOLOGICAL INFORMATION (Continued)

For Males And Females: Adverse reactions, if they occur, are usually observed at the beginning of therapy and generally disappear on continued medication or upon decreasing the dose. In a sample of about 3,500 anxious patients, the most frequent adverse reaction to Lorazepam is sedation (15.9%), followed by dizziness (6.9%), weakness (4.2%), and unsteadiness (3.4%). Less frequent adverse reactions are disorientation, depression, nausea, change in appetite, headache, sleep disturbance, agitation, dermatological symptoms, eye-function disturbance, together with various gastrointestinal symptoms and autonomic manifestations. The incidence of sedation and unsteadiness increased with age. Small decreases in blood pressure have been noted but are not clinically significant, probably being related to the relief of anxiety produced by Lorazepam. Transient amnesia or memory impairment has been reported in association with the use of benzodiazepines. Overdosage of Lorazepam has produced confusion (continuing), convulsions (seizures), drowsiness (severe) or coma, shakiness, slow heartbeat, slow reflexes, slurred speech (continuing), staggering, troubled breathing, weakness (severe), aplastic anemia, bone marrow changes, respiratory depression, and coma.

SYMPTOMS OF OVEREXPOSURE BY ROUTE OF EXPOSURE: The health hazard information provided below is pertinent to medical employees using this product in an occupational setting. The following paragraphs describe the symptoms of exposure by route of exposure.

INHALATION: Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.

CONTACT WITH SKIN or EYES: Contact with the skin may cause mild irritation, which is alleviated upon rinsing. Prolonged or reaped skin contact may cause dermatitis (dry, red skin). Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.

SKIN ABSORPTION: This product and its components are not known to be absorbed through intact skin.

INGESTION: Ingestion is not a significant route of occupational overexposure. Acute ingestion of large quantities of this product caused by poor hygiene practices may cause adverse symptoms. Symptoms of ingestion overexposure may include drowsiness, dizziness, tiredness, weakness, dry mouth, diarrhea, upset stomach, changes in appetite, restlessness or excitement, constipation, difficulty urinating, frequent urination, blurred vision, changes in sex drive or ability, shuffling walk, persistent, fine tremor or inability to sit still, fever, difficulty breathing or swallowing, severe skin rash, yellowing of the skin or eyes, and irregular heartbeat. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for "Other Potential Health Effects".

HAZARDOUS MATERIAL IDENTIFICATION SYSTEM

HEALTH HAZARD	(BLUE)	2*
FLAMMABILITY HAZARD	(RED)	1
PHYSICAL HAZARD	(YELLOW)	0

PROTECTIVE EQUIPMENT

EYES	RESPIRATORY	HANDS	BODY
	SEE SECTION 8		SEE SECTION 8

For Routine Industrial Use and Handling Applications

Hazard Scale: **0** = Minimal **1** = Slight **2** = Moderate
3 = Serious **4** = Severe * = Chronic hazard

INJECTION: Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection.

OTHER POTENTIAL HEALTH EFFECTS-Therapeutic Doses: Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included the following: abnormal thinking, including disorientation, delusions (holding false beliefs that cannot be changed by facts), or loss of sense of reality, agitation, behavior changes, including aggressive behavior, bizarre behavior, decreased inhibition, or outbursts of anger, convulsions (seizures), hallucinations (seeing, hearing, or feeling things that are not there), hypotension (low blood pressure), muscle weakness, skin rash or itching, sore throat, fever, and chills, trouble in sleeping, ulcers or sores in mouth or throat (continuing), uncontrolled movements of body, including the eyes, unusual bleeding or bruising, unusual excitement, nervousness, or irritability, unusual tiredness or weakness (severe), yellow eyes or skin. Therapeutic use for more than 4 months of Lorazepam can lead to addiction. Withdrawal symptoms such as irritability, nervousness, trouble in sleeping, abdominal or stomach cramps, confusion, fast or pounding heartbeat, increased sense of hearing, increased sensitivity to touch and pain, and increased sweating. Withdrawal symptoms can also include the loss of sense of reality, mental depression, muscle cramps, nausea or vomiting, sensitivity of eyes to light, tingling, burning, or prickly sensations, trembling or shaking, confusion as to time, place, or person, convulsions (seizures), feelings of suspicion or distrust and hallucinations (seeing, hearing, or feeling things that are not there) have occurred.

