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

Product identifier
Product Name 
COMBIGAN® (Brimonidine Tartrate, 0.2%/Timolol, 0.5%) Ophthalmic Solution

Other means of identification
Product Code 
FG00011
Synonyms 
Brimonidine tartrate/timolol maleate ophthalmic solution

Recommended use of the chemical and restrictions on use
Recommended Use 
Intra-ocular Pressure (IOP) Alpha-Adrenergic Receptor

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

Reproductive toxicity 
Category 2

Label elements

Emergency Overview

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>60 - 100*</td>
</tr>
<tr>
<td>Sodium Phosphate Monobasic Monohydrate</td>
<td>10049-21-5</td>
<td>N/A</td>
<td>1 - 5*</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>63449-41-2</td>
<td>264-151-6</td>
<td>0.1 - 1*</td>
</tr>
</tbody>
</table>

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

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.

Chemical Name
Benzalkonium Chloride

Note to physicians
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.
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Liquid</td>
</tr>
<tr>
<td>Color</td>
<td>clear, light yellow</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>pH</td>
<td>6.9</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>&gt; 100</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 93.3</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td>No information available</td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.0</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
</tbody>
</table>

Other Information

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular weight</td>
<td>No information available</td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
</tr>
<tr>
<td>Density</td>
<td>No information available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
</table>
Delayed and immediate effects as well as chronic effects from short and long-term exposure

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

Numerical measures of toxicity - Product Information

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

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

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.

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

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

<table>
<thead>
<tr>
<th>Hazard Category</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute health hazard</td>
<td>No</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden release of pressure hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

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)

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

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water 7732-18-5</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
</tbody>
</table>

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