SAFETY DATA SHEET

This SDS was created in accordance with Regulation EC 1907/2006 and all amendments. MSD urges each user or recipient of this SDS to read the entire data sheet to become aware of the hazards associated with this material.

SECTION 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

PRODUCT IDENTIFIER

SDS NAME: **AFRIN NO-DRIP Nasal Spray Solutions**

SYNONYM(S): Afrin 0.5mg/mL Nasal Spray Solution
Afrin 0.5mg/mL Nasal Spray Solution Menthol
Afrin 0.5mg/mL Nasal Spray Solution Glycerol
Afrin 0.5mg/mL Nasal Spray Solution Chamomile

SDS Number: SP002467

REACH REGISTRATION NUMBER Not available

RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

IDENTIFIED USE(S): Consumer Product

USE(S) ADVISED AGAINST: None known.

DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

EU SUPPLIER/MANUFACTURER: Schering-Plough Labo N.V.
Industriepark, 30-Zone A
B-2220 Heist-op-den-Berg
Belgium

MERCK SDS HELPLINE: +1 (908) 473-3371 (Worldwide)
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SDS EMAIL: mercksds@merck.com

EMERGENCY TELEPHONE NUMBER

EMERGENCY NUMBER(S): +1 (908) 423-6000 (24/7/365) English Only

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

The brand-names or trademarks indicated by CAPITAL LETTERS in this [M]SDS are the property of, licensed to, promoted or distributed by Merck & Co., Inc., its subsidiaries or related companies.

SECTION 2. HAZARDS IDENTIFICATION

CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

Classification according to EC Directive 1272/2008:
Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008.

Classification according to EC Directives 67/548/EEC (substances) or 1999/45/EC (mixtures):
Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC DIrective 1999/45/EC.

COLOR: Opaque
FORM: Liquid
ODOR: Characteristic odor

LABEL ELEMENTS

Based on available data, this mixture does not meet the criteria to be classified as hazardous in accordance with Directive 1272/2008.

OTHER HAZARDS

Health-Related Hazards:

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

May cause effects to:
central nervous system
cardiovascular system

LISTED CARCINOGENS

No carcinogens or potential carcinogens listed by IARC or EU Directive 90/394 (Annex I) in this mixture.

Environmental-Related Hazards:

This substance has not been fully tested to meet the criteria for listing as a PBT or a vPvB.

Other Hazards:

SECTION 3. COMPOSITION AND INFORMATION ON INGREDIENTS

SUBSTANCE

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

INGREDIENT	CAS NUMBER	EC NUMBER	REACH REGISTRATION NUMBER	EU CLASSIFICATION	GHS CLASSIFICATION	PERCENT	REASON FOR LISTING
Oxymetazoline Hydrochloride	2315-02-8	219-015-0	Not available	T+;R26/28 T;R48/23	STOT RE 1 (H372) Acute Tox. 2 (H300) Acute Tox. 2 (H330)	0.05	Classified Active Pharmaceutical Ingredient

Fields in the above table that do not contain data indicate that the substance(s) have not been listed or classified according to EU criteria.

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.

See section 16 for definitions of risk phrases and GHS classifications.

SECTION 4. FIRST AID MEASURES

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.

FIRST AID RESPONDER PROTECTION: Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves with appropriate personal protective equipment. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. DO NOT use mouth-to-mouth method if victim ingested or inhaled the substance.

MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Although some ingredients used in the manufacture of this product are considered hazardous on an individual basis, the final formulation of this product is considered non-hazardous when used according to manufacturer's directions.

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.

INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

NOTE TO PHYSICIAN: In cases of overexposure treat supportively and symtomatically.

SECTION 5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA

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

UNSUITABLE EXTINGUISHING MEDIA:
None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

SPECIAL FIRE HAZARDS:
None known.

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

ADVICE FOR FIREFIGHTERS

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

See Section 9 for Physical and Chemical Properties.

SECTION 6. ACCIDENTAL RELEASE MEASURES

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

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

METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

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

PRECAUTIONS FOR SAFE HANDLING

HANDLING:
Keep containers adequately sealed during material transfer, transport, or when not in use. Wash face, hands, and any exposed skin after handling. Do not eat, drink, or smoke when using this substance or mixture.

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.

CONDITIONS FOR SAFE STORAGE, INCLUDING ANY IMCOMPATIBILITIES

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

SPECIFIC END USE(S)
Refer to Section 1 for identified use(s).

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.

CONTROL PARAMETERS

OCCUPATIONAL EXPOSURE BAND (OEB):
OEB 5: <1 mcg/m^3. Materials in an OEB 5 category are considered extreme health hazards. The OEB is a range of airborne concentrations expressed as an 8-hour Time Weighted Average (8-hr. TWA) and is intended to be used with Industrial Hygiene Risk Assessment to assist with industrial hygiene sampling and selection of proper controls for worker protection. Consult your site safety and industrial hygiene staff for guidance on handling and control strategies.

INTERNAL OCCUPATIONAL EXPOSURE LIMIT (8-hr TWA):
0.2 mcg/m^3

Wipe Limit:
2 mcg/100 cm2

EXPOSURE LIMIT VALUES:

See Internal Occupational Exposure Limit listed above.

