



BIO-PHARM Incorporated

# Oxymetazoline HCl Nasal solution, USP

## Safety Data Sheet

Prepared according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 09/02/2015

Supersedes: N/A

Version: 1.0

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product name : Oxymetazoline HCl Nasal solution, USP  
Product form : Mixture  
Other means of identification : Pharmaceutical  
Active Ingredient: 0.05% Oxymetazoline hydrochloride (w/v)

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

Use of the substance/mixture : Use for Dry Nasal Membranes

#### 1.3. Details of the supplier of the safety data sheet

BIO-PHARM INC.  
2091 HARTEL STREET  
LEVITTOWN, PA 19057  
PHONE: (215) 949-3711

#### 1.4. Emergency telephone number

Emergency number : 1-866-845-1611

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### GHS-US classification

Not classified

#### 2.2. Label elements

##### GHS-US labelling

No labelling applicable

#### 2.3. Other hazards

No additional information available

#### 2.4. Unknown acute toxicity (GHS US)

No data available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substance

Not applicable

#### 3.2. Mixture

Name	Product identifier	%
Contains no hazardous ingredients at levels requiring disclosure by the OSHA Hazard Communication Standard (29 CFR 1910.1200).	N/A	100

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a comfortable position for breathing.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center or medical professional. Get medical attention if you feel unwell.

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

Symptoms/injuries : Not expected to present a significant acute hazard under anticipated conditions of normal use.

Symptoms/injuries after inhalation : May cause respiratory irritation.

Symptoms/injuries after skin contact : May cause skin irritation.

Symptoms/injuries after eye contact : Direct contact with the eyes is likely to be irritating.

Symptoms/injuries after ingestion : May cause gastrointestinal irritation.

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

No additional information available.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Foam. Carbon dioxide. Dry powder. Sand.

### 5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.

Explosion hazard : Product is not explosive.

Reactivity : No dangerous reactions known under normal conditions of use.

### 5.3. Advice for firefighters

Precautionary measures fire : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Evacuate area. Ventilate area. Keep upwind. Spill should be handled by trained clean-up crews properly equipped with respiratory equipment and full chemical protective gear (see Section 8).

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

#### 6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

For containment : Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for cleaning up : Take up liquid spill into absorbent material. Wash spill area thoroughly with plenty of water. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

### 6.4. Reference to other sections

See Sections 8 and 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Do not handle until all safety precautions have been read and understood. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep the container tightly closed. Store in a dry, cool and well-ventilated place. Avoid freezing. Protect from light.

Storage temperature : 20 - 25 °C

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No data available

### 8.2. Exposure controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

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Personal protective equipment : Gloves. Protective goggles.



Hand protection : Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection : Use eye protection suitable to the environment. Avoid direct contact with eyes.

Skin and body protection : Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection : Use NIOSH-approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

Physical state : Liquid

Color : Colorless to pale yellow

Odor : No data available

Odor Threshold : No data available

pH : 4 - 6.5

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point : No data available

Flash point : Not a fire hazard

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Flammability (solid, gas) : No data available

Vapour pressure : No data available

Relative vapour density at 20 °C : No data available

Relative density : 0.920-1.120

Solubility : No data available

Log Pow : No data available

Log Kow : No data available

Viscosity, kinematic : No data available

Viscosity, dynamic : No data available

Explosive properties : No data available

Oxidising properties : No data available

Explosive limits : Not an explosion hazard

#### 9.2. Other information

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

No dangerous reactions known under normal conditions of use.

#### 10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

#### 10.3. Possibility of hazardous reactions

Hygroscopic. Reacts with most nonnoble metals such as iron or steel, building materials (such as cement).

#### 10.4. Conditions to avoid

Excessive heat.

#### 10.5. Incompatible materials

Bromine trifluoride. Lithium.

#### 10.6. Hazardous decomposition products

Carbon oxides (CO, CO<sub>2</sub>).

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### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
	pH: 4 - 6.5
Serious eye damage/irritation	: Not classified
	pH: 4 - 6.5
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Symptoms/injuries after inhalation	: May cause respiratory irritation.
Symptoms/injuries after skin contact	: May cause skin irritation.
Symptoms/injuries after eye contact	: Direct contact with the eyes is likely to be irritating.
Symptoms/injuries after ingestion	: May cause gastrointestinal irritation.

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : No information available.

#### 12.2. Persistence and degradability

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Persistence and degradability	No information available.
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#### 12.3. Bioaccumulative potential

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Bioaccumulative potential	No information available.
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#### 12.4. Mobility in soil

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Ecology - soil	No information available.
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#### 12.5. Other adverse effects

Other adverse effects : No data available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods	: Obtain the consent of pollution control authorities before discharging to wastewater treatment plants.
Waste disposal recommendations	: Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment.

### SECTION 14: Transport information

In accordance with DOT

Not hazardous for transport

#### Additional information

Other information : No supplementary information available.

#### Transport by sea

No additional information available

#### Air transport

No additional information available

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### SECTION 15: Regulatory information

#### 15.1. US Federal regulations

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All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) Inventory or are exempt

SARA Section 311/312 Hazard Classes      None

##### Sodium phosphate dibasic (7558-79-4)

Section 302 (EHS) TPQ

Section 304 EHS RQ

CERCLA RQ      5000    lb

Section 313      Not Listed on US SARA Section 313

##### Hydrogen chloride (7647-01-0)

Section 302 (EHS) TPQ

Section 304 EHS RQ

CERCLA RQ      5000    lb

Section 313      Not Listed on US SARA Section 313

#### 15.2. International regulations

No additional information available.

#### 15.3. US State regulations

##### California Proposition 65

WARNING! This product contains chemicals known to the state of California to cause cancer, birth defects, or other reproductive harm.

##### Ethyl alcohol (64-17-5)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	No significance risk level (NSRL)
No	Yes	No	No	Not available

##### Ethyl alcohol (64-17-5)

U.S. - Massachusetts - Right To Know List  
U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

##### 1,2-Propylene glycol (57-55-6)

U.S. - New Jersey - Right to Know Hazardous Substance List  
U.S. - Pennsylvania - RTK (Right to Know) List

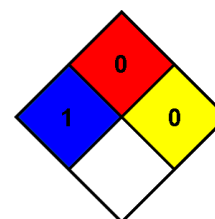
##### Hydrogen chloride (7647-01-0)

U.S. - Massachusetts - Right To Know List

### SECTION 16: Other information

Indication of changes      : Revision 1.0: New SDS Created.  
Revision date      : 09/02/2015  
Other information      : Author: BCS.

NFPA health hazard      : 1 - Exposure could cause irritation but only minor residual injury even if no treatment is given.  
NFPA fire hazard      : 0 - Materials that will not burn.  
NFPA reactivity      : 0 - Normally stable, even under fire exposure conditions, and are not reactive with water.



#### HMIS III Rating

Health      : 1

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Flammability	: 0
Physical	: 0
Personal Protection	: B

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