

Material Safety Data Sheet

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

Material- / Compound-Number: M000013 / C-022406
Product Name: Brimonidine Tartrate
Synonym: -
CAS-Number: 70359-46-5
Use of the Substance/Preparation: Active Pharmaceutical Ingredient for use in eye-drops
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2. HAZARDS IDENTIFICATION

Classification of the substance or mixture

According to Regulation (EC) No 1272/2008
acute toxicity, oral category 3

According to European Directive 67/548/EEC
Toxic if swallowed

Label Elements

Labelling according Regulation (EC) No 1272/2008 (EU-GHS/CLP)
Pictogram



Signal word

Danger

Hazard statement(s)

H301 Toxic if swallowed
H320 Causes eye irritation

Precautionary statement(s)

P264 Wash thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P330 Rinse mouth.
P301+P310 IF SWALLOWED: Immediately call a doctor

Material Safety Data Sheet

According to European Directive 67/548/EEC
Hazard symbol(s)



R-phrases
R25 Toxic if swallowed
R36 Irritating to eyes
S-phrase(s)
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3. COMPOSITION/INFORMATION ON INGREDIENTS

Product Name: Brimonidine Tartrate
IUPAC Name: C15H16BrN5O6
Molecular Formula: C-022406
Molecular weight: 442.22
Component Concentration: 90-100%
CAS-No.: 70359-46-5
Other: -

4. FIRST AID MEASURES

Inhalation: Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible overexposure, or with symptoms including chest pain, difficulties breathing, loss of consciousness or other adverse effects, which may be delayed.

Skin Contact: Using appropriate personal protective equipment, remove contaminated clothing and immediately flush exposed area with copious amounts of water. Obtain medical attention if skin reaction including symptoms of hypersensitivity (e.g. skin rash, hives, itching) occurs, which may be immediate or delayed.

Eye Contact: Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

Ingestion: Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

5. FIRE FIGHTING MEASURES

Fire and Explosion Hazards: The flammability of this material has not been determined. As with many organic dusts, explosions can occur if this material is dispersed as a dust cloud and ignited.

Material Safety Data Sheet

Extinguishing Media:	Water, dry powder, foam and carbon dioxide extinguishers are recommended.
Special Firefighting Procedures:	Since toxic, corrosive or flammable vapors might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters. Move containers from the fire area, if possible, without increased personal risk. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products:	Toxic, corrosive or flammable thermal decomposition products are expected when the material is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Fence or cordon the affected area and do not allow individuals to touch or walk through the spilled material unless wearing appropriate protective clothing (including dust mask P3 and chemically compatible gloves). Avoid dust generation.
Environmental Precautions:	Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas. If spill is outdoors, cover with plastic sheet to minimize spreading or contact with rain.
Clean-up Methods:	Collect and place spilled material in a suitable, properly labeled container for recovery or disposal. After all solid or absorbent material has been collected the area should be vacuumed with HEPA-filter equipped apparatus.
Decontamination Procedures:	No specified decontamination or detoxification procedures have been identified for this material. Consider use of water, detergent solutions, or other soluble solvents for clean-up and decontamination operations.

7. HANDLING AND STORAGE

Handling:	Avoid dispersion as a dust cloud. Depending on the scale of operation, use of appropriate exhaust ventilation is recommended to provide routine control of fire and explosion hazards during handling of this material. Bond and earth (ground) all plant and equipment to ensure that no isolated conductors are present. Isolated conductors can accumulate sufficient electrostatic charge to produce discharges of many hundreds of milli-Joules.
Storage:	Keep in tightly closed containers or packages away from moisture, direct sunlight and sources of ignition. Avoid prolonged storage at elevated temperatures (greater than 20°C).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limits:	No studies have been conducted.
Engineering Controls:	Open handling is not recommended. Consider segregating operations, use of enclosures, and sealed transfer systems. Local exhaust ventilation should be used in conjunction with other control measures for removing material incidentally released.

Material Safety Data Sheet

Eye Protection:	Wear approved safety glasses with side shields or goggles if eye contact is possible.
Gloves:	The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Glove selection must take into account any solvents and other hazards present. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided. For solid handling laminated film, nitrile or neoprene gloves are recommended.
Respirators:	If respiratory protective equipment is used, the type will depend on air concentrations present, required protection factor as well as hazards, physical properties and warning properties of all substances present. For solid handling a dust mask P3 is recommended.
Other Equipment:	Wear appropriate protective clothing to avoid skin contact. An eye wash station should be available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Appearance and Odor:	White solid
Acid / Base Properties:	-
Melting Point:	212 °C
Boiling Point:	-
Solubility in Water:	-
Solubility in Organic Solvents:	-
Dust Explosion Properties:	-
Thermal Decomposition:	-

10. STABILITY AND REACTIVITY

Conditions to be Avoided:	Avoid direct sunlight, moisture, conditions that might generate heat and dispersion as a dust cloud.
Substances to be Avoided:	No studies have been conducted. Avoid contact with strong oxidizing or reducing agents.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity:	The oral LD50 for Brimonidine Tartrate was determined to be 50 mg/kg in mice and 100 mg/kg in rats
Inhalation Toxicity:	No studies have been conducted.
Skin Effects:	Prolonged contact with the skin may result in irritation
Eye 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. Monkeys treated with up to 0.8% solution showed no local or systemic effects.
Target Organ Effects:	No specific target organ effects have been identified.
Sensitization:	No studies have been conducted.
Genetic Toxicity:	Brimonidine tartrate was not mutagenic or cytogenic in a series of <i>in</i>

Material Safety Data Sheet

Carcinogenicity:	<i>vitro</i> and <i>in vivo</i> 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. No studies have been conducted.
Reproductive Effects:	In reproduction studies performed in rats at oral doses more than 100 times (0.66 mg base/kg) the plasma drug concentration in humans receiving multiple ophthalmic doses, brimonidine tartrate produced no evidence of impaired fertility or harm to the fetus. Reproduction and fertility studies in rats demonstrated no adverse effect on male or female fertility at doses up to 21,000 times the systemic exposure following the maximum recommended human ophthalmic dose.
Pharmacological Effects:	No studies have been conducted.
Other Adverse Effects:	Oral administration of Brimonidine Tartrate 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

12. ECOLOGICAL INFORMATION

Ecotoxicity, Bioaccumulation or other Adverse Effects:	No information is available about the potential of this material to produce adverse environmental effects.
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13. DISPOSAL CONSIDERATIONS

Disposal Recommendations:	Collect for recycling or recovery if possible. The recommended method of disposal is incineration.
Regulatory Requirements:	Observe local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

UN-No.:	2811
Class:	6.1
Hazard Label:	6.1
Packing Group:	II
Proper Technical Name:	Brimonidine Tartrate
Proper Shipping Name:	TOXIC SOLID, ORGANIC, N.O.S.

International Air Transport (IATA Requirements)

Classification and Labeling As UN Classification and Labeling above

International Maritime Transport (IMDG Requirements)

Classification and Labeling As UN Classification and Labeling above

US Domestic Transport (DOT Requirements)

Classification and Labeling As UN Classification and Labeling above

European Ground Transport (ADR/RID Requirements)

Classification and Labeling As UN Classification and Labeling above

Material Safety Data Sheet

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1272/2008.

Toxic Control Substances Act (TSCA): This substance is not subject to TSCA requirements.

16. OTHER INFORMATION

The information and recommendations in this MSDS are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material for any particular purpose.