HEALTH EFFECTS OR RISKS FROM EXPOSURE: An Explanation in Lay Terms. Overexposure to this product may cause the following health effects:

ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin.

11. TOXICOLOGICAL INFORMATION (Continued)

CHRONIC: Repeated skin contact may cause dermatitis (dry, red skin). Prolonged or repeated exposure to Lorazepam may cause habituation or addiction. Lorazepam is a reproductive toxin by ingestion and intravenous injection and causes fetal developmental abnormalities. Lorazepam is an allergen; subsequent exposures to very small amounts may cause allergic reaction (e.g., itching, rash, difficulty breathing) in sensitive individuals. In the event of acute or chronic exposures to therapeutic doses of this product, effects described in "Other Potential Health Effects" may result. See Section 11 (Toxicological Information, for additional information).

TARGET ORGANS: ACUTE: Industrial Exposure: Skin, eyes. Therapeutic Doses: Cardiovascular system, central nervous system. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Cardiovascular system, central nervous system and reproductive system, skin.

IRRITANCY OF PRODUCT: This product is not known to irritate contaminated tissue.

SENSITIZATION OF PRODUCT: The Lorazepam component of this product may be an allergen; subsequent exposures to very small amounts may cause allergic reaction (e.g., itching, rash, difficulty breathing) in sensitive individuals.

TOXICITY DATA: The following are toxicity data for the active component of this product, Lorazepam. This MSDS presents LD_{50} (oral-rat) and LD_{50} (oral, mouse) data currently available for the active component. No human toxicity data are available for Lorazepam. Additional data are available for the active component and data are available for other components of this product, but are not presented in this MSDS. Contact Watson Pharmaceuticals for more information.

LORAZEPAM:

TDLo (Oral-Woman) 2420 μg/kg: female 36-39 week(s) after conception lactating female 2 day(s) post-birth: Reproductive: Effects on Newborn: other neonatal measures or effects

TDLo (Oral-Woman) 380 ug/kg/19 days-intermittent: Blood: aplastic anemia, changes in bone marrow (not otherwise specified)

TDLo (Oral-Human) 28 μg/kg: Behavioral: changes in psychophysiological tests

TDLo (Oral-Child) 71 μg/kg: Behavioral: general anesthetic, hallucinations, distorted perceptions, ataxia

LORAZEPAM (continued):

TDLo (Oral-Child) 1208 μg/kg: Behavioral: somnolence (general depressed activity), Vascular: BP lowering not characterized in autonomic section, Lungs, Thorax, or Respiration: pleural thickening

TDLo (Oral-Human) 21 μg/kg: Behavioral: somnolence (general depressed activity), alteration of classical conditioning

LD_{50} (Oral-Rat) 4500 mg/kg

LD_{50} (Oral-Mouse) 1850 mg/kg

SUSPECTED CANCER AGENT: No evidence of carcinogenic potential emerged in rats during an 18-month study with Lorazepam.

ACGIH lists Starch and Stearates such as Magnesium Stearate as a TLV-A4 (Not Classifiable as Human Carcinogen). The remaining components of this product are not found on the following lists: FEDERAL OSHA Z LIST, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

REPRODUCTIVE TOXICITY INFORMATION: The safety of use of Lorazepam during pregnancy has not been established; therefore, it is not recommended for use during pregnancy or lactation. Several studies have suggested an increased risk of congenital malformations associated with the use of the benzodiazepines, chlordiazepoxide and diazepam, and meprobamate, during the first trimester of pregnancy. Since Lorazepam is also a benzodiazepine derivative, its administration is rarely justified in women of childbearing potential. If the drug is prescribed to a woman of childbearing potential, she should be warned to contact her physician regarding discontinuation of the drug if she intends to become or suspects that she is pregnant. Lorazepam injection should not be used during pregnancy. There are insufficient data regarding obstetrical safety of parenteral Lorazepam, including use in cesarean section. Such use, therefore, is not recommended. Listed below is information concerning the effects of this product and its components on the human reproductive system.

