

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE

Product identifier

Product Name Brimonidine Tartrate Ophthalmic Solution, 0.1%

Other means of identification

Synonyms Brimonidine Tartrate Ophthalmic drops

Recommended use of the chemical and restrictions on use

Recommended Use Alpha-Adrenergic Receptor Intra-ocular Pressure (IOP)

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet

Manufactured for
 Somerset Therapeutics,
 LLC. Somerset, NJ
 08873

Customer Care 1-800-417-9175

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status

This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements

Emergency Overview

The product contains no substances which at their given concentration, are considered to be hazardous to health

Appearance Liquid	Physical state Liquid	Odor Slight
Chemical Name Potassium Chloride	Symptoms The most common adverse reactions to potassium chloride are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarrhea. One the most severe adverse side effects is hyperkalemia, There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation.	

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Brimonidine	Prolonged or repeated exposure can cause central nervous system effects. allergic conjunctivitis, burning sensation, conjunctival folliculosis, conjunctival hyperemia, eye pruritus, hypertension, ocular allergic reaction, oral dryness, and visual
Chemical Name Potassium Chloride	Medical Conditions Aggravated by Exposure Contraindications occur in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate the following conditions: chronic renal failure, systemic acidosis, acute dehydration, extensive tissue break down and adrenal insufficiency. Other contraindications occur in any patient in whom there is structural, pathological or pharmacologic cause for arrest or delay in tablet passage through the gastrointestinal tract.
Brimonidine tartrate	Antihypertensives/cardiac glycosides may lower blood pressure. Use with CNS depressants may result in an additive or potentiating effect. Tricyclic antidepressants may potentially blunt the hypotensive effect of systemic clonidine. Monoamine oxidase inhibitors may result in increased hypotension.

Other Information

Unknown Acute Toxicity 99.9% 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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.
Brimonidine tartrate	70359-46-5
Sodium carboxymethylcellulose	9004-32-4
Sodium borate	1303-96-4
Boric acid	10043-35-3
Sodium chloride	7647-14-5
Potassium chloride	7447-40-7
Calcium chloride	7440-70-2
Magnesium chloride	7786-30-3
iPRES 25	NA
Water for injection	7732-18-5
Hydrochloric acid	7647-01-0
Sodium hydroxide	1310-73-2

4. FIRST AID MEASURES

First aid measures

Eye contact	Rinse immediately with plenty of water and seek medical advice.
Skin Contact	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

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Chemical Name
Potassium Chloride
Brimonidine tartrate

Note to physicians
No information available.
Treat symptomatically.

5. FIRE-FIGHTING MEASURES

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 chemical

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.

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.

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.

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.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Boric Acid	STEL: 6 mg/m ³ inhalable particulate matter TWA: 2 mg/m ³ inhalable particulate matter	N/A	N/A	N/A
Hydrochloric Acid NF	Ceiling: 2 ppm	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m ³ Ceiling: 5 ppm Ceiling: 7 mg/m ³	IDLH: 50 ppm Ceiling: 5 ppm Ceiling: 7 mg/m ³	N/A
Sodium Borate	STEL: 6 mg/m ³ inhalable particulate matter TWA: 2 mg/m ³ inhalable particulate matter	(vacated) TWA: 10 mg/m ³	TWA: 5 mg/m ³	N/A
Potassium Chloride	N/A	N/A	N/A	5000
Brimonidine tartrate	N/A	N/A	N/A	12.5

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., lab coat, 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liqui	Appearance	Liquid
Color	dclear	Odor	Slight
Odor threshold	No information available		

Property

pH	<u>Values</u>
Melting point/freezing point	7.2
Boiling point / boiling range	No information available
Flash point	>100
Evaporation rate	>93.33
Flammability (solid, gas)	No information available
Flammability Limit in Air	No information available

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Upper flammability limit: 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	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available
Other Information	
Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

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 information supplied.

Hazardous Decomposition

Products None known based on information supplied.

