

19829



MATERIAL SAFETY DATA SHEET

BAYER CORPORATION
CONSUMER CARE DIVISION
36 Columbia Road
Morristown, NJ 07962-1910

TRANSPORTATION EMERGENCY
CALL CHEMTREC: 800-424-9300
DISTRICT OF COLUMBIA: 202-483-7616

NON-TRANSPORTATION
BAYER EMERGENCY PHONE...: (800) 331-4536
BAYER INFORMATION PHONE.: (800) 331-4536

1. CHEMICAL PRODUCT IDENTIFICATION:

PRODUCT NAME.....: Neo-synephrine 12-Hour Spray
PRODUCT CODE.....: N-560
CHEMICAL FAMILY.....: Nasal decongestant

2. COMPOSITION/INFORMATION ON INGREDIENTS:

INGREDIENT NAME /CAS NUMBER EXPOSURE LIMITS CONCENTRATION (%)

\*\*\*\*\* HAZARDOUS INGREDIENTS \*\*\*\*\*

This pharmaceutical product, available without a prescription, is for human use. These materials are not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. This Material Safety Data Sheet is not intended for industrial exposures.

3. HAZARDS IDENTIFICATION:

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\* EMERGENCY OVERVIEW \*
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\* Color: Colorless or slightly yellow; Form: Liquid; Odor: \*
\* Odorless or slight characteristic odor; Product poses little \*
\* or no hazard if spilled and no unusual hazard if involved in \*
\* a fire; See Potential Health Effects if the recommended \*
\* dosage is exceeded. \*
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POTENTIAL HEALTH EFFECTS:

Product Code: N-560
Approval date: 03/07/97

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3. HAZARDS IDENTIFICATION (Continued)

ROUTE(S) OF ENTRY.....: Appropriate route of entry: nasal spray

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE:

NOTE: This is a pharmaceutical material available without a prescription - use only as directed. See product packaging for further information concerning adverse effects and drug interaction precautions..

ACUTE INHALATION.....: If recommended dosage is exceeded burning, stinging, sneezing, or increase of nasal discharge may occur. Symptoms of excessive exposure may include insomnia, nervousness, dizziness, headaches, palpitations and elevated blood pressure.

ACUTE SKIN CONTACT.....: None known.

ACUTE EYE CONTACT.....: None known.

ACUTE INGESTION.....: None known.

CHRONIC EFFECTS OF EXPOSURE....: May be harmful to the nasal mucus membranes with symptoms as described under Acute Inhalation.

CARCINOGENICITY.....: The components of this product are not listed by NTP, IARC or regulated as a carcinogen by OSHA.

MEDICAL CONDITIONS

AGGRAVATED BY EXPOSURE.....: Persons with heart disease, high blood pressure, thyroid disease, diabetes, or enlargement of the prostate gland should not use this product unless directed by a physician.

4. FIRST AID MEASURES:

FIRST AID FOR EYES.....: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

FIRST AID FOR SKIN.....: Flush skin with plenty of soap and water. Contact a physician if irritation develops.

FIRST AID FOR INHALATION: In case of overdose, contact your regional poison control center or physician immediately. For additional information, contact Bayer Corporation at 1-800-800-4793.

FIRST AID FOR INGESTION.: In case of overdose, contact your regional poison control center or physician immediately. For additional information, contact Bayer Corporation at 1-800-800-4793.

5. FIRE FIGHTING MEASURES:

FLASH POINT.....: Not Applicable

EXTINGUISHING MEDIA.....: Water

5. FIRE FIGHTING MEASURES (Continued)

SPECIAL FIRE FIGHTING PROCEDURES: Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

6. ACCIDENTAL RELEASE MEASURES:

SPILL OR LEAK PROCEDURES.....: Spills should be taken up with an appropriate absorbent and placed in normal trash. Spill area can be washed with water. Small spills may be flushed into the sewer with excess water.

7. HANDLING AND STORAGE:

STORAGE TEMPERATURE(MIN/MAX): Room temperature.

SHELF LIFE.....: Do not use after expiration date.

SPECIAL SENSITIVITY.....: Protect from light.

HANDLING/STORAGE PRECAUTIONS: Keep this and all drugs out of the reach of children. Avoid contact with eyes and skin. Wash thoroughly after handling. Store in a dry place away from excessive heat. Reseal containers immediately after use. Protect from freezing. Use normal precautions for storage of a drug.

8. PERSONAL PROTECTION:

EYE PROTECTION REQUIREMENTS.....: None for normal use.

SKIN PROTECTION REQUIREMENTS.....: None for normal use.

VENTILATION REQUIREMENTS.....: Under normal conditions of use, special ventilation is not required.

RESPIRATOR REQUIREMENTS.....: Under normal conditions of use, respiratory protection is not required.

WORK PRACTICES.....: Normal clinical practice. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.

ADDITIONAL PROTECTIVE MEASURES.....: Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

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9. PHYSICAL AND CHEMICAL PROPERTIES:  
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PHYSICAL FORM.....: Liquid  
COLOR.....: Colorless or slightly yellow  
ODOR.....: Odorless or slight characteristic odor  
pH .....: Not Established  
BOILING POINT.....: Approx. 212 F (100 C)  
MELTING/FREEZING POINT.....: Approx. 32 F (0 C)  
SOLUBILITY IN WATER .....: Soluble  
SPECIFIC GRAVITY .....: Not Established  
BULK DENSITY.....: Not Established  
VAPOR PRESSURE .....: Not Established

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10. STABILITY AND REACTIVITY:  
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STABILITY.....: This is a stable material.  
HAZARDOUS POLYMERIZATION...: Will not occur.  
INCOMPATIBILITIES.....: See product packaging for drug interaction.  
INSTABILITY CONDITIONS.....: None known.  
DECOMPOSITION PRODUCTS.....: Not Applicable.

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11. TOXICOLOGICAL INFORMATION:  
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ACUTE TOXICITY  
ORAL LD50.....: 7.87 ml/kg (rat)

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12. ECOLOGICAL INFORMATION:  
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NO ECOLOGICAL INFORMATION AVAILABLE

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13. DISPOSAL CONSIDERATIONS  
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WASTE DISPOSAL METHOD.....: Waste disposal should be in accordance with  
existing federal, state and local environmental control laws.

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14. TRANSPORTATION INFORMATION:  
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TECHNICAL SHIPPING NAME.....: Nasal decongestant  
PRODUCT LABEL.....: Neo-synephrine Maximum Strength 12-Hour Spray

DOT (DOMESTIC SURFACE)  
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HAZARD CLASS OR DIVISION .....: Non-Regulated

IMO / IMDG CODE (OCEAN)  
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HAZARD CLASS DIVISION NUMBER...: Non-Regulated

ICAO / IATA (AIR)  
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HAZARD CLASS DIVISION NUMBER...: Non-Regulated  
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15. REGULATORY INFORMATION:  
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OSHA STATUS.....: This product is not hazardous under the criteria  
of the Federal OSHA Hazard Communication Standard  
29 CFR 1910.1200.

TSCA STATUS.....: This product is exempt from TSCA Regulation under  
Section 3 (2)(B)(vi) when used for pharmaceutical  
application.

CERCLA REPORTABLE QUANTITY...: None

SARA TITLE III:

SECTION 302 EXTREMELY

HAZARDOUS SUBSTANCES...: None

SECTION 311/312

HAZARD CATEGORIES.....: Non-hazardous under Section 311/312

SECTION 313

TOXIC CHEMICALS.....: None

RCRA STATUS.....: Under RCRA, it is the responsibility of the  
product user to determine at the time of  
disposal, whether a material containing the  
product or derived from the product, should be  
classified as a hazardous waste. (40 CFR  
261.20-24)

The following chemicals are specifically listed by individual states; other  
product specific health and safety data in other sections of the MSDS may also  
be applicable for state requirements. For details on your regulatory  
requirements you should contact the appropriate agency in your state.

15. REGULATORY INFORMATION (Continued)

COMPONENT NAME /CAS NUMBER	CONCENTRATION	STATE CODE
Water 7732-18-5	Greater than 75 %	PA3, NJ4
Phenylmercuric Acetate 62-38-4	.002 %	CA2, MA
Sorbitol 50-70-4	1 - 5 %	PA3, NJ4

CA2 = Warning! This chemical is known to the State of California to cause birth defects or other reproductive harm.

MA = Massachusetts Hazardous Substance List

NJ4 = New Jersey Other - included in 5 predominant ingredients > 1%

PA3 = Pennsylvania Non-hazardous present at 3% or greater.

ADDITIONAL INFORMATION: ACTIVE INGREDIENT: Oxymetazoline HCl 0.05% INACTIVE INGREDIENTS: Benzalkonium Chloride, Glycine, Phenylmercuric Acetate 0.002%, Purified Water, Sorbitol, and may also contain Sodium Chloride.

16. OTHER INFORMATION:

HMIS RATINGS:                    Health    Flammability    Reactivity  
   1                    0                    0  
   0=Minimal 1=Slight 2=Moderate 3=Serious 4=Severe

Bayer's method of hazard communication is comprised of Product Labels and Material Safety Data Sheets. HMIS ratings are provided by Bayer as a customer service.

REASON FOR ISSUE.....: Establish MSDS  
PREPARED BY.....: R. Ruppel-Kerr  
APPROVED BY.....: Llew C. Williams  
APPROVAL DATE.....: 03/07/97  
SUPERSEDES DATE.....: 05/12/93  
MSDS NUMBER.....: 28863

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