Mutagenicity: No studies regarding mutagenesis have been performed on Lorazepam.

Embryotoxicity: Reproductive studies in animals were performed in mice, rats, and two strains of rabbits. Occasional anomalies (reduction of tarsals, tibia, metatarsals, malrotated limbs, gastroschisis, malformed skull, and microphthalmia) were seen in drug-treated rabbits without relationship to dosage. Although all of these anomalies were not present in the concurrent control group, they have been reported to occur randomly in historical controls. At doses of 40 mg/kg and higher, there was evidence of fetal resorption and increased fetal loss in rabbits which was not seen at lower doses. The clinical significance of the above findings is not known. However, an increased risk of congenital malformations associated with the use of minor tranquilizers (chlordiazepoxide, diazepam, and meprobamate) during the first trimester of pregnancy has been suggested in several studies. Benzodiazepines have been reported to increase the chance of birth defects when used during the first 3 months of pregnancy. Although similar problems have not been reported with the Lorazepam, the chance always exists since all of the benzodiazepines are related.

Teratogenicity: Use of benzodiazepines during pregnancy, especially during the last weeks, may cause body temperature problems, breathing problems, difficulty in feeding, drowsiness, or muscle weakness in the newborn infant. In humans, blood levels obtained from umbilical cord blood indicate placental transfer of Lorazepam.

Reproductive Toxicity: Use of a benzodiazepine during pregnancy may cause the baby to become dependent on the medicine. This may lead to withdrawal side effects after birth. Although it is unknown whether not oral Lorazepam is excreted in human milk, other Benzodiazepines may pass into the breast milk and cause drowsiness, difficulty in feeding, and weight loss in nursing babies of mothers taking Lorazepam. Use in lactating mothers is not recommended.

ACGIH BIOLOGICAL EXPOSURE INDICES (BEIs): Currently, ACGIH Biological Exposure Indices (BEIs) have not been determined for the components of this product.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

ENVIRONMENTAL STABILITY: The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.

EFFECT OF MATERIAL ON PLANTS or ANIMALS: No specific information is currently available on the effect of this product on plants or animals in the environment. This product may be harmful to contaminated plant and animal life, especially in large quantities.

EFFECT OF CHEMICAL ON AQUATIC LIFE: No information is currently available on the effect of this product on aquatic plants or animals in the environment. Release of this product to an aquatic environment may be harmful to aquatic plant and animal life in contaminated bodies of water, especially in large quantities.

13. DISPOSAL CONSIDERATIONS

PREPARING WASTES FOR DISPOSAL: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of the EU and its member states or Canada and its Provinces. This product, if unaltered by handling, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All gowns, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

U.S. EPA WASTE NUMBER: Not applicable to wastes consisting only of this product.

14. TRANSPORTATION INFORMATION

THIS PRODUCT IS NOT HAZARDOUS AS DEFINED BY 49 CFR 172.101 BY THE U.S. DEPARTMENT OF TRANSPORTATION.

PROPER SHIPPING NAME:	Not Regulated
HAZARD CLASS NUMBER and DESCRIPTION:	Not Applicable
UN IDENTIFICATION NUMBER:	Not Applicable
PACKING GROUP:	Not Applicable
DOT LABEL(S) REQUIRED:	Not Applicable

EMERGENCY RESPONSE GUIDEBOOK NUMBER (2004): Not Applicable

MARINE POLLUTANT: No component of this product is classified by the U.S. DOT as a Marine Pollutant (as defined by 49 CFR 172.101, Appendix B).

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not considered as Dangerous Goods, per regulations of Transport Canada.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product is not considered as Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is not considered as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product is not considered by the United Nations Economic Commission for Europe to be dangerous goods.

15. REGULATORY INFORMATION

UNITED STATES REGULATIONS:

U.S. SARA REPORTING REQUIREMENTS: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA THRESHOLD PLANNING QUANTITY: There are no specific Threshold Planning Quantities for any component of this product. The default Federal MSDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) therefore applies, per 40 CFR 370.20.

U.S. CERCLA REPORTABLE QUANTITIES (RQ): Not applicable.

