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## Section 1. Identification

**Product identifier**

**Product Identity** Scopolamine 1 mg/ 3 days TDS

**Other means of identification** None

**Relevant identified uses of the substance or mixture and uses advised against**

Scopolamine transdermal system with anticholinergic effects indicated for the treatment of nausea and vomiting associated with motion sickness and postoperative nausea and vomiting (PONV).

The concurrent use of scopolamine transdermal system with other drugs that cause CNS adverse reactions of drowsiness, dizziness or disorientation (e.g., sedatives, hypnotics, opiates, anxiolytics and alcohol) or have anticholinergic properties (e.g., other belladonna alkaloids, sedating antihistamines, meclizine, tricyclic antidepressants and muscle relaxants) may potentiate the effects of scopolamine transdermal system.

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

**Company Name** Manufacturer: LTS Lohmann Therapie-Systeme AG  
Lohmannstraße 2, 56626 Andernach, Germany

Abbreviated New DRUG Application Holder:  
Rhodes Pharmaceuticals L.P.  
Company Address:  
4701 International Boulevard W. Suite 307  
Wilson, NC 27893

**Emergency**

**Customer Service:** Phone: (252) 265-1755  
Fax: (252) 265-1777

## Section 2. Hazard(s) identification

**Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).**

The substance is not classified according to the OSHA Hazcom or WHMIS regulations.

**Label elements**

The substance is not classified according to the OSHA Hazcom or WHMIS regulations.

**[Prevention]**

No GHS prevention statements

**[Response]**

No GHS response statements



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**[Storage]**

No GHS storage statements

**[Disposal]**

No GHS disposal statements

**Other hazards**

This product contains no PBT/vPvB chemicals.

This product contains no endocrine disrupting chemicals.

**Section 3. Composition/information on ingredients**

This product contains the following substances that present a hazard within the meaning of the OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).

Ingredient/Chemical Designations	Weight %	GHS Classification	Notes
Polyisobutylene CAS Number: Proprietary Synonyms: No available information	45 - 70	Not Classified	-----
White mineral oil (petroleum) CAS Number: 8042-47-5 Synonyms: No available information	10 - 30	Aspiration hazard, category 1;H304	-----
Hexadecanoic acid, 1-methylethyl ester CAS Number: 142-91-6 Synonyms: Isopropyl palmitate	3 - 7	Not Classified	-----
Polyvinyl pyrrolidone CAS Number: 9003-39-8 Synonyms: No available information	3 - 7	Not Classified	-----
Scopolamine CAS Number: Proprietary Synonyms: No available information	3 - 7	Acute toxicity(oral), category 4;H302	-----

The actual concentration or concentration range is withheld as a trade secret.

\*PBT/vPvB - PBT-substance or vPvB-substance.

The full texts of the phrases are shown in Section 16.

**Section 4. First aid measures**

**Description of first aid measures**

**General**

In all cases of doubt, or when symptoms persist, seek medical attention.  
Never give anything by mouth to an unconscious person.

**Inhalation**

Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious, place in the recovery position and obtain immediate medical attention. Give nothing by mouth.

**Eyes**

Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.

**Skin**

Product intended for skin use, seek medical attention if irritation occurs.



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**Ingestion** If swallowed, obtain immediate medical attention.

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

**Overview** No specific symptom data available.  
Treat symptomatically.

**Section 5. Fire-fighting measures**

**Extinguishing media**

Recommended extinguishing media; alcohol resistant foam, CO<sup>2</sup>, powder, water spray.  
Unsuitable extinguishing media: Do not use; water jet.

**Special hazards arising from the substance or mixture**

Hazardous decomposition: No hazardous decomposition data available.

**Advice for fire-fighters**

As with all fires, wear positive pressure, self-contained breathing apparatus, (SCBA) with a full face piece and protective clothing. Persons without respiratory protection should leave area. Wear SCBA during clean-up immediately after fire. No smoking.

**ERG Guide No.** ---

**Section 6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

None needed under normal use.

