Schering-Plough HealthCare Products, Inc.
3030 Jackson Avenue
Memphis, TN 38151

# MATERIAL SAFETY DATA SHEET

*Schering-Plough urges each user or recipient of this MSDS to read the entire data sheet to become aware of the hazards associated with this material.*

## SECTION 1. IDENTIFICATION OF SUBSTANCE AND CONTACT INFORMATION

**MSDS NAME:** **AFRIN/DURATION-Oxymetazoline Nasal Sprays**

**SYNONYM(S):**

**US Products:**
AFRIN Original Nasal Spray
AFRIN Severe Congestion Nasal Spray
AFRIN Extra Moisturizin Nasal Spray
AFRIN Sinus Nasal Spray
DURATION Nasal Spray

**International Products:**
AFRAZINE Menthol; AFRAZINE Nasal Spray; AFRIN 12 Horas; AFRIN Adulto Solucion Nasal; AFRIN Atomizacion Nasal; AFRIN Atomizador Nasal; AFRIN Cherry Scented; AFRIN Cherry Solution Nasal; AFRIN Gotas Nasales; AFRIN Extra Moisturizing Nasal Spray; AFRIN Lub Adulto; AFRIN Menthol Nasal Drops; AFRIN Menthol Nasal Spray; AFRIN Menthol Nasal Spray 0.05%; AFRIN Menthol Spray; AFRIN Mentol; AFRIN Mentol Atomizador Nasal 0.5 mg; AFRIN Mentolado; AFRIN Nasal Drops; AFRIN Nasal Solution (0.05%); AFRIN Nasal Spray; AFRIN Nasal Spray Pump; AFRIN Nasal-Adulto; AFRIN Nose Drops; AFRIN Original Nasal Spray; AFRIN Semprot Hidung; AFRIN Severe Congestion Nasal Spray; AFRIN Sinus Nasal Spray; AFRIN Solucion Nasal 0.05%; AFRIN Tetes Hidung Untuk Dewasha; AFRIN/DURATION Nasal Solution (0.05%); AFRINE Atomizacion Nasal; AFRINE Mentolada; CLARITIN Nasal Pump; CORICIDIN Nasal Mist; CORICIDIN Nasal Spray; DRIXIN Menthol Naese Spray; DRIXIN Naese Spray; DRIXIN Nasal Solution; DRIXIN Nasdroppar 0.5 mg/mL; DRIXIN Nose Drops; DRIXINE Adult Metered Pump Nasal Spray; DRIXINE Adult Nasal Drops; DRIXINE Adult Nasal Spray; DRIXINE Menthol Nasal Spray; DRIXINE Nasal Spray; DRIXINE Nose Drops; DRIXORAL Decongestant Nasal Spray; DURATION Nasal Spray; DURATION Spray; FRINAT Mentolado Solution; FRINAT Solucion Nasal; NASOROX; Oxymetazoline Mentholated Nasal Solution; RESPIR Atomizador; RESPIR Balsamico; RESPIR Gotas; RESPIR Spray 20 mL

**MSDS NUMBER:** SP000312

**EMERGENCY NUMBER(S):** Schering-Plough Security Control Center (908) 820-6921 (24 hours)

Safety/Environmental Affairs (901) 320-2384

Transportation Emergencies - CHEMTREC:
(800) 424-9300 (Inside Continental USA)
(703) 527-3887 (Outside Continental USA)

**INFORMATION:** Safety/Environmental Affairs (901) 320-2384

**SCHERING-PLOUGH MSDS HELPLINE:** (800) 770-8878 (US and Canada)
(908) 473-3371 (Worldwide)
Monday to Friday, 9am to 5pm (US Eastern Time) .

**ADDITIONAL INFORMATION:** See Section 16 for Complete list of product brandnames.



## SECTION 2. HAZARDS IDENTIFICATION

## SECTION 2. HAZARDS IDENTIFICATION

### EMERGENCY OVERVIEW

Liquid
Clear, Colorless
Characteristic odor

May be harmful if swallowed.

*May cause effects to:*
central nervous system
cardiovascular system

Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.

**POTENTIAL HEALTH EFFECTS:**

Oxymetazoline nasal sprays may cause central nervous system and cardiac effects if not used according to manufacturer's directions.

The health hazard information presented below is for the active ingredient in this product.

Oxymetazoline is a potent decongestant drug active that causes vasoconstriction and cardiac effects. It is highly toxic by acute inhalation, ocular, and oral exposure. Ingestion of oxymetazoline hydrochloride causes systemic effects including adverse cardiovascular symptoms (palpitations, hypertension, or slow heart beat) and central nervous system symptoms (dizziness, spastic paralysis, insomnia, central nervous system depression) as well as cyanosis. There is limited repeated-dose toxicity data available. No known adverse effects to the fetus have been demonstrated after oxymetazoline exposure to pregnant women.

Oxymetazoline has been reported to have addictive properties and patient abuse has resulted in severe central nervous system effects including amphetamine-like properties and associated paranoid psychosis and secondary mania.

In laboratory animals, oxymetazoline was shown to be slightly irritating to the eyes and not-sensitizing on the skin. It has caused adverse cardiac conduction, increased blood pressure, and slow heartbeat.

**LISTED CARCINOGENS**

| CHEMICAL NAME | CAS NUMBER | OSHA | IARC | NTP | ACGIH |
|---|---|---|---|---|---|
| Povidone. | 9003-39-8 | | 3 Classification not possible from current data. | | |

## SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

**PRODUCT USE:** Drug product

**CHEMICAL FORMULA:** Mixture.

The formulations for these products are proprietary information. These formulations have the same hazardous profile; however, the presence of hazardous ingredients may vary by formulation. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the Chemical Composition table. Active ingredients in any concentration are listed.

**CHEMICAL COMPOSITION**

| CHEMICAL NAME | CAS NUMBER | PERCENT |
|---|---|---|
| Oxymetazoline Hydrochloride. | 2315-02-8 | 0.05 |
| Polyethylene Glycol. | 25322-68-3 | <10 |
| Sorbitol. | 50-70-4 | <10 |
| Povidone. | 9003-39-8 | <10 |
| Propylene Glycol. | 57-55-6 | <10 |

**ADDITIONAL INFORMATION:** This MSDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate MSDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

## SECTION 4. FIRST AID MEASURES

**INHALATION:** Remove to fresh air. If any trouble breathing, get immediate medical attention. Administer artificial respiration if breathing has ceased. If irritation or symptoms occur or persist, consult a physician.

**SKIN CONTACT:** In keeping with good hygienic practices, wash exposed areas thoroughly with soap and water.

**EYE CONTACT:** Rinse eyes with water or saline solution. Get medical attention if effects occur or persist.

**INGESTION:** Do not induce vomiting unless under the direction of a qualified medical professional or Poison Control Center. IMMEDIATELY consult a physician. Do not attempt to give anything by mouth to a seizing, drowsy or unconscious person. If alert, rinse mouth and drink a glass of water.

## SECTION 5. FIRE FIGHTING MEASURES

**FLAMMABILITY DATA:**

Flash Point: >93.3 deg C ( >200 deg F )

**SPECIAL FIRE FIGHTING PROCEDURES:**
Wear full protective clothing and self-contained breathing apparatus (SCBA).

**SUITABLE EXTINGUISHING MEDIA:**
Carbon dioxide (CO2), extinguishing powder or water spray.

**THERMAL DECOMPOSITION PRODUCTS:**
Carbon monoxide (CO). Carbon dioxide (CO2).

See Section 9 for Physical and Chemical Properties.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

**PERSONAL PRECAUTIONS:**
Wear appropriate personal protective equipment as specified in Section 8. Keep personnel away from the clean-up area.

