SAFETY DATA SHEET

Issuing Date 08-Oct-2019 **Revision date** 08-Oct-2019 **Revision Number** 1

1. Identification

Product identifier

Product Name Scopolamine Patch

Other means of identification

Product Code(s) FG00105

Synonyms None

Recommended use of the chemical and restrictions on use

Uses/ Identified uses Pharmaceutical

Restrictions on use No information available

Details of the supplier of the safety data sheet

Manufacturer

400 Interpace Parkway
Parsippany, NJ. 07054
USA

Teva Corporate Headquarters
5 Bazel Street PO Box 3190
Petah Tikva, Israel

Emergency telephone number

Emergency Telephone United States/Canada/Puerto Rico: 1-800-424-9300 (Chemtrec) [24-hrs]
International: +1-703-741-5970 (Chemtrec) [24-hours]

E-mail SDS.TevaIL@teva.co.il

2. Hazard(s) identification

Classification

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

Acute toxicity - Oral	Category 3
Acute toxicity - Dermal	Category 3
Acute toxicity - Inhalation (Vapors)	Category 4
Acute toxicity - Inhalation (Dusts/Mists)	Category 2
Serious eye damage/eye irritation	Category 2A
Specific target organ toxicity (single exposure)	Category 3

Hazards not otherwise classified (HNOC)
Not applicable

Label elements

Danger

Hazard statements
Toxic if swallowed
Toxic in contact with skin
Fatal if inhaled
Causes serious eye irritation
May cause drowsiness or dizziness



Appearance No information available **Physical state** Patch **Odor** No information available

Precautionary Statements - Prevention
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
Use only outdoors or in a well-ventilated area
Do not breathe dust/fume/gas/mist/vapors/spray
Wear respiratory protection
Wear protective gloves/protective clothing/eye protection/face protection

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
If eye irritation persists: Get medical advice/attention
IF ON SKIN: Wash with plenty of water and soap
Call a POISON CENTER or doctor if you feel unwell
Take off immediately all contaminated clothing and wash it before reuse
IF INHALED: Remove person to fresh air and keep comfortable for breathing
Immediately call a POISON CENTER or doctor
IF SWALLOWED: Immediately call a POISON CENTER or doctor
Rinse mouth

Precautionary Statements - Storage
Store locked up
Store in a well-ventilated place. Keep container tightly closed

Precautionary Statements - Disposal
Dispose of contents/container to an approved waste disposal plant

Other information
Very toxic to aquatic life with long lasting effects
Very toxic to aquatic life

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity
3.03 % of the mixture consists of ingredient(s) of unknown acute oral toxicity
3.03 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
8.04 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
97.61 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical Name	CAS No	Weight-%	Trade secret
Ethyl acetate	141-78-6	91.96	*
(Z)-9-Octadecen-1-ol	143-28-2	3.03	*
Isopropyl Myristate	110-27-0	2.62	*
Scopolamine	51-34-3	2.39	*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. First-aid measures

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

Inhalation If breathing has stopped, give artificial respiration. Get medical attention immediately. Remove to fresh air. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If breathing is difficult, (trained personnel should) give oxygen. IF exposed or concerned: Get medical advice/attention.

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.

Skin contact Get immediate medical advice/attention. Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

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. Do not breathe dust. Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Use personal protective equipment as required. See section 8 for more information. Avoid contact with skin, eyes or clothing.

Most important symptoms and effects, both acute and delayed

Symptoms Coughing and/ or wheezing. Difficulty in breathing. Burning sensation. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media No information available.

Specific hazards arising from the chemical Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

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. Avoid generation of dust. Do not breathe dust. Keep people away from and upwind of spill/leak.

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

For emergency responders Use personal protection recommended in Section 8.

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 Take up mechanically, placing in appropriate containers for disposal.

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

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Take off contaminated clothing and wash before reuse. In case of insufficient ventilation, wear suitable respiratory equipment. Handle product only in closed system or provide appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Avoid breathing vapors or mists.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Store locked up.

