
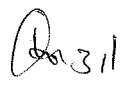


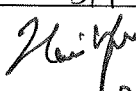


CERTIFICATE FOR SAFETY DATA SHEET

Name of the product: Buspirone Hydrochloride Tablets USP 5mg, 7.5mg, 10mg, 15mg & 30mg

Product Code: 2001630(5mg), 2004489(7.5mg), 2001634(10mg), 2001633(15mg), 2001635(30mg)

SDS Number: SDS/D1-054-00

Activity	Department	Name	Sign & Date
Prepared By (FD)	FD	B. M. Shivaraj	 31/01/19
Reviewed By (FD)	FD	Pradeep eye	 31/01/19
Reviewed By (RA)	RA	Muddala mohammal	 31/01/19
Approved By (FD)	FD	Sudarshan Nimbalkar	 31/01/19
Authorized By (TSGQA/DQA)	DQA	B.S. HARISH PRASAD	 31/01/2019

Safety data Sheet	
Company Name:	Strides Pharma Science Limited
	SDS Number: SDS/D1-054-00
Section 1: Identification	
Product Identifier	
Product name:	Buspirone Hydrochloride Tablets USP, 5 mg, 7.5 mg, 10 mg, 15 mg & 30 mg
Trade name:	Not applicable
Product Code No.:	2001630(5mg), 2004489(7.5mg), 2001634(10mg), 2001633(15mg), 2001635(30mg)
Relevant identified use of the substance or mixture and use advised against	
Recommended Use:	Pharmaceutical product for the treatment of anxiety (anxiolytic)
Restrictions on Use:	Not applicable
Details of the supplier of the safety data sheet:	
Manufacturer name:	Strides Pharma Science Limited
Address:	Strides Pharma Science Limited No. 36/7 Suragajakkanahalli, Indlavadi Cross, Anekal Taluk, Bengaluru – 562106 India (IND)
Telephone Number-General:	+91-80-67840307/309
Emergency Telephone Number:	+91-80-67840307/309
Note: <i>This safety data sheet is written to provide safety, health and environmental information for people handling the formulated product in the work place. It is not intended to provide information relevant to consumer use of the product (PIL will be applicable for consumer).</i>	
Section 2: Hazard Identification:	
Hazard Overview	<p>ACUTE: The primary health effects that may be experienced by medical personnel exposed to this product is mild irritation of contaminated skin.</p> <p>CHRONIC: Repeated skin contact may cause dermatitis (dry, red skin). 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).</p> <p>TARGET ORGANS: ACUTE: Industrial Exposure: Skin, eyes. Therapeutic Doses: Central nervous system and gastrointestinal system. CHRONIC: Industrial Exposure: Skin. Therapeutic Doses: Central nervous system, gastrointestinal system, and skin.</p>
Potential Health Effects	<p>Employees administering the product should not experience adverse effects if handled properly. Adverse effects from therapeutic doses have included the following:</p> <p>Dizziness, drowsiness, nervousness, insomnia, light headedness, difficulty concentrating, excitement, anger, hostility, confusion, and depression.</p> <p>Rapid heartbeat and palpitations. Blurred vision.</p>



	<p>Nausea, dry mouth, gastric distress, diarrhea, constipation, and vomiting. Muscle and joint pain. Numbness, incoordination, tremor, and burning, prickling, itching, or tingling of the skin. Rash. Headache, fatigue, weakness, sweating, and clamminess.</p>		
Signal word	Not available		
Health Hazard	<p>The chief health hazard associated with overexposures during normal use and handling is the potential for irritation of contaminated skin. Individuals who have had allergic reactions to products containing Buspirone Hydrochloride or any of the other ingredients in this product may experience allergic reactions to this product. Therapeutic use of Buspirone Hydrochloride can cause adverse symptoms of the central nervous system, gastrointestinal system, and skin.</p>		
Hazard statement	<p>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, sodium oxides, magnesium oxides, sodium oxides, and hydrogen chloride).</p> <p>Reactivity Hazards: This product is not reactive.</p> <p>Environmental Hazards: Large quantities released to the aquatic and terrestrial environment may have an adverse effect.</p> <p>Emergency Considerations: Emergency responders should wear appropriate protection for the situation to which they respond.</p>		
Label elements			
Precautionary statements	Not Available		
Prevention	Not available		
Response	Not available		
Other Hazards	May cause allergic reactions		
Storage /Disposal	Keep containers tightly closed in a room temperature, Store in a dry place Protected from light		
EU classification	Not available		
US GHS Classification	Not available		
Section 3: Composition/Information on Ingredients			
Mixtures:			
Composition			
Components (Chemical Name)	Identifiers (CAS No.)	% Composition	Classification according to regulations (US GHS/EU EINECS)
Buspirone Hydrochloride	33386-08-2	*	251-489-4
Cellulose	9004-34-6	*	232-674-9
Colloidal silicon	7631-86-9	*	231-545-4



