Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray
Synonyms: Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray, 137 mcg/50 mcg per spray

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317, USA
+1.724.514.1800
Contact e-mail: SDScontact@viatris.com
For any suspected reports of adverse events, product quality complaints or medical/product information questions, please email: druginfo@mylan.com.

Emergency telephone number

Emergency Telephone: 24 hr. Emergency Contact ChemTel
International: +1-813-248-0585
US & Canada: 1-800-255-3924
Mexico: 800-099-0731

Other Contact Information

FDA Adverse Events Reporting Number: For reporting adverse health events call: +1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

Classification

Reproductive toxicity, Category 2

Label elements

Signal word: Warning
Hazard statements: H361 - Suspected of damaging fertility or the unborn child
Precautionary Statements - Prevention: Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Precautionary Statements - Response: IF exposed or concerned: Get medical advice/attention
Precautionary Statements - Storage: Store locked up
Precautionary Statements - Disposal: Dispose of contents/container to an approved waste disposal plant

Other Hazards
No information available.

Unknown acute toxicity
No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

Mixture

Chemical name	CAS No	Weight-%	Hazard statements
Azelastine Hydrochloride	79307-93-0	< 1	H302 - Harmful if swallowed H336 - May cause drowsiness or dizziness H361 - Suspected of damaging fertility or the unborn child
Fluticasone Propionate	80474-14-2	< 1	H372 - Causes damage to organs through prolonged or repeated exposure

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Description of first aid measures
Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.
General advice: Show this safety data sheet to the doctor in attendance.
Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.
Skin contact: Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact: In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion: Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.
Self-protection of the first aider: First aider: Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Most important symptoms and effects, both acute and delayed
Symptoms: Headache. Fatigue. Dizziness. Drowsiness. Itching. Irritation. Dysgeusia (taste disturbances).
Chronic symptoms: May damage fertility or the unborn child.

Indication of any immediate medical attention and special treatment needed
Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES

Extinguishing media
Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical
Fire hazard: Not flammable.
Explosive hazard: Not an explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.
Hazardous combustion products: Carbon oxides. Nitrogen oxides. Hydrogen chloride. Oxides of sulfur. Fluorinated oxides.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.
Firefighting instructions: Use water spray or fog; do not use straight streams.
Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.
Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.
Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Environmental precautions

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.
Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills:. Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.
Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Store at room temperature. Keep at temperatures between 20 and 25 °C (68 and 77 °F). Do not refrigerate. Do not freeze. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep container upright. Protect from light. Keep out of reach of children. Store locked up.
Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves.
Eye/face protection: Safety glasses with side shields are recommended for medical or industrial exposures.
Skin and body protection: Wear suitable protective clothing.
Respiratory protection: Use appropriate respiratory protection.
General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Liquid
Appearance:	Suspension
Color:	White
Odor:	No data available
Odor threshold:	No data available
pH:	6.0
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available
Oxidizing properties:	No data available

Other Information

VOC Content (%): No data available

10. STABILITY AND REACTIVITY

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: May cause drowsiness or dizziness. May cause irritation.
Ingestion: Based on available data, the classification criteria are not met.
Eye contact: Specific test data for the substance or mixture is not available.
Skin contact: Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Headache. Fatigue. Dizziness. Drowsiness. Itching. Irritation. Dysgeusia (taste disturbances).

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.
Respiratory or skin sensitization: Based on available data, the classification criteria are not met.
Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Contains a known or suspected reproductive toxin.
STOT - single exposure: Based on available data, the classification criteria are not met.
STOT - repeated exposure: Based on available data, the classification criteria are not met.
Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

No information available.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Chemical name	Partition coefficient
Glycerol (CAS #: 56-81-5)	-1.75
Phenylethyl Alcohol (CAS #: 60-12-8)	1.36
Edetate Disodium (CAS #: 139-33-3)	-4.3

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

14. TRANSPORT INFORMATION

Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

DOT Not regulated

TDG Not regulated

IATA Not regulated

IMDG Not regulated

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

Ozone-depleting substances (ODS): Not applicable

Persistent Organic Pollutants: Not applicable

The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations

US State Regulations:

Chemical name	New Jersey	Massachusetts	Pennsylvania
Glycerol 56-81-5	X	X	X
Cellulose Microcrystalline 9004-34-6	X	X	X

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 17-January-2025

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:

Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
TWA: TWA (time-weighted average)
STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:
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This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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