**SPILL RESPONSE / CLEANUP:**
All spills should be handled according to site requirements and based on precautions cited in the MSDS. In the case of liquids, use proper absorbent materials. For laboratories and small-scale operations, incidental spills within a hood or enclosure should be cleaned by using a HEPA filtered vacuum or wet cleaning methods as appropriate. For large dry or liquid spills or those spills outside enclosure or hood, appropriate emergency response personnel should be notified. In manufacturing and large-scale operations, HEPA vacuuming prior to wet mopping or cleaning is required.

See Sections 9 and 10 for additional physical, chemical, and hazard information.

## SECTION 7. HANDLING AND STORAGE

**HANDLING:**
Keep containers adequately sealed during material transfer, transport, or when not in use.

Appropriate handling of this material is dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. See Section 8 (Exposure Controls) for additional guidance.

**STORAGE:**
Store in a cool, dry, well ventilated area.

See Section 8 for exposure controls and additional safe handling information.

## SECTION 8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

The following guidance applies to the handling of the active ingredient(s) in this formulation. The end-user should perform an appropriate risk assessment when handling other forms or formulations of this active ingredient.

**S-P HEALTH HAZARD CATEGORY (HHC):**
The Schering-Plough Health Hazard Category (HHC) for this material is HHC4. Materials in this category are considered extreme health hazards. Health Hazard Categories are intended to be a component of workplace risk assessment. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

**S-P OCCUPATIONAL EXPOSURE GUIDELINE (OEG):**
Schering-Plough Corporation has established an Occupational Exposure Guideline (OEG) of 0.6 mcg/$m^3$ or 600 ng/$m^3$ (8-hr TWA) for oxymetazoline. Consult your site safety and industrial hygiene professional(s) for additional guidance.

**HHC/OEG NOTATION(S):**
This material has a notation of "E" for its ability to cause systemic toxicity by ocular exposure.

**EXPOSURE CONTROLS:**
The health hazard risks of handling this material are dependent on many factors, including physical form, duration and frequency of process or task, and effectiveness of engineering controls. Site-specific risk assessments should be conducted to determine the feasibility and the appropriateness of all exposure control measures. Exposure controls for normal operating or routine procedures follow a tiered strategy. Engineering controls are the preferred means of long-term or permanent exposure control. If engineering controls are not feasible, appropriate use of personal protective equipment (PPE) may be considered as alternative control measures. Exposure controls for non-routine operations must be evaluated and addressed as part of the site-specific risk assessment.

**RECOMMENDED PERSONAL PROTECTIVE EQUIPMENT (PPE):**

| | |
|---|---|
| Respiratory Protection: | None required for consumer use of this product. |
| | Respiratory protective equipment (RPE) may be required for certain laboratory and large-scale manufacturing tasks if potential airborne breathing zone concentrations of substances exceed the relevant exposure limit(s). Workplace risk assessment should be completed before specifying and implementing RPE usage. Potential exposure points and pathways, task duration and frequency, potential employee contact with the substance, and the ability of the substance to be rendered airborne during specific tasks should be evaluated. Initial and ongoing strategies of quantitative exposure measurement should be obtained as required by the workplace risk assessment. All RPE must conform to local and regional specifications for efficacy and performance. Consult your site or corporate health and safety professional for additional guidance. |
| Skin Protection: | None required for consumer use of this product. |
| | Gloves that provide an appropriate barrier to the skin are recommended if there is potential for contact with this material. Consult your site safety staff for guidance. |
| Eye Protection: | None required for consumer use of this product. |
| | Safety glasses with side shields. Use of goggles or full face protection may be required based on hazard, potential for contact, or level of exposure. Consult your site safety staff for guidance. |
| Body Protection: | None required for consumer use of this product. |
| | In small-scale or laboratory operations, lab coats or equivalent protection is required. Disposable Tyvek or other dust impermeable suit should be considered based on procedure or level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. |
| | In large-scale or manufacturing operations, disposable Tyvek or other dust impermeable suit is recommended and based on level of exposure. Use of additional PPE such as shoe coverings, gauntlets, hood, or head covering may be necessary. Consult your site safety staff for guidance. |

