

Product Name:  
Issued:

Multidose Propofol Emulsion for Injection  
Apr-26-2007



ANIMAL HEALTH

## MATERIAL SAFETY DATA SHEET

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Manufacturer Name and Address:** Abbott Laboratories  
200 Abbott Park Road  
Abbott Park, Illinois 60064

**Customer Service Telephone:** 1 - 888 - 299 - 7416 (Abbott Animal Health 8:00 am - 5:00 pm CST)

**Emergency Telephone:** 1 (800) 424-9300 CHEMTREC (USA)  
1 (703) 527 3887 CHEMTREC (INTERNATIONAL)

**Product Name:** Multidose Propofol Emulsion for Injection

**Synonyms:** Propofol ES; Propofol Injectable Emulsion, 10 mg/mL

**Product Use:** Veterinary use. Injectable anaesthetic agent.

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
2,6-Diisopropylphenol 2078-54-8	Proprietary	Not Listed	Not Listed	Not Applicable	2 mg/m <sup>3</sup> for 8-hr TWA : 10 mg/m <sup>3</sup> for 15-min STEL	None
Water 7732-18-5	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Soybean Oil 8001-22-7	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Glycerol 56-81-5	Proprietary	15 mg/m <sup>3</sup> (total mist) and 5 mg/m <sup>3</sup> (respirable mist)	10 mg/m <sup>3</sup> (total mist)	Not Applicable	Not Applicable	None
Egg Phosphatide L-02-3139	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Benzyl Alcohol 100-51-6	Proprietary	Not Listed	Not Listed	10 ppm (44.23 mg/m <sup>3</sup> )	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.

### 3. HAZARDS IDENTIFICATION

**Emergency Overview:**

White to slightly off-white aqueous emulsion.  
Odorless.

Expected to have a low hazard potential. Rare cases of self-injection have been reported to cause death.

**Product Name:**  
**Issued:**

**Multidose Propofol Emulsion for Injection**  
**Apr-26-2007**

**Routes of Exposure:**

**Oral:** Unlikely  
**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:** Respiratory System, Cardiovascular System , Nervous System.

**Carcinogenicity Rating:**

<b>Ingredients</b>	<b>Percent</b>	<b>OSHA:</b>	<b>NTP:</b>	<b>IARC:</b>	<b>ACGIH:</b>
2,6-Diisopropylphenol	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Water	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Soybean Oil	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Glycerol	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Egg Phosphatide	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Benzyl Alcohol	Proprietary	Not Listed	Listed	Not Listed	Not Listed

**NFPA Rating:** Not determined.

Health: 0  
Fire: 0  
Reactivity: 0

**Signs and Symptoms:** No signs and symptoms from occupational exposure are known. Clinical data suggests the following: headaches, vomiting, nausea, slow heart rate, decreased blood pressure, sedation, anaphylatic reactions, sleep.

**Notes to Physician:** Injection of propofol in normal volunteers produced psychoactive effects that could be construed as pleasant.

**Medical Conditions Aggravated by Exposure:** No medical conditions aggravated by occupational exposure are known. Clinical data suggests any pre-existing ailments of the following organs: respiratory system, central nervous system, cardiovascular system. Hypersensitivity to the material and/or similar materials.

**4. FIRST AID MEASURES**

**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.

**Product Name:** Multidose Propofol Emulsion for Injection  
**Issued:** Apr-26-2007

**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.

**Notes To Physician:** Monitor central nervous system and cardiovascular function, as necessary.

## 5. FIRE FIGHTING MEASURES

### **Flammability:**

**Lower Explosive Limit:** Not determined.

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

### **Fire-Fighting Information:**

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

**Special Protective Equipment:** Wear protective clothing and self-contained breathing apparatus.

**Special Exposure Hazards:** Avoid inhalation of combustion products.

## 6. ACCIDENTAL RELEASE MEASURES

**Methods of Cleaning and Collecting:** Clean up promptly. Absorb with suitable material. 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:** Handle according to label instructions.

**Storage:** Store according to label instructions. Store at room temperature. Protect from light.

**Special Precautions:** Should not be used beyond the indicated expiration date.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

**Respiratory Protection:** Respiratory protection is not needed during normal product use.

**Eyes:** Eye protection not required during typical product use conditions. Wear eye protection appropriate to handling activities.

**Gloves:** If skin contact is anticipated: Impervious gloves.

**Product Name:** Multidose Propofol Emulsion for Injection  
**Issued:** Apr-26-2007

**Other PPE Data:** Not determined.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** White to slightly off-white aqueous emulsion.  
**Odor:** Odorless.  
**Boiling Pt. @ 760 mm Hg (°C):** Not determined.  
**Melting/Freezing Point:** Not determined.  
**Vapor Pressure (mm Hg)** Not determined.  
**Bulk Density at 20°C:** 0.996 g/mL  
**Solubility:** Slightly soluble in: water (11.2 grams/l)  
**Specific Gravity:** Not determined.  
**pH:** 6 - 9.0  
**Viscosity (centipoise):** 1.54 cps at 25 deg. C

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable from a safety point of view.

