



300 Northfield Road
Bedford, OH 44146
Telephone: (440) 232-3320
-or- (800) 562-4797

MATERIAL SAFETY DATA SHEET

Section I - IDENTITY

Common/Trade Name: Propofol Injectable Emulsion, 10 mg/ml in 20, 50 and 100 ml vials

Chemical Names: Phenol, 2, 6-diisopropyl

Synonyms: Diprivan®; 2, 6-Bis(1-methylethyl)phenol; ICI 35868; 2, 6-Diisopropylphenol, Phenol; 2, 6-bis(1-methylethyl)-; Propofol

Manufacturer's Name: BEN VENUE LABORATORIES, INC.

Address: 300 NORTHFIELD ROAD
BEDFORD, OH 44146

Emergency Telephone Number: Chemtrec: 1(800)424-9300

Telephone Number for Info.: (440)232-3320 -or- (800)562-4797

Medical Emergency: Professional Services 1(800)521-5169

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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Propofol	1	2078-54-8	NONE	NONE	0.5 mg/m ³ (BVL OEL)
Soybean Oil	10	8001-22-7	NONE	NONE	NONE
Egg Lecithin	1.2	8002-43-5	NONE	NONE	NONE
Glycerin	2.25	56-81-4	NONE	NONE	NONE
Benzyl Alcohol	0.1	100-51-6	NONE	NONE	NONE
Water for Injection	85.45	7732-18-5	NONE	NONE	NONE

Sodium Hydroxide is used to adjust pH of 7-8.5

Propofol Emulsion is a sterile injectable liquid drug provided in a vial.

Section III - HEALTH HAZARD DATA

Routes of Entry: Exposure may occur via contact with skin/eyes, inhalation of aerosols and accidental ingestion. Propofol Emulsion should be used under the supervision of a physician (trained in its use) to monitor the anesthetic's side effects. It is not readily absorbed into the skin.

Health Hazard (Acute & Chronic): Propofol Emulsion is a fast acting, short duration general anesthetic. Acute effects are moderate to severe irritation to skin, eyes and respiratory tract. Ingestion of large amounts and injection may induce central nervous system depression and possible unconsciousness.

Medical Conditions Generally Aggravated by Exposure: May cause allergic reaction in sensitized persons and a risk of seizure to persons with epilepsy.

Carcinogenicity: NTP? NO **IARC Monographs?** NONE **OSHA Regulated?** NO

Signs & Symptoms of Exposure: Exposure may cause irritation to skin, eyes, and respiratory tract, depression of the central nervous system leading to shallow breathing, headache, nausea, lethargy and unconsciousness.

BVL Hazard Category: 2

Section IV - FIRST AID MEASURES

Eye Exposure: Flush eyes with large volumes of water for 15 or more minutes. Get medical attention if irritation or signs of exposure are noted.

Skin Exposure: Remove contaminated clothing, wash skin with water and soap for 15 minutes. Get medical attention if irritation or signs of exposure are noted.

Ingestion: If ingestion occurs, flush mouth with water and seek medical attention if central nervous system depression occurs. Never give anything by mouth to an unconscious person.

Injection: In cases of accidental injection, wash and disinfect area, get medical attention.

Inhalation: If difficulty with breathing, remove from exposure, administer oxygen. Seek attention of a physician immediately. When appropriate and trained in CPR, provide artificial respiration.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): 234°F **LEL:** Not Determined **UEL:** Not Determined

Flammable Limits: Not Determined

Extinguishing Media: Use water or an ABC multi-purpose extinguisher.

Special Fire Fighting Procedures: As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke.

Unusual Fire/Explosion Hazards: Heat of the fire could cause vials to burst.

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Propofol Emulsion with absorbent materials and dispose according to local, state, and federal guidelines.

Release to Air: If aerosolized, reduce exposures by ventilating area; clean up spill immediately to prevent evaporation.

Release to Water: Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal disposal guidelines.

Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

Steps to be taken in case material is released or spilled: See Section VI above.

Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive aerosols are generated.

Waste Disposal Method: Incineration in an approved incinerator is recommended. Refer to local, state, and federal rules.

Precautions to be taken in handling and storing: Store between 4-22°C (40-72°F). Do not freeze.

Other Precautions: None Known

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Respiratory Protection: Under normal use, respirators are not required. If aerosols are generated, a disposable dust/mist respirator (N95) may be used. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Ventilation: Handle product in a well-ventilated area.

Protective Gloves: Latex or nitrile

Eye Protection: Safety glasses

Other Protective Clothing or Equipment: Lab Coat

Work/Hygienic Practices: Wash hands following use. No eating, drinking, or smoking while handling this product.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Specific Gravity: 0.955

Appearance and Odor: White to faintly yellow,
Slight phenolic odor

Melting Point: Approx. 0°C

Boiling Point: 242°C (468° F)

Evaporation Rate: Approx. to water

Vapor Pressure: 0.142 mmHg @ 20° C

Solubility in Water: Soluble

Vapor Density: Not available

pH: 7-8.5

Section X - STABILITY AND REACTIVITY DATA

Stability: Stable

Incompatibility (Materials to Avoid): water-reactive materials and oxidizers.

Hazardous Decomposition or Byproducts: Decomposition products of this compound may include potentially hazardous byproducts such as oxides of carbon.

Hazardous Polymerization: Will not occur

Conditions to Avoid: Storage near water reactive materials, emits toxic fumes under fire/heat.

Section XI - TOXICOLOGICAL INFORMATION

For Propofol Emulsion (active ingredient) RTECS Number SLO810000

LD_{L0} human, intravenous = 386 mg/kg

LD₅₀ rat, oral = 500 mg/kg

LD₅₀ rat, Intravenous = 42 mg/kg

LD₅₀ mouse, oral = 1100 mg/kg

LD₅₀ mouse, intravenous = 50 mg/kg

LD₅₀ mouse, intraperitoneal = 170 mg/kg

LD₅₀ dog, intravenous = 30 mg/kg

Additional reproductive health data is available from the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Propofol. Handle in a manner to prevent spills or releases to the environment.

Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.
Review local, state, and federal regulations for your regulatory area.

Section XIV - TRANSPORTATION INFORMATION

Propofol Emulsion is not a DOT hazardous material.
Propofol Emulsion is not a DOT Marine Pollutant.

Section XV - REGULATORY INFORMATION

SARA 313 listed?:	NO
CERCLA listed?:	NO
RCRA listed?:	NO
TSCA listed?:	YES, Section 8(b)

Section XVI - OTHER DATA

1. Use of this product should be through or under the direction of a physician.
This MSDS does not address the therapeutic use of this material
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company Management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):
1 = Low Toxicity
2.= Moderate Toxicity
3 = Potent or Toxic
4 = Highly Potent or Toxic
5 = Extremely Potent or Toxic

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