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Revision Number 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING**GHS product identifier****Product Name** ALPHAGAN® P (Brimonidine Tartrate Ophthalmic Solution), 0.10% and 0.15%**Other means of identification****Synonyms** None**Recommended use of the chemical and restrictions on use****Recommended Use** alpha-adrenergic receptor**Uses advised against** No information available**Supplier's details****Supplier Address**Allergan, Inc.
2525 Dupont
Irvine, CA
TEL: 1-714-246-4500**Emergency telephone number****Emergency Telephone Number** Chemtrec 1-800-424-9300**2. HAZARDS IDENTIFICATION****Classification**

Specific Target Organ Toxicity (Repeated Exposure) Category 2

GHS Label elements, including precautionary statements**Emergency Overview****Signal Word****Warning****Hazard Statements**

- May cause damage to the cardiovascular system through prolonged or repeated exposure.

**Appearance** Clear, Liquid**Physical State** Liquid.**Odor** Slight

Precautionary Statements

Prevention

- Do not breathe dust/fume/gas/mist/vapors/spray.

General Advice

- Get medical attention/advice if you feel unwell

Storage

- None

Disposal

- Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)

Not applicable

Other information

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 (fewer than 10% of all clinical subjects).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No	Weight %	Trade secret
Brimonidine tartrate	70359-46-5	0.1-0.15	*

* Where range is displayed, the exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures

Eye Contact	Rinse thoroughly with plenty of water, also under the eyelids. Get medical attention if irritation persists.
Skin Contact	Wash skin with soap and water. Get medical attention if symptoms occur.
Inhalation	IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Get medical attention.

Most important symptoms/effects, acute and delayed

Most Important Symptoms/Effects Irregular cardiac activity. Central nervous system depression. Headache. Eye irritation/reactions.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to Physician 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 No information available.

Specific Hazards Arising from the Chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

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, protective equipment and emergency procedures

Personal Precautions Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Refer to Section 8 for personal protective equipment.

Environmental Precautions

Environmental Precautions See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment Small spills: Wipe up with absorbent material (e.g. cloth, fleece). Large spills: Prevent further leakage or spillage if safe to do so. Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

Methods for Cleaning Up Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8.

Conditions for safe storage, including any incompatibilities

Storage Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products Oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines Allergen OEL: Brimonidine Tartrate: 12.5 ug/m³ (8 hr. TWA)

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Boric acid 10043-35-3	TWA: 2 mg/m ³ inhalable fraction STEL: 6 mg/m ³ inhalable fraction	-	-
Sodium borate 1303-96-4	STEL: 6 mg/m ³ inhalable fraction TWA: 2 mg/m ³ inhalable fraction	(vacated) TWA: 10 mg/m ³	TWA: 5 mg/m ³

Appropriate engineering controls

Engineering Measures Showers
 Eyewash stations
 Ventilation systems

Individual protection measures, such as personal protective equipment

Eye/Face Protection No special protective equipment required. If splashes are likely to occur, wear: Safety glasses with side-shields.
Skin and Body Protection No protective equipment is needed under normal use conditions. Risk of contact: Lightweight protective clothing. Protective gloves.
Respiratory Protection None required under normal usage.
Hygiene Measures Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feeding stuffs. Provide regular cleaning of equipment, work area and clothing. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid	Appearance	Clear Liquid
Odor	Slight	Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks/ - Method</u>
pH	7.1-7.3	None known
Melting Point/Range	No data available	None known
Boiling Point/Boiling Range	>100 °C / >212 °F	None known
Flash Point	>93.33 °C / >200 °F	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limits in Air		
upper flammability limit	No data available	
lower flammability limit	No data available	
Vapor Pressure	No data available	None known
Vapor Density	No data available	None known
Specific Gravity	1.0	None known
Water Solubility	Soluble in water.	None known
Solubility in other solvents	No data available	None known
Partition coefficient: n-octanol/water	No data available	None known
Autoignition Temperature	No data available	None known
Decomposition Temperature	No data available	None known
Viscosity	No data available	None known

Flammable Properties Not flammable

Explosive Properties No data available

Oxidizing Properties No data available

Other information

VOC Content (%) No data available

10. STABILITY AND REACTIVITY

Reactivity

Not reactive under normal conditions.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing.

Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Heat.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

None known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation

Not an expected route of exposure. Inhalation of mist may cause irritation to the respiratory system.

Eye Contact

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 (fewer than 10% of all clinical subjects).

Skin Contact

Prolonged skin contact may cause skin irritation.

Ingestion

May cause irritation to the gastrointestinal tract. Ingestion of large quantities may cause central nervous system effects.

