

Issuing Date: 11/06/2014

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**1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING****Product Identifier**

**MSDS Number:** 1101312  
**Product Name:** Transderm Scop® Transdermal Therapeutic System

**Other means of identification**

**Product Code(s):** NDC 0067-4345-04, NDC 10019-553-01, NDC 10019-553-02, NDC 10019-553-88, NDC 10019-553-90, NDC 10019-553-03, NDC 10019-553-04  
**Synonyms:** None

**Recommended use of the chemical and restrictions on use**

**Product Use:** Pharmaceutical.  
**Product Type:** Regulated Prescription Drug  
**Uses advised against** No information available

**Details of the supplier of the safety data sheet**

BAXTER HEALTHCARE CORPORATION  
1 BAXTER PARKWAY  
DEERFIELD, ILLINOIS 60015  
(800) 933-0303

**Emergency telephone number**

Rocky Mountain Poison and Drug Center: USA (888) 990-0996  
OUTSIDE USA (303) 389-1422  
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

**2. HAZARDS IDENTIFICATION****Classification****OSHA Regulatory Status**

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral	Category 4
Specific target organ toxicity (single exposure)	Category 1

**Label Elements****Emergency Overview****Danger****Hazard Statements**

Harmful if swallowed  
Causes damage to organs



**Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Do not breathe dust/fume/gas/mist/vapors/spray

**Precautionary Statements - Response**

Specific treatment (see supplemental first aid instructions on this label)  
IF exposed: Call a POISON CENTER or doctor/physician  
IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
Rinse mouth

**Precautionary Statements - Storage**

Store locked up

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Hazards not otherwise classified (HNOC)****Other Information**

Unknown Acute Toxicity 98.5 % of the mixture consists of ingredient(s) of unknown toxicity

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Component	CAS-No	Weight-%
Scopolamine hydrobromide (HBr)	114-49-8	1.5
Mineral Oil	8012-95-1	12.4
Polyisobutylene	9003-27-4	11.4

**4. FIRST AID MEASURES****First Aid Measures**

<b>General Advice</b>	Treat symptomatically and supportively.
<b>Eye contact:</b>	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.
<b>Skin contact:</b>	In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.
<b>Inhalation:</b>	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.
<b>Ingestion:</b>	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

**Most important symptoms and effects, both acute and delayed**

No information available.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

**5. FIRE-FIGHTING MEASURES****Suitable extinguishing media**

Use foam or all purpose dry chemicals to extinguish.

**Specific hazards arising from the chemical**

No information available.

**Special protective equipment for firefighters**

Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

**6. ACCIDENTAL RELEASE MEASURES****Personal precautions, protective equipment and emergency procedures**

Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).

**Environmental Precautions**

See Section 12 for environmental precautions.

**Methods and material for containment and cleaning up****Methods for Containment:**

If emergency personnel are unavailable, contain spilled material.

**Methods for cleaning up**

Shovel or sweep up. Place spilled material in an appropriate container for disposal.

**7. HANDLING AND STORAGE****Precautions for Safe Handling**

**Technical measures/precautions:** Do not ingest. Avoid eye contact. Wash thoroughly after handling.

**Conditions for safe storage, including any incompatibilities**

**Technical measures and storage conditions** Keep in a cool, well-ventilated place. Store at room temperature between 20°C and 25°C (68°F and 77°F).

**Incompatible materials** No special restrictions on storage with other products.

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Occupational Exposure Limits****Exposure Limits:**

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Scopolamine hydrobromide (HBr) 114-49-8	None	None	None	None	None	None
Mineral Oil 8012-95-1	5 mg/m <sup>3</sup> 5 mg/m <sup>3</sup> (vacated)	None	None	5 mg/m <sup>3</sup>	None	None
Polyisobutylene 9003-27-4	None	None	None	None	None	None

**Appropriate engineering controls**

**Engineering Measures** Good general ventilation should be sufficient to control airborne levels.

**Individual protection measures, such as personal protective equipment**

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<b>Eye protection</b>	Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.
<b>Hand protection</b>	Not required.
<b>Skin and body protection</b>	Not required.
<b>Respiratory protection</b>	No personal respiratory protective equipment normally required.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Physical state:</b>	Solid.
<b>Appearance:</b>	Adhesive dermal patch
<b>Color:</b>	Tan
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	Not applicable.
<b>Melting point / melting range:</b>	No information available
<b>Boiling point / boiling range:</b>	No information available
<b>Flash point:</b>	No information available
<b>Evaporation rate:</b>	No information available
<b>Flammability (solid, gas):</b>	No information available
<b>Flammable limits</b>	No information available
<b>in air-upper (%):</b>	
<b>Flammable limits</b>	No information available
<b>in air-lower (%):</b>	
<b>Vapor pressure:</b>	No information available
<b>Vapor Density:</b>	No information available
<b>Density:</b>	No information available
<b>Solubility:</b>	No information available
<b>Partition coefficient</b>	No information available
<b>(n-octanol/water):</b>	
<b>Autoignition temperature:</b>	No information available
<b>Decomposition Temperature:</b>	No information available
<b>Viscosity:</b>	No information available
<b>Explosive Properties:</b>	No information available
<b>Oxidizing Properties:</b>	No information available

### Other Information

## 10. STABILITY AND REACTIVITY

### Reactivity

No data available

### Chemical Stability

Stable under recommended storage conditions

### Possibility of Hazardous Reactions

None under normal processing

### Conditions to Avoid

No data available

### Incompatible materials

None known

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**Hazardous Decomposition Products**

No data available

**11. TOXICOLOGICAL INFORMATION**

Component	Inhalation LC50	Dermal LD50	Oral LD50
Scopolamine hydrobromide (HBr) 114-49-8	-	-	= 1270 mg/kg ( Rat )
Mineral Oil 8012-95-1	2062 ppm 4 h (Rat)	-	> 24 g/kg ( Rat )
Polyisobutylene 9003-27-4	-	-	-

**Information on likely routes of exposure**

<b>Inhalation:</b>	Inhalation not likely under normal use conditions.
<b>Eye contact:</b>	May cause temporary blurring of vision and dilation of pupils. May cause eye irritation.
<b>Skin contact:</b>	May cause slight irritation in sensitive individuals.
<b>Ingestion:</b>	May be harmful if swallowed.

**Information on Toxicological Effects**

**Symptoms:** No information available.

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

<b>Irritation:</b>	Not classified.
<b>Corrosivity:</b>	Not classified.
<b>Sensitization:</b>	Not classified.
<b>Mutagenic effects:</b>	Not classified
<b>Carcinogenic effects:</b>	Not classified

Component	ACGIH	IARC	NTP	OSHA
Scopolamine hydrobromide (HBr) 114-49-8	-	-	-	-
Mineral Oil 8012-95-1	-	Group 1 Group 3	-	Present
Polyisobutylene 9003-27-4	-	-	-	-

<b>Reproductive toxicity:</b>	No impairment to fertility based on animal data. Fetotoxic at high doses based upon animal data.
<b>STOT - single exposure:</b>	Respiratory system.
<b>STOT - repeated exposure:</b>	Not classified.
<b>Aspiration Hazard:</b>	Not classified.

**Numerical measures of toxicity - Product Information**

**Unknown Acute Toxicity** 98.5 % of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

ATEmix (oral) 1270 mg/kg

## 12. ECOLOGICAL INFORMATION

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Scopolamine hydrobromide (HBr) 114-49-8	None.	None.	None.	None.
Mineral Oil 8012-95-1	None.	None.	None.	None.
Polyisobutylene 9003-27-4	None.	None.	None.	None.

### Ecotoxicity

No information available

100 % of the mixture consists of components(s) of unknown hazards to the aquatic environment

### Persistence and degradability

No information available.

### Bioaccumulative potential

No information available

### Mobility in soil

No information available.

### Other adverse effects

No information available.

## 13. DISPOSAL CONSIDERATIONS

### Waste treatment methods

**Waste from residues/unused  
products**

In accordance with local and national regulations

**Contaminated Packaging**

In accordance with local and national regulations.

## 14. TRANSPORT INFORMATION

DOT

Not regulated

## 15. REGULATORY INFORMATION

### U.S. Regulations:

**TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

### OTHER REGULATIONS:

Component	Weight-%	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Scopolamine hydrobromide (HBr) 114-49-8	1.5	Not Listed	Not Listed	Not Listed	Not Listed
Mineral Oil 8012-95-1	12.4	Not Listed	Not Listed	Not Listed	Not Listed
Polyisobutylene 9003-27-4	11.4	Not Listed	Not Listed	Not Listed	Not Listed

**STATE REGULATIONS:**

Component	California Prop. 65	Minnesota Right-To -Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Scopolamine hydrobromide (HBr) 114-49-8	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Mineral Oil 8012-95-1	Not Listed	Present	Not Listed	Not Listed	Present	Present	Present
Polyisobutylene 9003-27-4	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

**CANADIAN REGULATIONS:**

Canada DSL Inventory List - This product complies with DSL

<b>16. OTHER INFORMATION</b>
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**This data sheet contains changes from the previous version in section(s):**

New GHS format. Changes to Section 1. Additional product codes.

**Additional information:**

Not Available.

**Prepared by** Baxter Research & Development  
**Issuing Date:** 11/06/2014  
**Revision Date:** 11/15/2016

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 the accuracy or completeness of the information contained 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.

**End of Safety Data Sheet**