dioxide			
Lactose	63-42-3	*	200-559-2
Magnesium Stearate	557-04-0	*	209-150-3
Sodium Starch Glycolate	906338-1	*	Not listed
*Percentage composition is not captured due to trade secret.			
Section 4: First aid measures			
General Information:			
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.		
Skin:	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:	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.		
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.		
Most important symptoms and effects both acute and delayed:			
Medical Conditions Aggravated by Exposure	Hypersensitivity to Buspirone Hydrochloride and central nervous system disorders may be aggravated by chronic overexposures to this product.		
Other hazards	Not Available		
UN GHS/ EU EINECS			
Effects:	Not Available		
Indication of immediate medical attention and special treatment needed	Hypersensitivity to Buspirone Hydrochloride and central nervous system disorders may be aggravated by chronic overexposures to this product. 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.		
Notes for the doctor	This product should only be given to patients by persons experienced in management of patients receiving the type of therapy intended for this product. General symptomatic and supportive measures should be used along with immediate gastric lavage. Respiration, pulse, and blood pressure should be		

	monitored as in all cases of drug over dosage. No specific antidote is known to Buspirone, and dialyzability of Buspirone has not been determined.
Special treatment	Not Available
Other information	NA
Section 5: Fire Fighting Measures	
Extinguishing media	
Suitable Extinguishing Media	Water spray jet, dry chemical, foam, carbon dioxide, Halon, other (Any "ABC" class)
Unsuitable Extinguishing Media	None Known
Firefighting Procedures	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment.
Un usual fire and Explosion Hazards:	Explosion Sensitivity to Mechanical Impact: Not sensitive. Explosion Sensitivity to Static Discharge: Not sensitive.
Hazardous combustion products:	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, sodium oxides, magnesium oxides, sodium oxides, and hydrogen chloride).
Protection of fire-fighters	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus (SCBA) and full protective equipment.
Special method of fire-fighting	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.
Section 6: Accidental Release Measures	
Personal precautions, Protective equipment and Emergency procedures	
Personal Precautions:	Protective equipment and Emergency procedures
Emergency procedures:	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.



Methods and material for containment and cleaning up			
Containment/Cleanup measures	Not applicable		
Prohibited materials	Not applicable		
Section 7: Handling and Storage			
Precautions for safe handling			
Protective measures:			
Safe handling:	Handle this material following standard medical practices and following the recommendations presented on the Package Insert.		
Fire Prevention	Not available		
Dust generation Preventions	Not available		
Environmental precautions	Not available		
Storage	Store at 20 °C to 25 °C (68 ° to 77 °F); excursions permitted between 15 °C to 30 °C (59 °F to 86 °F) [see USP controlled room temperature].		
Storage conditions			
Special Packaging Materials	Not applicable		
Requirement for storage rooms and assembly: Not applicable			
Incompatible materials or ignition sources: Store this product away from incompatible materials			
Section 8: Exposure Controls and personal protection			
Control parameters:			
Exposure Limits/Guidelines: Refer the occupational exposure limits / guidelines for the individual product components			
Exposure Limits			
Component Name	Result	OSHA/NIOSH	Other agency Information
Buspirone Hydrochloride	NE	NE	NE
Cellulose	OSHA/NIO SH	10 (total dust) 5 (resp. frac.)	NE
Colloidal Silicon dioxide	NE	NE	NE
Lactose	NE	NE	NE
Magnesium Stearate (Limits for Stearate)	NE	NE	ACGIH-TLVs – 10mg/m ³
Sodium Starch Glycolate	NE	NE	NE
Personal protective equipment			
Engineering Controls	Not available		
Personal protective equipment:			
Hands	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. If		