Component Information

Brimonidine Tartrate (active ingredient): Oral LD50 = 50 mg/kg (mouse); 100 mg/kg (rat). Clinical signs included sedation, ataxia, prostration, ptosis, reduced blink reflex, hypotension, hypothermia, respiratory depression/arrest, and circulatory collapse. At 10 mg/kg, transient decreased motor activity, ataxia and/or prostration were observed in both species.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Brimonidine tartrate	100 mg/kg (Rat) 50 mg/kg (Mouse)	-	-

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Prolonged or repeated exposure can cause central nervous system effects.

Delayed and immediate effects and also chronic effects from short and long term exposure

Sensitization

No information available.

Mutagenic Effects	Brimonidine Tartrate was not mutagenic or cytogenic in a series of in vitro and in vivo studies including the Ames test, host-mediated assay, chromosomal aberration assay in Chinese Hamster Ovary (CHO) cells, cytogenic studies in mice and dominant lethal assay.
Carcinogenicity	Did not show carcinogenic effects in animal experiments. Contains no ingredient listed as a carcinogen.
Reproductive Toxicity	Animal testing did not show any effects on fertility.
Developmental Toxicity	Animal testing did not show any effects on fetal development.
STOT - single exposure	Based on available data, the classification criteria are not met.
STOT - repeated exposure	May cause damage to organs through prolonged or repeated exposure. See listed target organs below.
Chronic Toxicity	Oral administration of Brimonidine Tartrate (active ingredient) for one year in rats resulted in toxicity only at the high dose (1.0 mg/kg/day). All changes were reversible within the 8 week recovery period. In monkeys, administration of Brimonidine Tartrate for one year resulted in sedation, slight hypotension, sinus bradycardia, and occasionally, sinus arrhythmia at a dose of 2.5 mg/kg/day. No observable effects were noted at a dose of 0.1 mg/kg/day.
Target Organ Effects	Brimonidine Tartrate at varying concentrations was administered in repeated doses (one drop into one eye twice per day) to rabbits for six months and monkeys for one year. Rabbits exhibited dose-dependent sedation at the 0.5 % concentration but not at the 0.2% concentration.
Aspiration Hazard	Cardiovascular system. No information available.

Numerical measures of toxicity - Product

LD50 Oral >5000 mg/kg; Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

Chemical Name	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Daphnia Magna (Water Flea)
Boric acid 10043-35-3		LC50 72 h: = 1020 mg/L flow-through (Carassius auratus)		EC50 48 h: 115 - 153 mg/L (Daphnia magna)
Sodium Chloride 7647-14-5		LC50 96 h: 4747-7824 mg/L flow-through (Oncorhynchus mykiss) LC50 96 h: 5560-6080 mg/L flow-through (Lepomis macrochirus) LC50 96 h: 6020-7070 mg/L static (Pimephales promelas) LC50 96 h: 6420-6700 mg/L static (Pimephales promelas) LC50 96 h: = 12946 mg/L static (Lepomis macrochirus) LC50 96 h: = 7050 mg/L semi-static (Pimephales promelas)		EC50 48 h: 340.7 - 469.2 mg/L Static (Daphnia magna) EC50 48 h: = 1000 mg/L (Daphnia magna)
Sodium borate 1303-96-4	EC50 96 h: = 158 mg/L (Desmodesmus subspicatus) EC50 96 h: 2.6 - 21.8 mg/L static (Pseudokirchneriella subcapitata)	LC50 96 h: = 340 mg/L (Limanda limanda)		LC50 48 h: 1085 - 1402 mg/L (Daphnia magna)

Sodium chlorite 7758-19-2		LC50 96 h: 100 - 500 mg/L static (Brachydanio rerio) LC50 96 h: > 100 mg/L static (Lepomis macrochirus) LC50 96 h: > 100 mg/L static (Oncorhynchus mykiss)	EC50 48 h: 0.012 - 0.018 mg/L Static (Daphnia magna) EC50 48 h: 0.25 - 0.33 mg/L Flow through (Daphnia magna) EC50 48 h: = 0.026 mg/L (Daphnia magna)
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Persistence and Degradability No information available.

Bioaccumulation No information available.

Other Adverse Effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods Dispose of in accordance with local regulations.

Contaminated Packaging Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT Not regulated.

TDG Not regulated.

MEX Not regulated.

IATA Not regulated.

IMDG/IMO Not regulated.

15. REGULATORY INFORMATION

International Inventories

TSCA Exempt
DSL Exempt

Legend

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations

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	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

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).

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.

U.S. State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances above threshold limits that are regulated by state right-to-know.

Chemical Name	New Jersey	Massachusetts	Pennsylvania	Illinois	Rhode Island
Boric acid				X	

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION						
<u>NFPA</u>	Health Hazard	1	Flammability	0	Instability 0	Physical and Chemical Hazards -
<u>HMIS</u>	Health Hazard	1*	Flammability	0	Physical Hazard 0	Personal Protection X

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General Disclaimer

The information provided on this SDS 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 guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as 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 material or in any process, unless specified in the text.

End of Safety Data Sheet