**Self-Heating Tendency:** Not determined.

**Materials to Avoid:** Oxidizers.

**Hazardous Decomposition Products:** Not determined.

**Hazardous Polymerization:** Not known to occur.

**Conditions to Avoid:** Not determined.

## 11. TOXICOLOGICAL INFORMATION

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

Ingredients	Percent	Acute Test	Value	Units	Species
2,6-Diisopropylphenol	Proprietary	LD50 =	518-1230	mg/kg	Rats Mice
Glycerol	Proprietary	LD50 >	4090	mg/kg	Animals
Benzyl Alcohol	Proprietary	LD50 =	1040-3100	mg/kg	Animals

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

Ingredients	Percent	Acute Test	Value	Units	Species
2,6-Diisopropylphenol	Proprietary	LD50 >	2000	mg/kg	Rabbits
Glycerol	Proprietary	LD50 >	10,000	mg/kg	Rabbits
Benzyl Alcohol	Proprietary	LD50 =	2000	mg/kg	Rabbits

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

Ingredients	Percent	Test	Value	Units	Species
Glycerol	Proprietary	LC 50 >	0.57	mg/L , 1 hour	Rats
Benzyl Alcohol	Proprietary	LC 50 =	2000	ppm	Rats

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined. Active Ingredient : Reported to produce skin irritation in humans.  
Minor ingredient: Produced mild skin irritation in rabbits.

**Product Name:** Multidose Propofol Emulsion for Injection  
**Issued:** Apr-26-2007

**Eye Irritation:** Not determined. Active Ingredient : Produced mild eye irritation in animal testing.  
Minor ingredient: Reported to produce eye irritation.

**Sensitization:** Not determined.

**Target Organ Effects:** Not determined. Active Ingredient : In clinical use target organ effects include:  
central nervous system.

In clinical use, propofol depresses the central nervous system with the rapid induction of anesthesia. Anesthesia is of short duration. Sedative doses can elicit psychoactive effects that could be construed as pleasant. In a dog study, animals were given single intravenous dose of 7.5, 11.5 and 19.5 mg/kg of propofol emulsion. There were dose related increase in anesthesia in animals; and at the high dose animals had difficulty walking normally. In an cat study, animals were given intravenous infusion of 13.5 mg/kg and 19.5 mg/kg in two intervals over 20 days with week recovery after each interval. Some animals were observed with apnea after induction. Some vomiting and gastrointestinal discomfort was observed in animals during recovery. In large amounts, glycerol has potential to produce and increase in urine output and cause hemolysis due to changes in osmolality.

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

Ingredients	Percent	Site of Tumors	Species	Dosage	Units	Route	Duration
Benzyl Alcohol	Proprietary	None.	Animals	200	mg/kg	Oral	Unspecified

**Mutagenicity:** Not determined. Active Ingredient : Negative in the Ames assay. Minor Ingredient : Negative in mutagenicity assays.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
2,6-Diisopropylphenol	Proprietary	Negative	No Data.	Negative	No Data.
Glycerol	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:** Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

**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

**Product Name:** Multidose Propofol Emulsion for Injection  
**Issued:** Apr-26-2007

**Waste Disposal Methods:** All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices. This material is not a RCRA hazardous waste.

## 14. TRANSPORT INFORMATION

**DOT/ADR:**  
**Status:** Not Regulated.

**ICAO/IATA:**  
**Status:** Not Regulated.

**IMDG:**  
**Status:** Not Regulated.

**TDG (Canada):**  
**Status:** Not Regulated.

## 15. REGULATORY INFORMATION

### SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
2,6-Diisopropylphenol	Proprietary	No	Not Applicable	Not applicable
Water	Proprietary	No	Not Applicable	Not applicable
Soybean Oil	Proprietary	No	Not Applicable	Not applicable
Glycerol	Proprietary	No	Not Applicable	Not applicable
Egg Phosphatide	Proprietary	No	Not Applicable	Not applicable
Benzyl Alcohol	Proprietary	No	Not Applicable	Not applicable

### SARA 311/312 Hazard Categories:

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

**TSCA Inventory Status:** Exempt.

**CERCLA Status:** Not determined.

**RCRA Status:** Not a RCRA Hazardous Waste.

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

### EC HAZARD CLASSIFICATION:

**Category of Danger:** None.

**Product Name:** Multidose Propofol Emulsion for Injection  
**Issued:** Apr-26-2007

**Indication of danger:** None.  
**GHS Classification:** Not determined.

**CANADIAN REGULATIONS:**

**Canadian Inventory:** Not determined.  
**Canadian NDSL:** Not determined.  
**WHMIS Hazard Class:** Not determined.

**Notes:**

1. SARA = Superfund Ammendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insectacide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

<b>16. OTHER INFORMATION</b>
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