	necessary, refer to U.S. OSHA 29 CFR 1910.138, and appropriate Standards of the EU and Canada for further information.
Eyes	Not normally needed during normal use. If necessary, refer to U.S. OSHA 29 CFR 1910.133, the European Standard EN166 and appropriate Standards of Canada for further information.
Skin	Wear gloves to prevent skin contact. Wash hands with soap and water whenever gloves are removed.
Respiratory protection	A respirator is not required for routine conditions of use of this product. If respiratory protection is needed, use only protection authorized in the U.S. Federal OSHA Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN149, and EU member states. Oxygen levels below 19.5% are considered IDLH by OSHA. In such atmospheres, use of a full-face piece pressure/demand SCBA or a full face piece, supplied air respirator with auxiliary self-contained air supply is required under OSHA's Respiratory Protection Standard (1910.134-1998).
Special requirements for PPE	Not available.
Protective measures	Not available.
Body protection	During patient administration, use of lightweight cotton gown or other medical attire is recommended. If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects may pierce the soles of the feet or where employee's feet may be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.

Section 9: Physical and Chemical properties

Information on physical and chemical Properties

Material Description:	Buspirone Hydrochloride Tablets, USP 5 mg are White to off white ovoid-rectangular uncoated tablet with score line on one side and engraved '5' on the other side.
	Buspirone Hydrochloride Tablets, USP 7.5 mg are White to off white colour, oval, biconvex tablets, debossed with 7.5 on one side and scoreline on other side.
	Buspirone Hydrochloride Tablets, USP 10 mg are White to off white ovoid - rectangular uncoated tablet with score line on one side and engraved '10' on the other side.
	Buspirone Hydrochloride Tablets, USP 15 mg are White to off white rectangular uncoated tablet with trisected score lines on one side and trisected score line with engraved '5' on each trisection of other side. The 15 mg tablet is in xx tablet design and scored so that it can be either bisected or trisected.
	Buspirone Hydrochloride Tablets, USP 30 mg are White to off white rectangular uncoated tablet with trisected score lines on one side and trisected score line with engraved '10' on each trisection of other side.
Physical Form:	Tablets



Color:	White		
Odour:	Not available		
Solubility	Not Soluble		
General Properties:			
Boiling point	Not available	Melting point	Not available
Water solubility:	Not Soluble	Solvent solubility:	Not available
Decomposition temperature	Not available	Viscosity	Not available
Density	Not available	Partition coefficient	Not available
Volatility & Flammability:	Not Available		
Vapor pressure	Not relevant	Vapour density	Not relevant
Evaporation rate	Not applicable	UEL (Upper Exposure limit)	Not applicable
Flash Point	Not applicable	LEL (Lower Exposure limit)	Not applicable
Flammability (solid, gas)	Not applicable	-	-

Section 10: Stability and Reactivity

Reactivity	
Chemical stability under normal ambient Temperature	This product is stable.
Conditions to avoid	High temperatures
Incompatible materials	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 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, sodium oxides, magnesium oxides, sodium oxides, and hydrogen chloride).

Section 11: Toxicological information

Information on toxicological effects	
<p>General Information: Individuals who have had allergic reactions to products containing Buspirone Hydrochloride 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:</p> <p><i>For Males And Females:</i> Dizziness, drowsiness, nervousness, insomnia, lightheadedness, difficulty concentrating, excitement, anger, hostility, confusion, depression, rapid heartbeat, palpitations, blurred vision, nausea, dry mouth, gastric distress, diarrhea, constipation, vomiting, muscle and joint pain, numbness, incoordination, tremor, burning, prickling, itching, or tingling of the skin, rash, headache, fatigue, weakness, sweating, and clamminess.</p>	
Component Name	CAS No
Acute Toxicity	