**Environmental precautions**

Use good personal hygiene practices.

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

Sweep up or pick up.

**Section 7. Handling and storage**

**Precautions for safe handling**

Handle containers carefully.

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

Incompatible materials: No data available.

**Specific end use(s)**

No data available.



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**Section 8. Exposure controls / personal protection**

**Control parameters**

**Exposure**

CAS No.	Ingredient	Source	Value
Proprietary	Scopolamine	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
142-91-6	Hexadecanoic acid, 1-methylethyl ester	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
8042-47-5	White mineral oil (petroleum)	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
Proprietary	Polyisobutylene	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit
9003-39-8	Polyvinyl pyrrolidone	OSHA	No Established Limit
		ACGIH	No Established Limit
		NIOSH	No Established Limit

Contains mineral oil. The exposure limits for oil mist are 5 mg/m<sup>3</sup> OSHA PEL and 5 mg/m<sup>3</sup> ACGIH.

**Exposure controls**

**Respiratory** None needed under normal use.

**Eyes** None needed under normal use.

**Skin** None needed under normal use.

**Engineering Controls** Provide adequate ventilation. Where reasonably practicable this should be achieved by the use of local exhaust ventilation and good general extraction. If these are not sufficient to maintain concentrations of particulates and any vapor below occupational exposure limits suitable respiratory protection must be worn.

**Other Work Practices** Use good personal hygiene practices.

**Section 9. Physical and chemical properties**

**Information on basic physical and chemical properties**

<b>Physical State</b>	Solid
<b>Color</b>	Tan Adhesive Derma Patch
<b>Odor</b>	Not Applicable
<b>Melting point / freezing point</b>	Not Available



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<b>Initial boiling point and boiling range</b>	Not Available
<b>Flammability (solid, gas)</b>	Not Applicable
<b>Upper/lower flammability or explosive limits</b>	<b>Lower Explosive Limit:</b> Not Available <b>Upper Explosive Limit:</b> Not Available
<b>Flash Point</b>	Not Available
<b>Auto-ignition temperature</b>	Not Available
<b>Decomposition temperature</b>	Not Available
<b>pH</b>	Not Available
<b>Viscosity (cSt)</b>	Not Available
<b>Solubility in Water</b>	Not Available
<b>Partition coefficient n-octanol/water (Log Kow)</b>	Not Available
<b>Vapor pressure (Pa)</b>	Not Available
<b>Relative Density</b>	Not Available
<b>Vapor Density</b>	Not Available
<b>Evaporation rate (Ether = 1)</b>	Not Available
<b>VOC Content</b>	Not Available

**Other information**

No other relevant information.

**Section 10. Stability and reactivity**

**Reactivity**

Hazardous Polymerization will not occur.

**Chemical stability**

Stable under normal circumstances.

**Possibility of hazardous reactions**

No data available.

**Conditions to avoid**

No data available.

**Incompatible materials**

No data available.

**Hazardous decomposition products**

No hazardous decomposition data available.



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## Section 11. Toxicological information

### Acute toxicity

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Ingredient	Oral LD50, mg/kg	Skin LD50, mg/kg	Inhalation Vapor LC50, mg/L/4hr	Inhalation Dust/Mist LC50, mg/L/4hr	Inhalation Gas LC50, ppm
Polyisobutylene - (Proprietary)	No data available.	No data available.	No data available.	No data available.	No data available.
White mineral oil (petroleum) - (8042-47-5)	> 5,000.00, Rat - Category: NA	No data available.	No data available.	No data available.	No data available.
Hexadecanoic acid, 1-methylethyl ester - (142-91-6)	No data available.	No data available.	No data available.	No data available.	No data available.
Polyvinyl pyrrolidone - (9003-39-8)	No data available.	No data available.	No data available.	No data available.	No data available.
Scopolamine- (Proprietary)	No data available.	No data available.	No data available.	No data available.	No data available.

