



# SAFETY DATA SHEET

Revision Date 29-Sep-2018

Version 2

## 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

### Product identifier

**Product Name** ALPHAGAN® P (Brimonidine Tartrate Ophthalmic Solution), 0.10% and 0.15%

### Other means of identification

**Product Code** FG00009

**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

#### **Manufacturer**

Allergan plc  
5 Giralda Farms  
Madison, NJ USA 07940  
+1-800-272-5525

**E-mail address** SDS@Allergan.com

### Emergency telephone number

**Emergency Telephone** Call CHEMTREC Day or Night  
Within USA or Canada: 1-800-424-9300  
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

## 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 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.

<b>Brimonidine tartrate</b>	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 disturbance.
<b>Chemical Name Potassium Chloride</b>	<b>Medical Conditions Aggravated by Exposure</b> 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 breakdown 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.
<b>Brimonidine tartrate</b>	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.	EINECS	Weight-%
PWDRD CELLULOSE BW40 NF	9004-32-4	N/A	10 - 30*
Magnesium Chloride	7786-30-3	232-094-6	10 - 30*
Boric Acid	10043-35-3	233-139-2	7 - 13*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	7 - 13*
HYDROCHLORIC ACID NF	7647-01-0	231-595-7	7 - 13*
disodium tetraborate decahydrate	1303-96-4	N/A	7 - 13*
Calcium Chloride	10043-52-4	233-140-8	7 - 13*
PURIFIED WATER USP	7732-18-5	231-791-2	5 - 10*
Potassium Chloride	7447-40-7	231-211-8	3 - 7*
Brimonidine tartrate	70359-46-5	N/A	1 - 5*

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

**4. FIRST AID MEASURES**

**First aid measures**

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	Consult a physician if necessary.

<b>Chemical Name</b>	<b>Note to physicians</b>
Potassium Chloride	No information available.
Brimonidine tartrate	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 <sup>3</sup> )
Boric Acid 10043-35-3	STEL: 6 mg/m <sup>3</sup> inhalable particulate matter TWA: 2 mg/m <sup>3</sup> inhalable particulate matter	N/A	N/A	N/A
HYDROCHLORIC ACID NF 7647-01-0	Ceiling: 2 ppm	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m <sup>3</sup> Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>	IDLH: 50 ppm Ceiling: 5 ppm Ceiling: 7 mg/m <sup>3</sup>	N/A
disodium tetraborate decahydrate 1303-96-4	STEL: 6 mg/m <sup>3</sup> inhalable particulate matter TWA: 2 mg/m <sup>3</sup> inhalable particulate matter	(vacated) TWA: 10 mg/m <sup>3</sup>	TWA: 5 mg/m <sup>3</sup>	N/A
Potassium Chloride 7447-40-7	N/A	N/A	N/A	5000
Brimonidine tartrate	N/A	N/A	N/A	12.5

70359-46-5			
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**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**

<b>Physical state</b>	Liquid	<b>Appearance</b>	Liquid
<b>Color</b>	clear	<b>Odor</b>	Slight
<b>Odor threshold</b>	No information available		

<u>Property</u>	<u>Values</u>
pH	7.2
Melting point/freezing point	No information available
Boiling point / boiling range	>100
Flash point	>93.33
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	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**

<b>Molecular weight</b>	No information available
<b>VOC Content (%)</b>	No information available
<b>Density</b>	No information available
<b>Bulk density</b>	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.

## 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
PWDRD CELLULOSE BW40 NF	= 27000 mg/kg ( Rat )	> 2 g/kg ( Rabbit )	> 5800 mg/m <sup>3</sup> ( 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 USP	= 3000 mg/kg ( Rat )	> 10 g/kg ( Rabbit )	> 42 g/m <sup>3</sup> ( Rat ) 1 h
HYDROCHLORIC ACID NF	238 - 277 mg/kg ( Rat )	> 5010 mg/kg ( Rabbit )	= 1.68 mg/L ( Rat ) 1 h
disodium tetraborate decahydrate	= 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
PURIFIED WATER USP	> 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 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 7786-30-3	2200: 72 h Desmodosmus 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 10043-35-3	N/A	1020: 72 h Carassius auratus mg/L LC50 flow-through	115 - 153: 48 h Daphnia magna mg/L EC50
SODIUM CHLORIDE USP 7647-14-5	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 promelas mg/L LC50 semi-static 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L	340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static 1000: 48 h Daphnia magna mg/L EC50

		LC50 static	
HYDROCHLORIC ACID NF 7647-01-0	N/A	282: 96 h Gambusia affinis mg/L LC50 static	N/A
Calcium Chloride 10043-52-4	N/A	10650: 96 h Lepomis macrochirus mg/L LC50 static	2280000 - 3948000: 48 h Daphnia magna µg/L LC50
Potassium Chloride 7447-40-7	2500: 72 h Desmodesmus subspicatus mg/L EC50	750 - 1020: 96 h Pimephales promelas mg/L LC50 static 1060: 96 h Lepomis macrochirus mg/L LC50 static	825: 48 h Daphnia magna mg/L EC50 83: 48 h Daphnia magna mg/L EC50 Static

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Boric Acid 10043-35-3	N/A	N/A	N/A	-0.757
Potassium Chloride 7447-40-7	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 70359-46-5	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 10043-35-3	Toxic
disodium tetraborate decahydrate 1303-96-4	Toxic

### 14. TRANSPORT INFORMATION

**DOT** Not regulated  
**TDG** Not regulated  
**ICAO (air)** Not regulated  
**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 10043-35-3	-	-	-	X
HYDROCHLORIC ACID NF 7647-01-0	-	Group 3	-	X
disodium tetraborate decahydrate 1303-96-4	-	-	-	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 NF 7647-01-0	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

Chemical Name	Hazardous Substances RQs	CERCLA/SARA RQ	Reportable Quantity (RQ)
HYDROCHLORIC ACID NF 7647-01-0	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	29-Sep-2018
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**