SAFETY DATA SHEET

PRODUCT: Brimonidine Tartrate Ophthalmic Solution 0.2%

Section 1: PRODUCT AND COMPANY INFORMATION

Wintac Limited 54/1, Boodhihal village, Nelamangala, Bangalore, India-562123. PRODUCT NAME: Brimonidine Tartrate Ophthalmic Solution 0.2%

Section 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW	
Appearance	Clear, greenish yellow solution, free from visible particles.

Eye: Brimonidine tartrate ophthalmic solution 0.2% is indicated for lowering intraocular pressure in patients with open-angle glaucoma or ocular hypertension. The preservative in Brimonidine tartrate ophthalmic solution 0.2%, benzalkonium chloride, may be absorbed by soft contact lenses. Patients wearing soft contact lenses should be instructed to wait at least 15 minutes after instilling Brimonidine tartrate ophthalmic solution 0.2% to insert soft contact lenses.
Skin: Irritant
Ingestion: Harmful if swallowed
Inhalation: Harmful if inhaled
Chronic Effects: Not known
Target Organs: Liver

Medical Conditions Aggravated by Long Term Exposure: No information is available on over dosage in humans. Treatment of an oral overdose includes supportive and symptomatic therapy; a patent airway should be maintained.

Section 3: COMPOSITION AND INFORMATION ON INGREDIENTS

Chemical Name	**CAS Number**
Brimonidine Tartrate	70359-46-5
Benzalkonium Chloride NF	8001-54-5
Citric acid Monohydrate USP	77-92-9
Sodium Citrate Dihydrate USP	54-64-8
Polyvinyl Alcohol USP	9002-89-5
Sodium Chloride USP	7647-14-5
Sodium Hydroxide NF	1310-73-2
Hydrochloric Acid NF	7647-01-0
Water for Injection USP	7732-18-5

Section 4: FIRST AID MEASURES

Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 20 minutes. If irritation occurs or persists, get medical attention.
Skin Contact:	Wash exposed area with soap and water, remove contaminated clothing and obtain medical assistance if irritation occurs.
Inhalation:	Remove person to fresh air, and if breathing stops, use artificial respiration. Contact physician..
Ingestion:	Wash out mouth and drink plenty of water and bland fluids. The use of an emetic drug and/or gastric lavage is advisable. Do not give anything to an unconscious person. Contact physician.

Note to Physicians: Although Brimonidine tartrate ophthalmic solution 0.2% had minimal effect on blood pressure of patients in clinical studies, caution should be exercised in treating patients with severe cardiovascular disease.

Brimonidine tartrate ophthalmic solution 0.2% has not been studied in patients with hepatic or renal impairment; caution should be used in treating such patients.

Brimonidine tartrate ophthalmic solution 0.2% should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension or thromboangiitis obliterans.

During the studies there was a loss of effect in some patients. The IOP-lowering efficacy observed with Brimonidine tartrate ophthalmic solution 0.2% during the first month of therapy may not always reflect the long-term level of IOP reduction. Patient's prescribed IOP-lowering medication should be routinely monitored for IOP.

Pregnancy: Teratogenic Effects: Pregnancy Category B.

Reproductive studies performed in rats with oral doses of 0.66 mg base/kg revealed no evidence of harm to the fetus due to Brimonidine tartrate ophthalmic solution 0.2%. Dosing at this level produced 100 times the plasma drug concentration level seen in humans following multiple ophthalmic doses.

There are no adequate and well-controlled studies in pregnant women. In animal studies, Brimonidine crossed the placenta and entered into the fetal circulation to a limited extent. Brimonidine tartrate ophthalmic solution 0.2% should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether this drug is excreted in human milk; in animal studies Brimonidine tartrate was excreted in breast milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media:	Dry chemical, carbon dioxide, halon, water spray or fog, and foam on surrounding materials
Hazardous Combustion Products:	Hydrogen Bromide and Nitrogen Oxides
Fire Fighting Procedures:	Wear self-contained breathing apparatus and protective clothing. Use water spray to keep fire-exposed containers cool. Do not spray water into the burning material.
Fire / Explosion Hazards:	Not applicable

Section 6: ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Use personal protective equipment
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.
Measures for Environmental Protections:	Contain the spill to prevent drainage into sewers, drains or streams. Use absorbent material to solidify the spill. Shovel or scoop up solidified waste

Section 7: HANDLING AND STORAGE

Handling	Avoid contact with product and use caution to prevent puncturing containers. No special protective equipment or procedures are required in the clinical or home environment.
Storage	Store product upright in original containers with the cap tightly closed at a controlled room temperature 15°-30°C (59°- 86° F). **KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN.**

Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limits	In the manufacturing plant, provide adequate ventilation for the raw material handling and compounding process, which will maintain the dust and vapor, levels below the TLV, STEL, and PEL values for the ingredients. Ventilation fans should be explosion proof. Use adequate personal protective equipment e.g. NIOSH-approved respirators, goggles or safety glasses, gloves and protective clothing. Ensure training in the handling of chemical material and use current Material Safety Data Sheets.
Hands:	Wear protective gloves when working with large quantities
Eyes:	(29 CFR 1910.133) Recommend goggles or chemical safety glasses.
Skin:	Thick impermeable gloves and protective clothing
Respiratory protection:	(29 CFR 1910.134) NIOSH approved respirator, with organic vapor, acid gas and HEPA filter recommended for handling raw materials. **Warning: Do not use air-purifying respirators in oxygen-depleted environments**. No respiratory protection is required in the clinical or home environment.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance Clear, greenish yellow solution,
Decomposition Temperature (°C): No data available.
Evaporation Rate (Gram/s): No data available
Vapour Pressure (kPa): No data available
Vapour Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available
Flammability: Auto ignition Temperature (Solid) (°C): No data available
Flammability (Solids): No data available
Flash Point (Liquid) (°C): No data available
Upper Explosive Limits (Liquid) (% by Vol.): No data available
Lower Explosive Limits (Liquid) (% by Vol.): No data available

Section 10: STABILITY AND REACTIVITY

Stability:	Stable at normal conditions
Conditions to Avoid:	Extreme heat or cold.
Incompatible Materials:	This product has the incompatibilities of water e.g. strong acids, bases, alkali metals, alkali hydrides and silver preparations.
Hazardous Decomposition Products	Hydrogen Bromide and Nitrogen Oxides
Hazardous Polymerization	Should not occur

Section 11: TOXICOLOGY INFORMATION

Toxicological information refers to raw materials product. Concentrations and toxicological effects are substantially reduced in the product.

CAS# 70359-46-5 **Brimonidine Tartrate**

May cause irritation to the eyes and skin. May be harmful to the digestive and respiratory tract.

CAS# 77-92-9 **Citric Acid**

May cause irritation to the eyes and respiratory tract. Mild irritant to the skin. Naturally occurring compound in plant and animal tissues. Generally recognized as safe in foods. Chronic oral over exposure can cause tooth enamel damage. Oral-rat LD_{50} 11,700 mg/kg. Severe irritation eye 750 mg/24 hr.

CAS # 9002-89-5 **Polyvinyl Alcohol**

Dust may cause irritation to eyes and respiratory tract. No known effects by skin contact or ingestion. Inhalation of dust can induce bronchitis or asthma attacks in some individuals. No known dermal effects due to acute exposure. Degradation products of stored material are methanol (PEL=260 mg/M^3) and methyl acetate (TLV=200 ppm). Decomposition products are acetaldehyde, crotonaldehyde and acetone. Oral-rat LD_{50} >10 mg/kg. Acetaldehyde: CAS# 75-07-0; TLV=100 ppm; Suspected Carcinogen. Crotonaldehyde: CAS# 4170-30-3; PEL=2 ppm; Suspected Carcinogen. Acetone: CAS# 67-64-1; TLV= 750 ppm.

CAS # 7647-14-5 **Sodium Chloride**

May cause irritation to eyes, skin, nerves, respiratory, and digestive tract. Eyes and respiratory tract can be irritated by solid or dust. Prolonged skin contact can cause irritation. Ingestion of large amounts can cause high blood pressure (hypertension) and congestion of the internal organs (esp. the meninges and brain), cramps, vomiting, prostration, coma and death.

CAS # 54-64-8 **Sodium Citrate Dihydrate**

May cause irritation to eyes, skin, respiratory, and digestive tract. Target organs are the central nervous system, kidneys and bones. Increased risk persons have impaired renal function, dehydration, sodium restricted diets or hypertension. This information may be based on general information regarding sodium salts. Ingestion of large doses can cause nausea, vomiting, convulsions, diarrhea, and hypernoia (hyper mental activity or imagination). Chronic exposure can cause urolithiasis (build-up of calcium deposits in the urinary tract) due to increased extraction of calcium from the bones.

Section 12: ECOLOGICAL INFORMATION

Chemical Fate Information: Product administered to patients presents a negligible impact on the environment.

Section 13: DISPOSAL CONDITIONS

Dispose of material according to Federal, State, and Local regulations. The method typically used is incineration.
EPA Designations: RCRA Hazardous Waste: Not Listed
SARA Title III: Not Listed

Section 14: TRANSPORTATION INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations

Section 15: REGULATORY INFORMATION

DOT Designations: Not classified as hazardous by DOT regulations.

EPA Designations: RCRA Hazardous Waste

(40 CFR 261.33) Not Listed

FDA Designations: Prescription only medication.

NDC No.70069-231-01 (5 ml)

70069-232-01 (10 ml)

70069-233-01 (15 ml)

OSHA Designations: (29 CFR 1910.1000, Table Z)

Not Listed

SARA Title III: Not listed under Section 313 of Toxic Release Reporting.

CALIFORNIA PROPOSITION 65: Not Listed

Section 16: OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.