### Carcinogen Data

CAS No.	Ingredient	Source	Value
Proprietary	Scopolamine	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
142-91-6	Hexadecanoic acid, 1-methylethyl ester	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
8042-47-5	White mineral oil (petroleum)	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
Proprietary	Polyisobutylene	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: No;
		ACGIH	No Established Limit
9003-39-8	Polyvinyl pyrrolidone	OSHA	Regulated Carcinogen: No;
		NTP	Known: No; Suspected: No;
		IARC	Group 1: No; Group 2a: No; Group 2b: No; Group 3: Yes;
		ACGIH	No Established Limit



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Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

**Possible routes of entry:** No data available.

**Symptoms and effects, both acute and delayed:**

No specific symptom data available.

Treat symptomatically.

## Section 12. Ecological information

**Toxicity**

No additional information provided for this product. See Section 3 for chemical specific data.

**Aquatic Ecotoxicity**

Ingredient	96 hr LC50 fish, mg/L	48 hr EC50 crustacea, mg/L	ErC50 algae, mg/L
Polyisobutylene - (Proprietary)	No data available.	No data available.	No data available.
White mineral oil (petroleum) - (8042-47-5)	101.00, Oncorhynchus mykiss	101.00, Daphnia magna	101.00, Pseudokirchneriella subcapitata
Hexadecanoic acid, 1-methylethyl ester - (142-91-6)	No data available.	No data available.	No data available.
Polyvinyl pyrrolidone - (9003-39-8)	> 1,000, Fish	No data available.	> 1,000, Algae
Scopolamine- (Proprietary)	No data available.	No data available.	No data available.

**Persistence and degradability**

There is no data available on the preparation itself.

**Bioaccumulative potential**

Not Available



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**Mobility in soil**

No data available.

**Results of PBT and vPvB assessment**

This product contains no PBT/vPvB chemicals.

**Other adverse effects**

No data available.

**Section 13. Disposal considerations**

**Waste treatment methods**

Dispose in trash.

**Section 14. Transport information**

	<b>DOT (Domestic Surface Transportation)</b>	<b>IMO / IMDG (Ocean Transportation)</b>	<b>ICAO/IATA</b>
<b>UN number</b>	Not Regulated	Not Regulated	Not Regulated
<b>UN proper shipping name</b>	Not Regulated	Not Regulated	Not Regulated
<b>Transport hazard class(es)</b>	<b>DOT Hazard Class:</b> Not Applicable <b>Sub Class:</b> Not Applicable	<b>IMDG:</b> Not Applicable <b>Sub Class:</b> Not Applicable	<b>Air Class:</b> Not Applicable <b>Sub Class:</b> Not Applicable
<b>Packing group</b>	Not Applicable	Not Applicable	Not Applicable
<b>Environmental hazards</b>	Marine Pollutant: No;		
<b>Special precautions for user</b>	Not Applicable		

**Section 15. Regulatory information**

**Regulatory Overview** The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.

Classification of the substance or mixture under OSHA's Hazard Communication Standard (1910.1200) revised 2024 (GHS revision 7).





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## Toxic Substance Control Act (TSCA)

CAS Number	Ingredient	Toxic Substance Control Act (TSCA)	Comments	Status
0000142-91-6	Hexadecanoic acid, 1-methylethyl ester	Yes		ACTIVE
Proprietary	Polyisobutylene	Yes	XU	ACTIVE
0009003-39-8	Polyvinyl pyrrolidone	Yes	XU	ACTIVE
Proprietary	Scopolamine	Yes		INACTIVE
0008042-47-5	White mineral oil (petroleum)	Yes	UVCB	ACTIVE

### EPCRA 302 Extremely Hazardous:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

### EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

### Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

### Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

### Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

### Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

### Proposition 65 Label Warning:

This product contains no chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

## Section 16. Other information

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The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

Disclaimer: The information presented herein is supplied as a guide to those who handle or use this product. Safe work practices must be employed when working with any materials. It is important that the end user makes a



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determination regarding the adequacy of the safety procedures employed during the use of this product.

**Authored by Quantum SDS: [www.sdsquantum.com](http://www.sdsquantum.com)**

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