



MATERIAL SAFETY DATA SHEET
OXYMETAZOLINE HCL NASAL SOLUTION, USP

BIO-PHARMA INC.
2091 Hartel Street
LEVITTOWN,
PA-19057
PHONE: (215)-949-3717

SECTION 1 – PRODUCT IDENTIFICATION AND HAZARDOUS COMPONENTS

PRODUCT NAME: Oxymetazoline HCl Nasal solution, USP

PRODUCT CLASS: Pharmaceutical

DESCRIPTION: Use for Dry Nasal Membranes

ACTIVE INGREDIENTS:

- Oxymetazoline HCl 0.05% w/v

SECTION 2 – PHYSICAL AND CHEMICAL CHARACTERISTICS

APPERANCE: White Clear Liquid

PH: 4.00-6.50

SECTION 3 – FIRE AND EXPLOSION DATA

FLASH POINT: Not a fire or Explosion Hazard.

EXTINGUISHING MEDIA: Not Applicable

SPECIAL FIRE FIGHTING PROCEDURE: Not Applicable

SECTION 4 – RECREATIVITY HAZARD DATA

STABILITY: STABLE

HAZARDOUS DECOMPOSITION OR BYPRODUCTS: No uniquely hazardous decomposition products are expected. If the product is burned, as with any organic material compounds, CO, and CO² can be produced by the packing material.

CORROSIVITY: Not considered to be corrosive for metals and glass.

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SPECIAL REMARKS ON REACTIVITY:

- Hygroscopic
- Reacts with most nonnoble metals such as iron or steel, building materials (such as cement)
- Sodium chloride is rapidly attacked by bromine trifluoride.
- Violent reaction with lithium. (Sodium chloride)

HAZARDOUS POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Excessive heat.

SECTION 5 – HEALTH HAZARD DATA

ROUTE OF ENTRY: Topical.

POTENTIAL HEALTH EFFECTS:

Although Oxymetazoline HCl that is used in the manufacture of the product is considered hazardous on individual basis, the final formulation of the product is considered non-hazardous when used according to manufacturers directions.

The active ingredient Oxymetazoline HCl is an adrenergic (vasoconstrictor) drug which can be toxic if ingested in larger than therapeutic quantities.

Oxymetazoline HCl can cause stinging, burning, and dryness of the nasal mucosa, sneezing, headache, lightheadedness, insomnia, elevated blood pressure, nausea, dizziness, nervousness, and change in heart rate.

Use of these products can cause intranasal stinging. Frequent or prolonged use may cause nasal congestion symptoms to recur or worsen. Use only as directed. These products should not be used by persons with heart disease, high blood pressure, thyroid disease, diabetes, or prostate gland enlargement.

TOXICITY (TOXICOLOGY):

Oxymetazoline HCl

Oral (LD-50): 0.68 mg/kg [Rat.]

Intraperitoneal (LD-50) 48 mg/kg [Rat.]

LD50 Intravenous: 1.07 mg/kg [Rat.]

Subcutaneous: 1.63 mg/kg [Rat.]

Oral: LD-50 \geq 1.0 ml/kg (finished product)

EMERGENCY FIRST AID PROCEDURES: If ingested in large quantities, give large amounts of water and induce vomiting, seek immediate medical attention. For eye contact, flush with plenty of cold water and seek medical attention if irritation persists.

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SECTION 6 – PRECAUTIONS FOR SAFE HANDLING

SPILL/LEAKAGE PROCEDURES:

Small Spill:

Dilute with water and mop up, or absorb with an inert dry material and place in an appropriate waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

Large Spill:

Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.

HANDLING AND STORAGE PRECAUTIONS: Store at controlled room temperature 15^oC for 30^oC (59^o for 86^o F). Protect from light. Keep bottle tightly closed.

OTHER PRECAUTIONS: Always follow prudent laboratory practices. Consult the PDR or the package insert for further information.

SECTION 7 – CONTROL MEASURES

VENTILATION: General ventilation is adequate (Local Exhaust).

PERSONAL PROTECTIVE EQUIPMENT: Impervious rubber gloves should be worn when handling spill of this material.

EYE PROTECTION: Safety Glasses with side shields

SECTION 8 – DISCLAIMER

The information contained in this Material Safety data Sheet has been compiled from reliable sources and is believed to be correct as of the date issued. It is the responsibility of the user to determine the appropriateness and applicability to their situation. BIO-PHARM INC. disclaims any expressed or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental, or consequential damages from use or reliance on the above information.