Buspirone Hydrochloride	33386-08-2	<p>TDLo (oral, man) = 4 mg/kg/2 weeks-intermittent: Behavioral: euphoria</p> <p>TDLo (oral, man) = 58 mg/kg: male 26 week(s) pre-mating: Reproductive: Paternal Effects: other effects on male</p> <p>TDLo (oral, human) = 285 g/kg: Behavioral: somnolence (general depressed activity), hallucinations, distorted perceptions; Sense Organs and Special Senses (Eye): miosis (pupillary constriction)</p> <p>LD50 (oral, rat) = 196 mg/kg LD50 (oral, mouse) = 655 mg/kg</p>
Cellulose	9004-34-6	Not Available
Colloidal silicon dioxide	7631-86-9	Not Available
Lactose	63-42-3	Not Available
Magnesium Stearate	557-04-0	Not Available
Sodium Starch Glycolate	906338-1	Not Available
Potential Health Effects	No evidence of carcinogenic potential was observed in rats during a 24-month study at approximately 133 times the maximum recommended human oral dose; or in mice, during an 18-month study at approximately 167 times the maximum recommended human oral dose.	
Inhalation	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms may include coughing, sneezing, and difficulty breathing.	
Acute (immediate)	Not Available	
Chronic (delayed)	Not Available	



Eye	
Acute (immediate)	Miosis (pupillary constriction)
Chronic (delayed)	
Ingestion	
Acute (immediate)	Not Available
Chronic (delayed)	Not Available
Chronic exposure	Not Available
Signs and symptoms of overexposure	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.
Germ cell mutagenicity	With or without metabolic activation, Buspirone did not induce point mutations in five strains of <i>Salmonella typhimurium</i> (Ames Test) or mouse lymphoma L5178YTK+ cell cultures, nor was DNA damage observed with Buspirone in Wi-38 human cells. Chromosomal aberrations or abnormalities did not occur in bone marrow cells of mice given one or five daily doses of Buspirone.
Reproductive toxicity	Currently, this product is not reported to cause reproductive effects in humans in therapeutic doses. No fertility impairment was observed in reproduction studies performed in rats and rabbits at Buspirone doses of approximately 30 times the maximum recommended human dose.
Sensitization	Individuals who have had allergic reactions to products containing Buspirone Hydrochloride or any of the other ingredients in this product may experience allergic reactions to this product.
Subchronic toxicity	Not Available
IARC	Not Available
ACGIH	Not Available
NTP	Not Available
Section 12: Ecological Information	
Ready biodegradability	The chemical (medicinal) components of this product will slowly degrade in the environment and form a variety of organic materials.
Inherent biodegradability	Not Available
Abiotic degradation	Not Available
Ecotoxicity	Not Available
Mobility	Not Available
Air pollution	Not Available
Section 13: Disposal Considerations	
Product Waste	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.	
Packaging waste	Reusable equipment should be cleaned with soap and water	
RCRA waste	Not Available	
Section 14: Transport information		
UN Number	Not applicable	
UN shipper name	Not applicable	
Transport hazard class:	This product is not considered as Dangerous Goods	
Environmental hazards	This product is not considered as Dangerous Goods	
Note	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).	
Section 15: Regulatory Information		
Safety, Health and environmental regulations/legislation specific for the substance or Mixture		
Components (Chemical Name)	Identifiers (CAS No.)	CERCLA/SARA Emission Reporting
Bupirone Hydrochloride	33386-08-2	Not Available
Cellulose	9004-34-6	Not Available
Colloidal Silicon dioxide	7631-86-9	Not Available
Lactose	63-42-3	Not Available
Magnesium Stearate	557-04-0	Not Available
Sodium Starch Glycolate	906338-1	Not Available
TSCA Status	FDA Exemption - not on inventory	
Reporting Requirements	ANSI Labelling: MAY CAUSE SKIN AND EYE IRRITATION. MAY CAUSE ALLERGIC REACTION. 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.	
Section 16: Other information		
Reason for revision: (Include Change control number)	New Safety data sheet prepared	
Revision date:	31/01/2019	
Version Number:	00	