SAFETY DATA SHEET

Issuing Date: 25-Sep-2007
Revision Date: 22-Dec-2014
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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No</th>
<th>Weight %</th>
<th>Trade secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brimonidine tartrate</td>
<td>70359-46-5</td>
<td>0.1-0.15</td>
<td>*</td>
</tr>
</tbody>
</table>

* 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

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  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  Allergan OEL: Brimonidine Tartrate: 12.5 ug/m³ (8 hr. TWA)
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

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

- 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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>LD50 Oral</th>
<th>LD50 Dermal</th>
<th>LC50 Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brimonidine tartrate</td>
<td>100 mg/kg (Rat)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>50 mg/kg (Mouse)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**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.

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.

Target Organ Effects  
Cardiovascular system.

Aspiration Hazard  
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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Toxicity to Algae</th>
<th>Toxicity to Fish</th>
<th>Toxicity to Microorganisms</th>
<th>Daphnia Magna (Water Flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boric acid 10043-35-3</td>
<td>LC50 72 h: = 1020 mg/L flow-through (Carassius auratus)</td>
<td>EC50 48 h: 115 - 153 mg/L (Daphnia magna)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium Chloride 7647-14-5</td>
<td>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)</td>
<td>EC50 48 h: 340.7 - 469.2 mg/L Static (Daphnia magna) EC50 48 h: = 1000 mg/L (Daphnia magna)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sodium borate 1303-96-4</td>
<td>EC50 96 h: = 158 mg/L (Desmodesmus subspicatus) EC50 96 h: 2.6 - 21.8 mg/L static (Pseudokirchneriella subcapitata)</td>
<td>LC50 96 h: = 340 mg/L (Limanda limanda)</td>
<td>LC50 48 h: 1085 - 1402 mg/L (Daphnia magna)</td>
<td></td>
</tr>
</tbody>
</table>
Sodium chlorite 7758-19-2

<table>
<thead>
<tr>
<th>LC50 96 h: 100 - 500 mg/L static (Brachydanio rerio)</th>
<th>EC50 48 h: 0.012 - 0.018 mg/L Static (Daphnia magna)</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 96 h: &gt; 100 mg/L static (Lepomis macrochirus)</td>
<td>EC50 48 h: &gt; 100 mg/L static (Oncorhynchus mykiss)</td>
</tr>
<tr>
<td>LC50 96 h: &gt; 100 mg/L static (Oncorhynchus mykiss)</td>
<td>EC50 48 h: &gt; 100 mg/L static (Lepomis macrochirus)</td>
</tr>
</tbody>
</table>

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/NDSL - 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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
<th>Illinois</th>
<th>Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boric acid</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

U.S. EPA Label Information

EPA Pesticide Registration Number  Not applicable

16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>NFPA</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Instability</th>
<th>Physical and Chemical Hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>X</td>
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</table>

<table>
<thead>
<tr>
<th>HMIS</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Physical Hazard</th>
<th>Personal Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1*</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
</tbody>
</table>

Prepared By  Product Stewardship  
23 British American Blvd.
Latham, NY 12110
1-800-572-6501

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Revision Note  Update to Format.

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