BUSPIRONE HYDROCHLORIDE HYDROCHLORIDE

TABLETS 5/10/15/30MG

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product name: Buspirone Hydrochloride Tablets USP

Material Name: Buspirone Hydrochloride

Chemical formula of active ingredient: C21H31N5O2 • HCl

Chemical name of active ingredient: 8-[4-[4-(2-pyrimidinyl)-1-piperazinyl]-butyl]-8-azaspiro [4,5] decane-7,9- dione monohydrochloride

How supplied: 5 mg, 10mg, 15mg & 30mg

Use: Anti-anxiety

Supplier of Data: **Strides Arcolab Ltd**
Opposite to IIMB, Bilekahalli
Bangalore – 560076
India

For emergency or
Product information, call 1 877 244 9825

2. COMPOSITION/INFORMATION ON INGREDIENTS

Product contains excipients: Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

Product Description: Buspirone Hydrochloride Tablets, USP are available as:

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. Tablets are packed in the bottles of 100 having NDC 64380-741-06.

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. Tablets are packed in the bottles of 100 having NDC 64380-742-06.

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. Tablets are packed in bottles of 60 having NDC 64380-743-03, 100 having NDC 64380-743-06 and 180 having NDC 64380-743-18.

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. Tablets are packed in bottles of 60 having NDC 64380-744-03.

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 USPcontrolled room temperature].

Health Hazards: 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.

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).

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.

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 may include coughing, sneezing, and difficulty breathing.

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 eye irritation.

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 can cause nausea, vomiting, dizziness, drowsiness, pupil constriction, and gastric distress. Symptoms of prolonged or repeated ingestion, as may occur when poor industrial hygiene is practiced, may include those described for ―Other Potential Health Effects‖. 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.

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:

Dizziness, drowsiness, nervousness, insomnia, lightheadedness, difficulty concentrating, excitement, anger, hostility, confusion, and depression.

Rapid heartbeat and palpitations.

Blurred vision.

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.

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.

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).

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.

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: Hypersensitivity to Buspirone Hydrochloride and central nervous system disorders 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. 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 overdosage. No specific antidote is

known to Buspirone Hydrochloride, and dialyzability of Buspirone Hydrochloride has not been determined.

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.

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: 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). 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 STORAGE

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 labelled. Store this product away from incompatible materials. Store this product in original container. Inspect bottles containing this product for leaks or damage. This product must be stored in a locked cabinet in a Controlled Substance Storage Room, per the requirements of regulations of the DEA and FDA.

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 CONTROL / PERSONAL PROTECTION

Occupational exposure band / handling category: No data available.

Protective clothing and equipment:

Wear gloves to prevent skin contact. Wash hands with soap and water whenever gloves are removed. Wear safety glasses with side shields or goggles when handling this material to prevent eye contact. Air hood, lab coat, apron, boots or other impermeable clothing may be worn when handling large amounts of Buspirone Hydrochloride

Respiratory protection: Under indicated use, air line mask is recommended.

Skin protection: Wear gloves to prevent skin contact. Wash hands with soap and water whenever gloves are removed.

Ventilation: Use local exhaust ventilation when necessary.

Comments: None

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 scored, oval white (5 mg and 10 mg) tablets and bisected and trisected, oval white (15 mg) 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, sodium oxides, magnesium oxides, sodium oxides, and hydrogen chloride).

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 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:

For Males And Females: Dizziness, drowsiness, nervousness, insomnia, light-headedness, 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.

IRRITANCY OF PRODUCT: This product may irritate contaminated tissue.

SENSITIZATION OF PRODUCT: 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.

TOXICITY DATA: The following are toxicity data for the active components of this product, Buspirone Hydrochloride. This MSDS presents Human, LD50 (oral, rat), and LD50 (oral, mouse) data currently available for the active components. Additional data are available for the active components and data are available for other components of this product, but are not presented in this MSDS.

BUSPIRONE HYDROCHLORIDE:

TDLo (oral, man) = 4 mg/kg/2 weeks-intermittent: Behavioural: euphoria

TDLo (oral, man) = 58 mg/kg: male 26 week(s) pre-mating: Reproductive: Paternal Effects: other effects on male

BUSPIRONE HYDROCHLORIDE (continued):

TDLo (oral, human) = 285 g/kg: Behavioural: somnolence (general depressed activity), hallucinations, distorted perceptions; Sense Organs and Special Senses (Eye): miosis (pupillary constriction)

BUSPIRONE HYDROCHLORIDE (continued):

LD50 (oral, rat) = 196 mg/kg

LD50 (oral, mouse) = 655 mg/kg

SUSPECTED CANCER AGENT: 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. ACGIH lists Stearates such as Magnesium Stearate as 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: Listed below is information concerning the effects of this product and its components on the human reproductive system. Buspirone Hydrochloride has been categorized as PREGNANCY CATEGORY B—NO EVIDENCE OF RISK, Human evidence is negative, but animal evidence is positive. Alternately, there is no human evidence and animal evidence is negative.

Mutagenicity: With or without metabolic activation, Buspirone Hydrochloride did not induce point mutations in five strains of *Salmonella typhimurium* (Ames Test) or mouse lymphoma L5178YTK+ cell cultures, nor was DNA damage observed with Buspirone Hydrochloride 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 Hydrochloride.

Embryotoxicity: Currently, this product is not reported to cause embryotoxic effects in humans in therapeutic doses.

Teratogenicity: Currently, this product is not reported to cause teratogenic effects in humans in therapeutic doses. No fetal damage was observed in reproduction studies performed in rats and rabbits at Buspirone Hydrochloride doses of approximately 30 times the maximum recommended human dose.

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 Hydrochloride doses of approximately 30 times the maximum recommended human dose.

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generation lines. An embryo toxin is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

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).

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 components of this product are not on the California Proposition 65 lists.

OTHER U.S. FEDERAL REGULATIONS: Not applicable

CAUTION! 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.

16. OTHER INFORMATION

None