**EXPOSURE LIMIT VALUES**

See Schering-Plough Occupational Exposure Guideline (OEG) listed above.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

| | |
|---|---|
| **FORM:** | Liquid |
| **COLOR:** | Clear, Colorless |
| **ODOR:** | Characteristic odor |
| **SOLUBILITY:** | |
| Water: | Soluble |

See Section 5 for flammability/explosivity information.

## SECTION 10. STABILITY AND REACTIVITY

**STABILITY/ REACTIVITY:**
Stable under normal conditions.

**INCOMPATIBLE MATERIALS / CONDITIONS TO AVOID:**
Strong Oxidizers.

**HAZARDOUS DECOMPOSITION PRODUCTS / REACTIONS:**
No dangerous decomposition is expected if used according to manufacturer's specifications.

## SECTION 11. TOXICOLOGICAL INFORMATION

The information presented below pertains to the formulated product unless indicated otherwise.

**ACUTE TOXICITY DATA**

**INHALATION:**
Oxymetazoline is considered to be highly toxic by inhalation based on its oral and IV acute toxicity data.

**EYE:**
Afrin/Duration-Oxymetazoline Nasal Sprays: Not irritating.

**ORAL:**
Afrin/Durantion-Oxymetazoline Nasal Sprays: Oral LD50: >2000 mg/kg
Decreased activity and kidney effects were noted in animals given high doses (2000 mg/kg). No effects were observed in animals given 1000 mg/kg.

**SENSITIZATION:**
Oxymetazoline (10%) was not a skin sensitizer in guinea pigs. Pulmonary congestion was noted in three study animals that died by Day 3 following intradermal injection. No deaths occurred following topical challenge.

**ADDITIONAL INFORMATION:**
In an experiment designed to study eye irritation, all six rabbits died, within 24 hours, following a single ocular dose of 51 mg (approximately 34 mg/kg) oxymetazoline.

Intravenous injection of oxymetazoline caused increased blood pressure and reflex bradycardia in dogs. By this route of administration, the acute minimal lethal dose of oxymetazoline in conscious dogs was between 250 - 350 µg/kg. Clinical signs in dogs receiving these doses are consistent with a shock syndrome associated with IV administration of sympathomimetic drugs. Treated dogs generally died in a shock-like state which was preceded by salivation, emesis, mydriasis, rapid breathing and excitement. This was followed by muscle twitching, body writhing, prostration, respiratory depression and cardiac arrest.

**REPEAT DOSE TOXICITY DATA**

**SUBCHRONIC / CHRONIC TOXICITY:**
Oxymetazoline repeated-dose toxicity has been evaluated in monkeys, dogs, rabbits and rats. The majority of these tests were subchronic ocular tolerance studies. In these studies, monkeys showed mild irritation upon administration as the most significant clinical finding. Ocular changes were more severe in rabbit eyes and included corneal edema and peripheral vascularization. Rats exposed to oxymetazoline by the inhalation route of exposure for 19-35 days showed irritation in the larynx and tail ischemia.

In a subchronic ocular tolerance test using oxymetazoline ophthalmic solution (0.025%), four male and five female monkeys were divided into three equal groups and treated with vehicle (buffered saline), low level (16 drops/day), or high level (36 drops/day) of oxymetazoline opthalmic solution. Animals were treated five days per week for 13 weeks. Minor discomfort was noted in the majority of oxymetazoline treated animals. No other significant changes in these monkeys were reported. "High level" oxymetazoline treatment (36 drops/day) would be considered a NOAEL.