U.S. TSCA INVENTORY STATUS: This product is regulated under Food and Drug Administration standards, it is not subject to requirements under TSCA.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65): The Lorazepam component of this product is on the Proposition 65 Lists, as a compound that cause development effects in humans. WARNING: This product contains a chemical known to the State of California to cause developmental toxicity.

OTHER U.S. FEDERAL REGULATIONS: Lorazepam is listed as a Schedule IV controlled substance in 21 CFR 1308.14. Its Drug Enforcement Agency Controlled Substance Number is 2885. Federal law prohibits dispensing this product without prescription.

CANADIAN REGULATIONS:

CANADIAN DSL INVENTORY STATUS: This product regulated by the Therapeutic Products Programme (TPP) of Health Canada and so it excepted from requirements of the DSL/NDSL Inventory.

15. REGULATORY INFORMATION (Continued)

CANADIAN ENVIRONMENTAL PROTECTION ACT (CEPA) PRIORITIES SUBSTANCES LISTS: The components of this product are not on the CEPA Priorities Substances Lists.

OTHER CANADIAN REGULATIONS: Not applicable.

CANADIAN WHMIS CLASSIFICATION and SYMBOL: Class D2A/B (Materials Causing Other Toxic Effects)

16. OTHER INFORMATION

ANSI LABELING (Based on 129.1, Provided to Summarize Occupational Exposure Hazards): WARNING! MAY CAUSE SKIN AND EYE IRRITATION. CONTAINS A REPRODUCTIVE TOXIN. REPEATED INGESTION CAN LEAD TO CHEMICAL ADDICTION WHEN TAKEN INTERNALLY. MAY CAUSE ALLERGIC REACTION. Do not taste or swallow. Avoid contact with skin, eyes, and clothing. Wash thoroughly after handling. Wear gloves, goggles, and appropriate body protection during handling or administration. FIRST-AID: In case of contact, flush skin or eyes with plenty of water. If adverse respiratory reaction occurs from allergic reaction, give oxygen and seek immediate medical attention. If ingested, DO NOT induce vomiting-seek immediate medical attention. IN CASE OF FIRE: Use water fog, dry chemical, CO_2, or "alcohol" foam. IN CASE OF SPILL: Pick up or sweep up spilled product. Place residual in appropriate container and seal. Dispose of according to applicable regulations. Consult Material Safety Data Sheet for additional information.

EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION: According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are excepted from classification and other criteria of 1272/2008.

EU LABELING AND CLASSIFICATION 67/548/EEC: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC.

COMPONENT GLOBAL HARMONIZATION, EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION FULL TEXT:

Lorazepam:

Signal Word: Danger

Classification: Reproductive Toxicity Cat. 2, Target Organ Toxicity, repeated exposure, category 1

Hazard Statements: H361

Precautionary Statements:

P260 - Do not breathe dust; P262 - Do not get in eyes, on skin, or on clothing; P280 - Wear protective gloves/protective clothing/eye protection/face protection

Hazard Symbol/Pictograms:

ALL OTHER COMPONENTS:

These components do not meet the criteria for classification of hazardous.

COMPONENT EU 67/548/EEC LABELING AND CLASSIFICATION FULL TEXT:

Lorazepam:

Hazard Classification: Harmful

Risk Phrases: R62+R63

Hazard Symbol:

EU SAFETY PHRASES: [S: ½]: Keep out of reach of children. (*This safety phrase can be omitted from the label when the substance or preparation is sold for industrial use only.*) [S: 13]: Keep away from food, drink, and animal feedingstuffs. [S: 22]: Do not breathe dust. [S: 24]: Avoid contact with skin. [S: 36/37]: Wear suitable protective clothing and gloves. [S: 45]: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). [S: 46]: If swallowed, seek medical advice immediately and show this container or label.

All Other Components:

Classification: An official classification for these substances has not been published in Commission Directives.

REFERENCES AND DATA SOURCES: Contact the supplier for information.

METHODS OF EVALUATING INFORMATION FOR THE PURPOSE OF CLASSIFICATION: Bridging principles were used to classify this product.

REVISION DETAILS: Updated with GHS information and added internal exposure limit

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