

Product Name: Vicodin Tuss
Issued: 10/25/2001



MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name and Address: Abbott Laboratories,
Pharmaceutical Products Division,
200 Abbott Park Road,
Abbott Park, Illinois 60064-3537

Customer Service Telephone: 1- 800 - 441 - 4987
Emergency Telephone: CHEMTREC: 1-800-424-9300

Product Name: Vicodin Tuss
List Number: 0730, 2275
National Drug Code Number: 0044-0730-16, 0074-2275-16

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Glycerol 56-81-5	Proprietary	15 mg/m3 TWA (total dust); 5 mg/m3 TWA (respirable fraction)	10 mg/m3 (total mist)	Not Applicable	Not Applicable	None
Guaifenesin 93-14-1	Proprietary	Not Listed	Not Listed	Not Applicable	2 mg/m3 TWA	None
Hydrocodone Bitartrate 34195-34-1	Proprietary	Not Listed	Not Listed	Not Applicable	5 mcg/m3 TWA	None
Propylene Glycol 57-55-6	Proprietary	Not Listed	Not Listed	50 ppm TWA (total); 10 mg/m3 TWA (aerosol only)	Not Applicable	None
Sorbitol 50-70-4	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None

Notes: OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.
Abbott EEL: Abbott Laboratories Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.
C: Ceiling Limit.

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3. HAZARDS IDENTIFICATION

Emergency Overview:

Clear colorless liquid.
Characteristic sweetish odor.
Potent drug. Reproductive hazard.

Routes of Exposure:

Oral: Clinical Route
Dermal: Unlikely
Inhalation: Unlikely

Hazard Information:

Ingestion Rating: Not determined.
Skin Absorption Rating: Not determined.
Inhalation Rating: Not determined.
Corrosiveness Rating: Not determined.
Skin Contact Rating: Not determined.
Skin Sensitization Rating: Not determined.
Eye Contact Rating: Not determined.
Target Organs: Nervous System •Respiratory System •Skin •Fetus •

Carcinogenicity Rating:

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Glycerol 56-81-5	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Guaifenesin 93-14-1	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Hydrocodone Bitartrate 34195-34-1	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Propylene Glycol 57-55-6	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Sorbitol 50-70-4	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed

NFPA Rating: Not determined.

Signs and Symptoms: Clinical data suggests the following: lightheadedness, dizziness, sedation, nausea, vomiting, cognitive dysfunction, incoordination, respiratory distress, rash.

Medical Conditions Aggravated by Exposure: Data suggest any preexisting ailments in the following organs: central nervous system, respiratory system, skin. Hypersensitivity to the material and/or similar materials.

4. FIRST AID MEASURES

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Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

FLAMMABILITY:
Autoignition Temp. (°C): Not determined.

FIRE-FIGHTING INFORMATION:

Suitable Extinguishing Media: Use appropriate medium for the underlying cause of the fire.

6. ACCIDENTAL RELEASE MEASURES

Methods of Cleaning and Collecting: Recover product. Place into appropriate container for disposal. Clean area with suitable cleaning materials. Dispose of as directed in Section 13.

Personal Precautions: Use personal protective equipment identified in Section 8.

Environmental Precautions: Not determined.

7. HANDLING AND STORAGE

Handling: Not determined.

Storage : Store according to label instructions.

Special Precautions: Not applicable.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: An approved respirator (i.e. NIOSH, etc.) should be worn when exposures are expected to exceed the applicable limits. Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions.

Gloves: Impervious gloves.

Other Personal Protection Data: Not determined.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear colorless liquid.
Odor: Characteristic sweetish odor.
Boiling Point @ 760 mm Hg (°C): Not determined.
Melting/Freezing Point (°C): Not determined.
Vapor Pressure (mm Hg) Not determined.
Bulk Density at 20°C: Not determined.
Solubility: Not determined.
Specific Gravity: Not determined.
pH: Not determined.
Viscosity (centipoise): Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Not determined.

