SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product Name	:	Brimonidine Tartrate and Timolol maleate Ophthalmic Solution 0.2%/0.5% - 5 mL, 10 mL and 15 mL.
Synonyms	:	Brimonidine tartrate/timolol maleate ophthalmic solution

Manufacturer or supplier's details

Details of the Supplier of the Safety Data Sheet	:	Caplin Steriles Limited, Survey No. 895 & 897, Guruvarajakandigai, Sirupuzhalpettai (Post), Gummidipoondi (Taluk), Thiruvallur (District), Pin Code: 601 201, Tamil Nadu (State), INDIA.
Emergency Telephone Number	:	+91-4467901901/02/03

Recommended use of the chemical and restrictions on use

Recommended use	:	Intra-ocular Pressure (IOP) Alpha-Adrenergic Receptor

SECTION 2: HAZARDS IDENTIFICATION

Classification:

OSHA Regulatory Status:

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity	Category 2

Label elements:

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US) : Warning

Hazard statements : H361 - Suspected of damaging fertility or the unborn child

Precautionary statements

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/ container to an approved waste disposal plant
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Other Information

Unknown Acute Toxicity: 2.5% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS Number	Concentration (%)
Benzalkonium Chloride	63449-41-2	0.1 – 1%*
Sodium Phosphate Monobasic Monohydrate	10049-21-5	1-5%*
Water for Injection	7732-18-5	60-100%*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

SECTION 4 : FIRST AID MEASURES

Eye contact	:	Rinse immediately with plenty of water and seek medical advice.
Skin	:	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	:	Remove to fresh air.
Ingestion	:	Consult a physician if necessary.
Chemical Name	:	Benzalkonium Chloride
Notes to Physician	:	Treat symptomatically

SECTION 5 :FIRE FIGHTING MEASURES

Extinguishing Media

Suitable Extinguishing Media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
Unsuitable Extinguishing Media	:	None Known

Specific hazards arising from the substance or mixture

Fire may produce irritating, corrosive and/or toxic gases

Explosion data

Sensitivity to mechanical impact: Not impact sensitive.

Sensitivity to static discharge:

Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6 :ACCIDENTAL RELEASE MEASURES

Personal precautions :	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
Environmental precautions :	See Section 12 for additional ecological information
Methods for containment :	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up :	Avoid creating dust.

SECTION 7 : HANDLING AND STORAGE

Advice on safe handling :	Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.
Storage Conditions :	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.
Incompatible materials :	None known based on information supplied.

SECTION 8 : EXPOSURE CONTROLS, PERSONAL PROTECTION

Control parameters

Exposure Guidelines : This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Engineering Controls: The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection: No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection: During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g.Labcoat,etc.)

Respiratory protection: Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

Material Description		
Physical form	:	Liquid
Color	:	Clear, light yellow
Odor Threshold	:	No data available
Appearance/Description	:	Liquid
Odor	:	Slight

General Properties

pH	:	6.9
Melting Point	:	No information available
Boiling Point	:	>100
Flash Point	:	> 93.3
Evaporation rate	:	No information available
Flammability (solid, gas)	:	No information available
Flammability Limit in Air		
Upper flammability limit	:	No information available
Lower flammability limit	:	No information available
Vapor Pressure	:	No information available
Vapor Density	:	No information available
Specific gravity	:	1.0
Water solubility	:	Soluble in water
Solubility in other solvents	:	Soluble in water
Partition coefficient	:	No information available
Autoignition temperature	:	No information available
Decomposition temperature	:	No information available
Explosive properties	:	No information available
Oxidising properties	:	No information available
Molecular weight	:	No information available
VOC content (%)	:	No information available
Density	:	No information available
Bulk density	:	No information available

SECTION 10 : Stability and Reactivity

Reactivity	:	Not defined as reactive substance
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None under normal processing.
Conditions to avoid	:	Aerosol formation
Incompatible materials	:	None known based on the information supplied
Hazardous decomposition products	:	None known based on the information supplied

SECTION 11 : TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	N/A	N/A
Benzalkonium Chloride	N/A	= 1420 mg/kg (Rat)	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Benzalkonium Chloride	Not Suspected of being a Mutagen.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	No information available	No information available

Numerical measures of toxicity - Product Information:

Unknown Acute Toxicity 2.5% of the mixture consists of ingredient(s) of unknown toxicity

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity
2.5% of the mixture consists of components(s) of unknown hazards to the aquatic environment
Other adverse effects No information available

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes : Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging : Do not reuse container. Dispose of contents/containers in accordance with local regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT	Not regulated
ICAO	Not regulated
IATA	Not regulated
IMDG	Not regulated
ADR	Not regulated
ADN	Not regulated
TDG	Not regulated

SECTION 15: REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Caplin use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city/state/country.

TSCA - No
DSL/NDSL - No
EINECS/ELINCS - No
CWA - No
CERCLA-No
SARA 311/312 – No
SARA 313 – No
OSHA – No
California Proposition 65 - No

SECTION 16: ADDITIONAL INFORMATION

SDS creation date	:	Jan 21, 2025
SDS Revision date	:	NA
Version #	:	00

Disclaimer: To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

---End of Safety Data Sheet---