**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 $mg/m^3$ for 8-hr TWA : 10 $mg/m^3$ 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 $mg/m^3$ (total mist) and 5 $mg/m^3$ (respirable mist) | 10 $mg/m^3$ (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 $mg/m^3$) | 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.

**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:**

| Ingredients | Percent | OSHA: | NTP: | IARC: | ACGIH: |
|---|---|---|---|---|---|
| 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.

**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.

**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.

**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 gastronintestinal 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

**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 Catagories:**

**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.

**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.

## 16. OTHER INFORMATION

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