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):

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.
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.
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.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

FORM:	Liquid
COLOR:	Opaque
ODOR:	Characteristic odor
ODOR THRESHOLD:	Not determined
pH:	Not determined
BOILING POINT / RANGE:	Not determined
MELTING POINT / RANGE:	Not determined
DECOMPOSITION TEMPERATURE:	Not determined
VAPOR PRESSURE:	Not determined
VAPOR DENSITY:	Not determined
SPECIFIC GRAVITY:	Not determined
SOLUBILITY:	
Water:	Soluble
PARTITION COEFFICIENT (log Pow):	Not determined
VISCOSITY:	Not determined
EVAPORATION RATE:	Not determined
FLAMMABILITY DATA:	
Flash Point:	>93.3 deg C (>200 deg F)
Flammability (solid, gas):	Not determined
UEL:	Not determined
LEL:	Not determined
Autoignition Temperature:	Not determined

SECTION 10. STABILITY AND REACTIVITY

STABILITY/ REACTIVITY:
Stable under conditions specified in Section 7 of this SDS. No hazardous reactions known.

CONDITIONS AND MATERIALS TO AVOID:
None known.

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.

LIKELY ROUTES OF EXPOSURE:
Skin, eye, inhalation, and ingestion.

ACUTE TOXICITY DATA

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

ORAL:
AFRIN No-Drip Nasal Sprays: Oral LD50: >2000 mg/kg

EYE:
AFRIN No-Drip Nasal Sprays: Slightly irritating.

SKIN:
No data available.

ASPIRATION:
No data available.

DERMAL AND RESPIRATORY 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.

MUTAGENICITY / GENOTOXICITY:
No data available.

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

Classification according to EC Directive 1272/2008:
Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008..

Classification criteria have not been met for the following endpoints due to lack of data, inconclusive data, technical impossibility to obtain the data, or data which are conclusive although insufficient for classification (available information to support classification criteria is given in Section 4 or Section 11 of this data sheet):
Inhalation toxicity. Dermal toxicity. Eye damage or irritation. Oral toxicity. Skin sensitization. Skin corrosion or irritation. Respiratory sensitization. Mutagenicity. Carcinogenicity. Reproductive toxicity. Specific target organ toxicity (STOT) - Single Exposure. Specific target organ toxicity (STOT) - Repeated Exposure.

See Section 4 for human health symptoms and effects.

SECTION 12. ECOLOGICAL INFORMATION

ECOTOXICITY DATA

This product has not been tested for ecotoxicity.

PERSISTENCE AND DEGRADABILITY

Biodegradation Results: No data available.

BIOACCUMULATIVE POTENTIAL

Partition Coefficient (log Pow) Results: No data available.

MOBILITY IN SOIL

Soil Adsorption/Desorption Results: No data available.

PBT and vPvB ASSESSMENT

This substance has not been assessed.

OTHER ADVERSE EFFECTS

ENVIRONMENTAL FATE AND EFFECTS: No data available.

SECTION 13. DISPOSAL CONSIDERATIONS

WASTE TREATMENT METHODS

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

SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Germany, Water Endangering Classes (WGK)

INGREDIENT	Annex 1	Annex 2 - Water Hazard Classes	Annex 3
Oxymetazoline Hydrochloride	Not listed.	Not listed.	Not listed.

Ozone Depleting Substance(s)

INGREDIENT	Listing
Oxymetazoline Hydrochloride	Not listed.

Persistent Organic Pollutants

INGREDIENT	Listing
Oxymetazoline Hydrochloride	Not listed.

EU Import and Export Restrictions

INGREDIENT	Requires PIC Notification	Requires Export Notification	Export Ban
Oxymetazoline Hydrochloride	Not listed.	Not listed.	Not listed.

SEVESO II EU Directive

INGREDIENT	Listing
Oxymetazoline Hydrochloride	Not listed.

REACH

INGREDIENT	Subject to Authorization	Candidate List for Authorization	Potential Substances of High Concern	Restrictions
Oxymetazoline Hydrochloride	Not listed.	Not listed.	Not listed.	Not listed.

CHEMICAL SAFETY ASSESSMENT

A Chemical Safety Assessment has not been done.

SECTION 16. OTHER INFORMATION

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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SUPERSEDES DATE: 23-Apr-2012

DEFINITIONS (referred to under Sections 2 and 3):

CLP Classifications:	• Based on available data, this mixture does not meet the criteria to be classified as hazardous according to EC DIrective 1272/2008.
Risk Phrases:	• Based on available data, this preparation does not meet the criteria to be classified as hazardous according to EC DIrective 1999/45/EC.

GLOSSARY:
IARC - International Agency for Research on Cancer, IARC Group 1 or 2A.
NTP - National Toxicology Program
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - International Carriage of Dangerous Goods by Road
API - Active Pharmaceutical Ingredient
CAS - Chemical Abstract Service
CLP - Classification, Labeling and Packaging
DOT - Department of Transportation
EC - European Council
ETAC - Estimated Target Airborne Concentration
GHS - Globally Harmonized System
HEPA - High Efficiency Particulate Arresting
HHC - Health Hazard Category
HPA - Hypothalamic Pituitary Adrenal
IATA - International Air Transport Association
IMO - International Maritime Organization
IP - Intraperitoneal Injection
LD50 - Lethal Dose, 50%
LC50 - Lethal Concentration, 50%
LOEL - Lowest Observed Effect Level
NEL - No Effect Level
NOAEL - No Adverse Effect Level
NOEL - No Observe Effect Level
OEG - Occupational Exposure Guideline
PBT - Persistent BioaccumulativeToxic
PG - Packing Group
PIC - Prior Informed Consent
PPE - Personal Protective Equipment
REACH - Registration, Evaluation, Authorization and Restriction of Chemical Substances
RPE - Respiratory Protective Equipment
SCBA - Self Contained Breathing Apparatus
STOT - Specific Target Organ Toxicity
TSCA - Toxic Substances Control Act
TWA - Time Weighted Average
UN - United Nations
vPvB - Very Persistent andVery Bioaccumulative
WGK - Water Hazard Class (Germany)