Self-Heating Tendency: Not determined.

Materials to Avoid: Not determined.

Hazardous Decomposition Products: Not determined.

Hazardous Polymerization: Not determined.

Conditions to Avoid: Not determined.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Oral: Data for component (s) given below.

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Ingredients	Percent	Acute Test	Value	Units	Species
Glycerol 56-81-5	Proprietary	LD50 >	4090	mg/kg	Animals
Guaifenesin 93-14-1	Proprietary	LD50 =	690 1510 2553	mg/kg mg/kg mg/kg	Mice Rats Rabbits
Hydrocodone Bitartrate 34195-34-1	Proprietary	LD50 =	375	mg/kg	Rats
Propylene Glycol 57-55-6	Proprietary	LD50 =	10,000-33,700	mg/kg	Animals
Sorbitol 50-70-4	Proprietary	LD50 =	15900-17800	mg/kg	Rats Mice

Acute Toxicity - Dermal: Not determined.

Ingredients	Percent	Acute Test	Value	Units	Species
Glycerol 56-81-5	Proprietary	LD50 >	10,000	mg/kg	Rabbits
Propylene Glycol 57-55-6	Proprietary	LD50 =	20,800	mg/kg	Rabbits

Acute Toxicity - Inhalation: Not determined.

Ingredients	Percent	Test	Value	Units	Species
Glycerol 56-81-5	Proprietary	LC 50 >	0.57	mg/L , 1 hour	Rats

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Hydrocodone Bitartrate 34195-34-1	Proprietary	LD50 (sc) =	150 86	mg/kg mg/kg	Rats Mice	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Not determined.

Target Organ Effects: Clinical dose is less than (<) 10 mg/day. In clinical use target organ effects include: central nervous system, respiratory system, skin.

Reproductive Effects: Not determined.

Ingredients	Percent	Reproductive Effects	Species	Dosage	Units	Route	Duration
Hydrocodone Bitartrate 34195-34-1	Proprietary	Fetal Abnormalities	Rabbits	3.6	mg/kg	Oral	During Gestation

Carcinogenicity: Not determined.

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Mutagenicity: Not determined.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay (Human Lymphocytes)
Glycerol 56-81-5	Proprietary	Negative	No Data.	No Data.	No Data.

Notes:

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

12. ECOLOGICAL INFORMATION

Aquatic Toxicity: Not determined.

Biodegradation: Not determined.

General Notes: None.

Notes:

1. EC50: Concentration in water that produces 50% mortality in *Daphnia* sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods: Incineration recommended in approved incinerator according to federal, state, and local regulations. This material is not a RCRA hazardous waste. This material is DEA regulated.

14. TRANSPORT INFORMATION

DOT:
Status: Not Regulated.

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ICAO/IATA:
Status: Not Regulated.

IMDG:
Status: Not Regulated.

TDG (Canada):
Status: Not determined.

15. REGULATORY INFORMATION

SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Glycerol 56-81-5	Proprietary	No	Not Applicable	Not applicable
Guaifenesin 93-14-1	Proprietary	No	Not Applicable	Not applicable
Hydrocodone Bitartrate 34195-34-1	Proprietary	No	Not Applicable	Not applicable
Propylene Glycol 57-55-6	Proprietary	No	Not Applicable	Not applicable
Sorbitol 50-70-4	Proprietary	No	Not Applicable	Not applicable

SARA 311/312 Hazard Catagories:

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

TSCA Inventory Status: Exempt.

CERCLA Status: Not regulated.

RCRA Status: Not a hazardous waste.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

EC HAZARD CLASSIFICATION:

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Category of Danger: Exempt.

Indication of Danger : Exempt.

ICH Classification: Not determined.

CANADIAN REGULATIONS:

Canadian Inventory: Not determined.

Canadian NDSL: Not determined.

WHMIS Hazard Class: Exempt

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. ICH = International Committee for Harmonization.

16. OTHER INFORMATION

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