



Scopolamine Transdermal System

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: Scopolamine Transdermal System

Synonyms: Scopolamine Transdermal System, 1 mg/3 days

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. For external use only.

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.

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Canonsburg, PA 15317, USA

+1.724.514.1800

Contact e-mail:

SDScontact@viatris.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

Skin sensitization, Category 1A

Label elements



Signal word:

Warning

Hazard statements:

H317 - May cause an allergic skin reaction

Precautionary Statements - Prevention: Wash face, hands and any exposed skin thoroughly after handling

Contaminated work clothing must not be allowed out of the workplace
 Wear protective gloves/protective clothing/eye protection/face protection
 Specific treatment (see supplemental first aid instructions on this label)
IF ON SKIN: Wash with plenty of water and soap
 Take off immediately all contaminated clothing and wash it before reuse
 If skin irritation or rash occurs: Get medical advice/attention
 Wash contaminated clothing before reuse

Precautionary Statements - Response:**Skin:****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
Scopolamine	51-34-3	1 - 10	H317 - May cause an allergic skin reaction H318 - Causes serious eye damage H336 - May cause drowsiness or dizziness

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

General advice: Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

Inhalation: Remove to fresh air. If breathing has stopped, give artificial respiration. Get medical attention immediately. If symptoms persist, call a physician.

Skin contact: Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. May cause an allergic skin reaction.

Eye contact: Get immediate medical advice/attention. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing. Do not rub affected area.

Ingestion: Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Get immediate medical advice/attention.

Self-protection of the first aider: Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Avoid contact with skin, eyes or clothing. Avoid breathing dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required. See section 8 for more information.

Most important symptoms and effects, both acute and delayed

Symptoms: Dry mouth. Dizziness. Somnolence. Impairment of vision. Confusion. Itching. Rashes. Hives. Burning sensation. Coughing and/or wheezing. Difficulty in breathing.

Indication of any immediate medical attention and special treatment needed

May cause sensitization in susceptible persons. Treat symptomatically.

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.

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. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak. Avoid generation of dust. Do not breathe dust.

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.

Other Information: Refer to protective measures listed in Sections 7 and 8.

Environmental precautions

Prevent further leakage or spillage if safe to do so.

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. Ensure adequate ventilation. Take off contaminated clothing and wash before reuse. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep at temperatures between 20 and 25 °C (68 and 77 °F). Keep container upright. Keep containers tightly closed in a dry, cool and well-ventilated place. Store locked up. Keep out of the reach of children.

Specific end use(s): Pharmaceutical. Use only as directed. For external use only. 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. Impervious gloves.

Eye/face protection: Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.

Skin and body protection: Skin sensitizer. Avoid contact with skin. Wear suitable protective clothing. Wash thoroughly after handling.

Respiratory protection: Use appropriate respiratory protection.

General hygiene considerations: Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Regular cleaning of equipment, work area and clothing is recommended. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Solid
Appearance:	Patches (heated and/or medicated)
Color:	Peach
Odor:	No data available

Odor threshold:	No data available
pH:	No data available
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
<u>Other Information</u>	
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

Excessive heat.

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: Not an expected route of exposure.

Ingestion: Not an expected route of exposure.

Eye contact: Not an expected route of exposure.

Skin contact: May cause sensitization by skin contact. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. May cause irritation. Prolonged contact may cause redness and irritation.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Dry mouth. Dizziness. Somnolence. Impairment of vision. Confusion. Itching. Rashes. Hives. Burning sensation. Coughing and/or wheezing. Difficulty in breathing.

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

Skin corrosion/irritation: May cause skin irritation.

Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Respiratory or skin sensitization: May cause sensitization by skin contact.

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: Based on available data, the classification criteria are not met.

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

There is no data for this product.

Chemical name	Partition coefficient
Scopolamine (CAS #: 51-34-3)	1.31

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: This product does not contain any substances regulated by state right-to-know regulations

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: 09-February-2023

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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