SAFETY DATA SHEET
Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Potassium Chloride	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 the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	Prolonged contact may cause redness and irritation.	Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms, including nausea, vomiting, diarrhea, and abdominal cramps and gastrointestinal ulceration. Ingestion of large quantity or chronic ingestion may cause hemorrhage and perforation or formation of digestive system strictures.
Brimonidine tartrate	May cause irritation of respiratory tract.	May cause eye irritation with susceptible persons. Repeated ocular use has been shown to produce oral dryness, eye irritation, ocular allergic reactions, headache or fatigue or drowsiness when used as directed. Ocular allergies have also been shown in sensitive individuals.	Avoid contact with skin.	May cause irritation to the gastrointestinal tract. Ingestion of large quantities may cause central nervous system effects.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Sodium carboxymethylcellulose	= 27000 mg/kg (Rat)	> 2 g/kg (Rabbit)	> 5800 mg/m ³ (Rat) 4 h
Magnesium Chloride	= 2800 mg/kg (Rat)	N/A	N/A
Boric Acid	= 2660 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 0.16 mg/L (Rat) 4 h
Sodium chloride	= 3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m ³ (Rat) 1 h
Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h
Sodium Borate	= 2660 mg/kg (Rat) = 3493 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	N/A
Calcium Chloride	= 1000 mg/kg (Rat)	> 5000 mg/kg (Rabbit)	N/A
water for injection	> 90 mL/kg (Rat)	N/A	N/A

Potassium Chloride	= 2600 mg/kg (oral Rat)	-	-
Brimonidine tartrate	= 100 mg/kg (Rt); 50 mg/kg (Mouse)	N/A	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
Boric Acid	No information available.	Presumed to have carcinogenic potential for humans.	Probable Reproductive Toxicant.	It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
				for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.
Potassium Chloride	Not mutagenic in the standard battery of tests.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium pool is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.
Brimonidine tartrate	Not mutagenic in the standard battery of tests.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	This product does not contain any known or suspected reproductive hazards.	It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.

Chemical Name	STOT - single exposure	STOT - repeated exposure
Potassium Chloride	No information available.	No information available.
Brimonidine tartrate	No information available.	Presumed to produce significant toxicity to specific target organ(s), Cardiovascular.

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 99.9% of the mixture consists of ingredient(s) of unknown toxicity

12. ECOLOGICAL INFORMATION

Ecotoxicity

100% of the mixture consists of component(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
Magnesium Chloride	2200: 72 h Desmodesmus subspicatus mg/L EC50	4210: 96 h Gambusia affinis mg/L LC50 static 1970 - 3880: 96 h Pimephales promelas mg/L LC50 static	140: 48 h Daphnia magna mg/L EC50 Static 1400: 24 h Daphnia magna mg/L EC50
Boric Acid	N/A	1020: 72 h Carassius auratus mg/L LC50 flow-through	115 - 153: 48 h Daphnia magna mg/L EC50
Sodium Chloride	N/A	4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 7050: 96 h Pimephales	340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1000: 48 h Daphnia magna mg/L EC50

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Chemical Name	Algae/aquatic plants	Fish	Crustacea
		promelas mg/L LC50 semi-static 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L	
		LC50 static	
Hydrochloric Acid	N/A	282: 96 h <i>Gambusia affinis</i> mg/L LC50 static	N/A
Calcium Chloride	N/A	10650: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static	2280000 - 3948000: 48 h <i>Daphnia magna</i> µg/L LC50
Potassium Chloride	2500: 72 h <i>Desmodesmus subspicatus</i> mg/L EC50	750 - 1020: 96 h <i>Pimephales promelas</i> mg/L LC50 static 1060: 96 h <i>Lepomis macrochirus</i> mg/L LC50 static	825: 48 h <i>Daphnia magna</i> mg/L EC5083: 48 h <i>Daphnia magna</i> mg/L EC50 Static

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Boric Acid	N/A	N/A	N/A	-0.757
Potassium Chloride	This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.	No information available	This product has not been tested for mobility in soil	-
Brimonidine tartrate	No information available	No information available	No information available	N/A

Other adverse effects No information available

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.

Chemical Name	California Hazardous Waste Status
Boric Acid	Toxic
Sodium borate	Toxic

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

SAFETY DATA SHEET
Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

IATA Not regulated
IMDG Not regulated
ADR Not regulated
ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA Not Listed
DSL/NDSL Not Listed
EINECS/ELINCS Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Chemical Name	ACGIH	IARC	NTP	OSHA
Boric Acid	-	-	-	X
Hydrochloric Acid	-	Group 3	-	X
Sodium borate	-	-	-	X

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard No
Chronic Health Hazard No
Fire hazard No
Sudden release of pressure hazard No
Reactive Hazard No

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

Chemical Name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Hydrochloric Acid	5000 lb	-	-	X

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

SAFETY DATA SHEET

Brimonidine Tartrate Ophthalmic Solution, 0.1% (5 mL, 10 mL and 15 mL)

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
Hydrochloric Acid	5000 lb	5000 lb	RQ 5000 lb final RQ RQ 2270 kg final RQ

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date 06.08.2024
Revision Note No information available

Disclaimer

The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet