

Issuing Date: 06-Nov-2014

Revision Date: 24-Dec-2021

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

SDS 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, NDC 0067-4346-04
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
US: (800) 933-0303
Canada: (855)-584-1368

Emergency telephone number

Verisk 3E Global Incident Response Hotline +1 760 476 3962; Access Code 335625

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

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

Carcinogenicity	Category 1A
Specific target organ toxicity (single exposure)	Category 1

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

May cause cancer
Causes damage to organs

**Precautionary Statements - Prevention**

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Do not breathe dust/fume/gas/mist/vapors/spray

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Use personal protective equipment as required

**Precautionary Statements -
Response**

Specific treatment (see supplemental first aid instructions on this label)
IF exposed: Call a POISON CENTER or doctor/physician

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 100 % of the mixture consists of ingredient(s) of unknown toxicity

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	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

Description of first aid measures

General Advice Treat symptomatically and supportively.

Eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation develops.

Skin contact: In case of contact, immediately flush skin with plenty of water. Get medical attention if irritation develops.

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention if symptoms occur.

Ingestion: 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

Contains a known or suspected carcinogen.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. See patient package insert in shipping carton for complete information.

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**

Keep unnecessary personnel away. 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:**

Chemical Name	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 ³ 5 mg/m ³ (vacated)	None	None	5 mg/m ³	None	None
Polyisobutylene 9003-27-4	None	None	None	None	None	None

Appropriate engineering controls**Engineering Measures**

No special containment is required. Good general ventilation should be sufficient to control airborne levels.

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

Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

Hand protection

Not required.

Skin and body protection	Not required.
Respiratory protection	No personal respiratory protective equipment normally required.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Solid.
Appearance:	Adhesive dermal patch
Color:	Tan.
Odor:	No information available
Odor Threshold:	No information available
pH:	No information available
Melting point / melting range:	No information available
Boiling point / boiling range:	No information available
Flash point:	No information available
Evaporation rate:	No information available
Flammability (solid, gas):	No information available
Flammable limits	No information available
in air-upper (%):	
Flammable limits	No information available
in air-lower (%):	
Vapor pressure:	No information available
Vapor density	No information available
Density:	No information available
Solubility:	No information available
Partition coefficient	No information available
(n-octanol/water):	
Autoignition temperature:	No information available
Decomposition temperature	No information available
Viscosity:	No information available
Explosive Properties:	No information available
Oxidizing Properties:	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 use conditions

Conditions to Avoid

No data available

Incompatible materials

None known

Hazardous decomposition products

No data available

11. TOXICOLOGICAL INFORMATION

Chemical Name	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

Inhalation:	Inhalation not likely under normal use conditions.
Eye contact:	May cause temporary blurring of vision and dilation of pupils. May cause eye irritation.
Skin contact:	May cause slight irritation in sensitive individuals.
Ingestion:	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

Irritation:	Not classified.
Corrosivity:	Not classified.
Sensitization:	Not classified.
Mutagenic effects:	Not classified.
Carcinogenic effects:	Contains a known or suspected carcinogen.

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

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

Numerical measures of toxicity - Product Information

Unknown Acute Toxicity 100 % 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) 8187 mg/kg

12. ECOLOGICAL INFORMATION

Chemical Name	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

Bioaccumulative potential

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

**Environmental hazard
Special Provisions**Not applicable
None**15. REGULATORY INFORMATION****U.S. Regulations:****TSCA Inventory List -**

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Chemical Name	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:

Chemical Name	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

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

Changes to Section 2. Changes to Section 4. Changes to Section 11.

Additional information:

Not Available.

Prepared by: Baxter Research & Development
Issuing Date: 06-Nov-2014
Revision Date: 24-Dec-2021

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