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH
Ethyl acetate 141-78-6	TWA: 400 ppm	TWA: 400 ppm TWA: 1400 mg/m^3 (vacated) TWA: 400 ppm (vacated) TWA: 1400 mg/m^3	IDLH: 2000 ppm TWA: 400 ppm TWA: 1400 mg/m^3

Appropriate engineering controls

Engineering controls	Showers Eyewash stations Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection	Wear safety glasses with side shields (or goggles). If splashes are likely to occur, wear safety glasses with side-shields.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing. Chemical resistant apron.
Respiratory protection	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
Environmental exposure controls	No information available.
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. Do not breathe dust. Take off contaminated clothing and wash before reuse. Contaminated work clothing should not be allowed out of the workplace.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Patch
Appearance	No information available
Color	No information available
Odor	No information available
Odor threshold	No information available

Property	**Values**	**Remarks • Method**
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility in other solvents	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available

K_{st} (bar.m/s)	No information available
Minimum Ignition Energy (mJ)	No information available
Molecular weight	No information available
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity No information available.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions Hazardous polymerization does not occur.

Conditions to avoid Excessive heat.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition products None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. Fatal if inhaled. (based on components). May cause irritation of respiratory tract. May cause drowsiness or dizziness.

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.

Skin contact Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation. Toxic in contact with skin. (based on components).

Ingestion Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Toxic if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Coughing and/ or wheezing. Difficulty in breathing. May cause redness and tearing of the eyes. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting.

Acute toxicity

Numerical measures of toxicity

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

ATEmix (oral)	202.56 mg/kg
ATEmix (dermal)	206.80 mg/kg
ATEmix (inhalation-dust/mist)	0.05 mg/l
ATEmix (inhalation-vapor)	15.67 mg/l

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

3.03 % of the mixture consists of ingredient(s) of unknown acute oral toxicity

3.03 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity
100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas)
8.04 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor)
97.61 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

Component Information

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Ethyl acetate 141-78-6	= 5620 mg/kg (Rat)	> 18000 mg/kg (Rabbit) > 20 mL/kg (Rabbit)	= 4000 ppm (Rat) 4 h
Isopropyl Myristate 110-27-0	> 10000 mg/kg (Rat)	= 5 g/kg (Rabbit)	> 41 mg/L (Rat) 1 h
Scopolamine 51-34-3	= 2650 mg/kg (Rat)	-	-

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 Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity No information available.

STOT - single exposure May cause drowsiness or dizziness.

STOT - repeated exposure No information available.

Target organ effects Respiratory system, Eyes, Skin.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Ethyl acetate 141-78-6	48 Hr EC50 Desmodesmus subspicatus: 3300 mg/L	LC50: 220 - 250mg/L (96h, Pimephales promelas) LC50: =484mg/L (96h, Oncorhynchus mykiss) LC50: 352 - 500mg/L (96h, Oncorhynchus mykiss)	-	48 Hr EC50 Daphnia magna: 560 mg/L [Static]
(Z)-9-Octadecen-1-ol 143-28-2	-	LC50: =0.0029mg/L (96h, Pimephales promelas)	-	-
Isopropyl Myristate 110-27-0	EC50: >100mg/L (72h, Desmodesmus subspicatus)	LC50: =8400mg/L (96h, Brachydanio rerio)	-	EC50: =100mg/L (48h, Daphnia magna)

Persistence and degradability No information available.

Bioaccumulation There is no data for this product.

Component Information

Chemical Name	Partition coefficient
Ethyl acetate 141-78-6	0.6
Isopropyl Myristate 110-27-0	>6

Other adverse effects No information available.

13. Disposal considerations

Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

US EPA Waste Number U112

Chemical Name	RCRA	RCRA - Basis for Listing	RCRA - D Series Wastes	RCRA - U Series Wastes
Ethyl acetate 141-78-6	-	Included in waste stream: F039	-	U112

California Hazardous Waste Status This product contains one or more substances that are listed with the State of California as a hazardous waste.

Chemical Name	California Hazardous Waste Status
Ethyl acetate 141-78-6	Toxic Ignitable

14. Transport information

DOT Not regulated

TDG Not regulated

MEX Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

RID Not regulated

ADR Not regulated

ADN Not regulated

15. Regulatory information

International Inventories

TSCA	Contact supplier for inventory compliance status.
DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
IECSC	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AICS	Contact supplier for inventory compliance status.

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

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.

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

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, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical Name	Hazardous Substances RQs	Extremely Hazardous Substances RQs
Ethyl acetate 141-78-6	5000 lb	-

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Ethyl acetate 141-78-6	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA	**Health hazards** 4	**Flammability** 0	**Instability** 0	**Physical and chemical properties** -
HMIS	**Health hazards** 4	**Flammability** 0	**Physical hazards** 0	**Personal protection** X

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)
Ceiling	Maximum limit value	*	Skin designation

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
RTECS (Registry of Toxic Effects of Chemical Substances)
World Health Organization

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Revision Note No information available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet