



SAFETY DATA SHEET

Revision Date 26-Jun-2017

Version 2

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Chemical Name Brimonidine
Product Code 59803-98-4
Contains Brimonidine
Molecular weight 442.2

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use 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.

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Company
ALLERGAN
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA
+1-800-272-5525
For further information, please contact
E-mail address SDS@Allergan.com

1.4. 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)

Emergency Telephone - §45 - (EC)1272/2008

Europe | 112

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral Category 3 - (H301)

Specific target organ toxicity (repeated exposure) Category 2 - (H373)

Classification according to Directive 67/548/EEC or 1999/45/EC

Full text of R-phrases: see section 16

Hazard symbols

T - Toxic

R-code(s)

T;R25

2.2. Label elements**Product identifier**

Contains Brimonidine

**Signal word**

Danger

Hazard statements

H301 - Toxic if swallowed

H373 - May cause damage to organs through prolonged or repeated exposure

Chemical Name**Brimonidine****Symptoms**

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.

Chemical Name**Brimonidine****Medical Conditions Aggravated by Exposure**

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.

Precautionary Statements - EU (§28, 1272/2008)

P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

P321 - Specific treatment (see .? on this label)

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to industrial incineration plant

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

2.3. Other hazards

No information available

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Chemical Name	EC No.	CAS No.	Weight-%	Classification according to Directive 67/548/EEC or 1999/45/EC	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
Brimonidine	-	59803-98-4	60-100	-	-	-

Full text of R-phrases: see section 16**Full text of H- and EUH-phrases: see section 16**

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice	Immediate medical attention is required.
Eye contact	Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.
Skin Contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
Inhalation	Immediate medical attention is required. Remove to fresh air. If not breathing, give artificial respiration. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation.
Ingestion	Do NOT induce vomiting. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person. Drink plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

4.3. Indication of any immediate medical attention and special treatment needed

Section 5: FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Dry chemical, CO2 or water spray. Dry chemical, CO2, alcohol-resistant foam or water spray. Move containers from fire area if you can do it without risk. Dike fire control water for later disposal; do not scatter the material.

Unsuitable extinguishing media

None known

5.2. Special hazards arising from the substance or mixture

Some are oxidizers and may ignite combustibles (wood, paper, oil, clothing, etc.)

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.

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

Use personal protective equipment as required. Keep people away from and upwind of spill/leak.

Do not get water inside containers or in contact with substance.

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. See Section 12 for additional ecological information.

6.3. Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading. Dike far ahead of liquid spill for later disposal.
Methods for cleaning up	Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

6.4. Reference to other sections

See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin, eyes or clothing. Use personal protective equipment as required. Wash contaminated clothing before reuse. Do not breathe dust/fume/gas/mist/vapors/spray. Do not eat, drink or smoke when using this product.

General Hygiene Considerations

When using do not eat, drink or smoke. Regular cleaning of equipment, work area and clothing is recommended. Avoid contact with skin, eyes or clothing. Wash hands thoroughly after handling. Keep away from food, drink and animal feeding stuffs.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. Keep out of the reach of children.

7.3. Specific end use(s)

Risk Management Methods (RMM)

The information required is contained in this Material Safety Data Sheet.

Incompatible materials None known based on information supplied.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Chemical Name	European Union	United Kingdom	France	Allergan OEL
Brimonidine 59803-98-4	-	-	-	12.5

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2. Exposure controls

Engineering Controls The following requirements list high level controls designed to control exposure below the OEL. More specific requirements may apply.

Powder Handling LEV or Down flow booth or ventilated enclosure

Solutions/Suspensions and coated tablet handling (no powders or aerosols) Not Applicable

Packaging (uncoated tablets, hot side work) Appropriate contained transfer device WIP/CIP for the hopper (if possible), and contained ventilated filler

Not defined As Reactive substance

10.2. Chemical stability

Stable under normal conditions.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

10.3. Possibility of hazardous reactions

Possibility of Hazardous Reactions

None under normal processing.

10.4. Conditions to avoid

Dust formation

10.5. Incompatible materials

None known based on information supplied.

10.6. Hazardous decomposition products

None under normal use conditions.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Brimonidine	100 mg/kg (rat); 50 mg/kg (mouse)		

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity
Brimonidine	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.	Studies in rats and rabbits have not shown teratogenicity or harm to the fetus.

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

Target Organ Effects Eyes.

The following values are calculated based on chapter 3.1 of the GHS document

ATEmix (oral) 100.00 mg/kg

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

12.2. Persistence and degradability

12.3. Bioaccumulative potential**12.4. Mobility in soil****12.5. Results of PBT and vPvB assessment**

No information available.

12.6. Other adverse effects

No information available

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products	Disposal should be in accordance with applicable regional, national and local laws and regulations.
Contaminated packaging	Dispose of contents/containers in accordance with local regulations.
Other Information	Waste codes should be assigned by the user based on the application for which the product was used.

Section 14: TRANSPORT INFORMATION

IMDG

14.1 UN/ID No.	UN2811
14.2 Proper shipping name	Toxic solid, organic, n.o.s.
14.3 Hazard Class	6.1
14.4 Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III
14.5 Marine pollutant	Not Applicable
14.6 Special Provisions	None
EmS-No.	F-A, S-A
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	No information available

RID

14.1 UN/ID No.	UN2811
14.2 Proper shipping name	Toxic solid, organic, n.o.s.
14.3 Hazard Class	6.1
14.4 Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III
14.5 Environmental hazard	Not Applicable
Classification code	T2
14.6 Special Provisions	None

ADR

14.1 UN/ID No.	UN2811
14.2 Proper shipping name	Toxic solid, organic, n.o.s.
14.3 Hazard Class	6.1
Labels	6.1

14.4 Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III, (E)
14.5 Environmental hazard	Not Applicable
14.6 Special Provisions	None
Classification code	T2
Tunnel restriction code	(E)

ICAO (air)

14.1 UN/ID No.	UN2811
14.2 Proper shipping name	Toxic solid, organic, n.o.s.
14.3 Hazard Class	6.1
14.4 Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III
14.5 Environmental hazard	Not Applicable
14.6 Special Provisions	None

IATA

14.1 UN/ID No.	UN2811
14.2 Proper shipping name	Toxic solid, organic, n.o.s.
14.3 Hazard Class	6.1
14.4 Packing Group	III
Description	UN2811, Toxic solid, organic, n.o.s., 6.1, III
14.5 Environmental hazard	Not Applicable
14.6 Special Provisions	None
ERG Code	6L

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

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

15.2. Chemical safety assessment

No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of R-phrases referred to under sections 2 and 3

R25 - Toxic if swallowed

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

Revision Date	26-Jun-2017
Revision Note	Not Applicable.

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

End of Safety Data Sheet

OEB	3
SDS Type	API