In dogs, ocular exposure of oxymetazoline at 0.05 mg/kg, 0.09 mg/kg, or 0.18 mg/kg, five days per week, for 13 weeks caused no effects (NOAEL is 0.18 mg/kg/day).

In rabbits, ocular administration of oxymetazoline opthalmic solution resulted in corneal edema and peripheral vascularization in both short- and long-term repeated-dose studies. Dilated pupils and sluggish papillary reflexes were also observed. Histopathological evaluations found one oxymetazoline treated eye with a necrotic area on the palpebral conjunctiva and slight vascular proliferation in four corneas.

Rats (>10/sex) received a daily, one hour inhaled dose of oxymetazoline or vehicle for 19-35 consecutive days. Due to severe toxicity, the dose of oxymetazoline was reduced twice during the experiment from 0.49 to 0.18 to 0.06 mg/kg; which is approximately equivalent to the estimated human dose in mg/m2 body surface area. Three rats died prior to the final dose reduction. Oxymetazoline hydrochloride produced histopathological changes in the larynx and tail. The larynx in 19/20 animals showed minimal to slight squamous metaplasia of the antero-ventral epithelium and 17/19 animals showed minimal keratinization of the affected epithelium and necrosis of the ventral pouch cartilage. Changes in the distal tail were suggestive of early ischemia. The respiratory tract changes described indicate that oxymetazoline HCl was a slight irritant in the rat at these inhaled levels.

**REPRODUCTIVE / DEVELOPMENTAL TOXICITY:**
No direct tests to determine the effect of oxymetazoline on fertility and fetal development have been completed in laboratory animals. A mixture of human epidemiology studies and case reports on the developmental effects of oxymetazoline are found in the medical literature. Overall, epidemiology studies do not show an association between birth defects and oxymetazoline exposure during pregnancy.

There is one case report of a child with multiple malformations (microcephaly, multiple sutural fusions, tetralogy of Fallot, and teratoma of the right tonsil) born to a mother who had been taking oxymetazoline on a chronic basis. The mother used an oxymetazoline decongestant product for 12 years to treat sinus problems and throughout pregnancy. During this period she reported taking oxymetazoline 2-3 times daily.

**CARCINOGENICITY:**
This material or product has not been evaluated for carcinogenicity.

## SECTION 12. ECOLOGICAL INFORMATION

**ECOTOXICITY DATA**

This product has not been tested for ecotoxicity.

**ENVIRONMENTAL DATA**

There are no environmental data available for this product.

## SECTION 13. DISPOSAL CONSIDERATIONS

**MATERIAL WASTE:**
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations. Incineration is the preferred method of disposal, when appropriate. Operations that involve the crushing or shredding of waste materials or returned goods must be handled to meet the recommended exposure limit(s).

**PACKAGING AND CONTAINERS:**
Disposal must be in accordance with applicable federal, state/provincial, and/or local regulations.

## SECTION 14. TRANSPORT INFORMATION

This material is not subject to the transportation regulations of DOT, IATA, IMO, and the ADR.

## SECTION 15. REGULATORY INFORMATION

**TSCA LISTING**

| CHEMICAL NAME | TSCA |
|---|---|
| Polyethylene Glycol. | Listed |
| Sorbitol. | Listed. |
| Povidone. | Listed |
| Propylene Glycol. | Listed |

**U.S. STATE REGULATIONS**

| CHEMICAL NAME | California Proposition 65 | CARTK | NJRTK | CTRTK | MARTK |
|---|---|---|---|---|---|
| Povidone. | | Listed. | | | |

| CHEMICAL NAME | PARTK | MNRTK | MIRTK | ILRTK | LARTK | RIRTK |
|---|---|---|---|---|---|---|
| Polyethylene Glycol. | | Listed. | | | | |
| Propylene Glycol. | Listed. | Listed. | | | | Listed. |

Fields in the above tables that do not contain data indicate that those materials have not been listed by local regulations.

## SECTION 16. OTHER INFORMATION

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Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy or completeness of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).

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