



TEVA PARENTERAL MEDICINES

# Material Safety Data Sheet

# Propofol Injectable Emulsion, 1%

## 1. PRODUCT IDENTIFICATION

**Product Name** Propofol Injectable Emulsion, 1%  
**Product Use** Medical Treatment; Sedative-Hypnotic Agent  
**Manufacturer** Teva Parenteral Medicines, Inc.  
**Address** 11 Hughes  
 Irvine, CA 92618-1902

**Chemtrec Emergency No.** 1-800-424-9300 (United States)  
 1-202-483-7617 (International Collect)

**Business Phone** 1-800-729-9991  
**Website Address** <http://www.newsicor.com>

**Common Names** Diprivan®  
**Chemical Name** 2,6-Diisopropylphenol

**Chemical Formula** C<sub>12</sub>H<sub>18</sub>O  
**Chemical Family** Phenol  
**How Supplied** 10 mg/mL solution in 20 mL, 50 mL and 100 mL vials

**Date of Preparation:** August 7, 2007

## 2. COMPOSITION AND INGREDIENTS

CHEMICAL NAME	CAS#	% by wt	EXPOSURE LIMITS IN AIR				
			ACGIH		OSHA		Other
			TLV	STEL	PEL (Total Dust)	PEL (Respirable Fraction)	TWA
Propofol	2078-54-8	1	NE	NE	NE	NE	NE
Soybean Oil	8001-22-7	10	NE	NE	NE	NE	NE
Glycerol	56-81-5	2.25	10 mg/m <sup>3</sup>	NE	15 mg/ m <sup>3</sup>	5 mg/ m <sup>3</sup>	NE
Egg Yolk Phospholipid	93685-90-6	1.2	NE	NE	NE	NE	NE
Sodium Metabisulfite	7681-57-4	0.025	5 mg/m <sup>3</sup>	NE	NE	NE	NE
Water for Injection	7732-18-5	Balance	NE	NE	NE	NE	NE

NE - Not Established

C - Ceiling Limit

NOTE: All WHMIS required information is included. It is located in appropriate sections based on the ANSI Z400.1 format

CHEMTREC NUMBER: Use only in the event of a chemical emergency involving a spill, leak, fire, exposure or accident involving this drug.



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Propofol Injectable Emulsion, 1%

### 3. HAZARD IDENTIFICATION

**EMERGENCY OVERVIEW:** Material is white oil in water emulsion. May be harmful if accidentally injected or swallowed. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Wash thoroughly after handling.

Symptoms of Overexposure by Route of Exposure: This material is intended for intravenous injection under the supervision of physicians.

Inhalation: Inhalation of significant amounts of the product is not anticipated to occur because of the small size of individual containers.

Contact with Skin or Eyes: Contact causes irritation. Effects may include stinging, watering, and redness of the eyes and redness and a burning sensation on the skin.

Ingestion: Ingestion is not an anticipated route of occupational exposure. However, Symptoms similar to those identified under injection may occur.

Injection: Local redness and pain are the primary symptoms of accidental injection in an occupational setting. Medical personnel are not anticipated to experience over-exposures to the therapeutic doses of this product. However, effects including central nervous system effects including sedation, weakness in parts of the body, depression of the respiratory system, changes in heart rate, cardiac arrest, nausea, vomiting, diarrhea, rash, anaphylaxis, hypotension, urine retention, protein-rich urine, coagulation problems, pain in the ears or eyes and changes in the sense of taste may occur. See package insert for adverse reactions associated with therapeutic doses of this product.

#### Health Effects or Risks From Exposure (An explanation in lay terms):

Acute: The primary health effects anticipated in an occupational setting include irritation of eyes and skin as well as redness and local swelling after accidental injection. In case of over-exposure by injection effects including central nervous system effects including sedation, weakness in parts of the body, depression of the respiratory system, changes in heart rate, cardiac arrest, nausea, vomiting, diarrhea, rash, anaphylaxis, hypotension, urine retention, protein-rich urine, coagulation problems, pain in the ears or eyes and changes in the sense of taste may occur.

Chronic: Chronic exposure to this product is not known to have any adverse effects in humans (see Section 11).

Pre-Existing Medical Conditions: Conditions aggravated by exposure may include skin disorders.

### 4. FIRST-AID MEASURES

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.





TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Propofol Injectable Emulsion, 1%

### 6. ACCIDENTAL RELEASE MEASURES

#### Spill and Leak Response:

For small releases of this product, wear latex or nitrile gloves and safety glasses. Absorb spilled liquid and rinse area thoroughly with soap and water.

For large or uncontrolled releases, stay upwind and away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Dike far ahead of spill for later recovery or disposal. Spilled material may be absorbed into an appropriate absorbent material. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

### 7. HANDLING and STORAGE

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

Storage and Handling Practices: Employees must be trained to properly use the product. Ensure vials are properly labeled. Store only in approved containers. Keep away from any incompatible materials or conditions (see Section 10). Store at temperatures between 4-22°C (40-72°F). Do not freeze. Shake well before use.

Protective Practices During Maintenance of Contaminated Equipment: When cleaning non-disposable equipment, wear latex or nitrile gloves (double gloving is recommended), goggles, and lab coat. Wash equipment with soap and water. All needles, syringes, vials and other disposable items contaminated with this product should be disposed of properly.



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

Propofol Injectable Emulsion, 1%

### 8. EXPOSURE CONTROLS - PERSONAL PROTECTION

Ventilation and Engineering Controls: Use with adequate ventilation. Follow standard medical product handling procedures.

Respiratory Protection: Not normally required for routine, medical administration of this product. A NIOSH certified air-purifying respirator with a type 95 filter may be used under conditions where airborne concentrations are expected to be excessive. Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air-purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions warrant a respirator's use.

Eye Protection: Approved eye protection (e.g., safety glasses with side shields) to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

Hand Protection: Use latex, nitrile, or rubber gloves. Check gloves for leaks. Wash hands before and after using gloves.

Body Protection: A full body gown which is closed at the front and has long sleeves is recommended.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

### 9. PHYSICAL and CHEMICAL PROPERTIES

Relative Vapor Density (air = 1):	Not determined	Evaporation Rate (n-BuAc=1):	<1
Specific Gravity (water = 1):	Approx. 1	Melting/Freezing Point:	Not determined
Solubility in Water:	Slightly	Boiling Point:	Approx. 100°C
Vapor Pressure, mm Hg @	Not determined	pH:	4.5-6.4
Odor Threshold: Odorless			
Appearance and Color: White , oil in water emulsion			

ND = No Data

### 10. STABILITY and REACTIVITY

Stability: Stable under normal conditions of storage and handling (see Section 7).

Materials With Which Substance is Incompatible: This product is generally compatible with other common materials in a medical facility. Keep away from strong oxidizers.

Hazardous Polymerization: Will not occur.

Conditions To Avoid: Avoid freezing. Heat may cause this product to decompose, destroying the product and producing irritating vapors and toxic gases (e.g., oxides of carbon and nitrogen).



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

Propofol Injectable Emulsion, 1%

### 11. TOXICOLOGICAL INFORMATION

Toxicity Data: The following information is for Propofol Disodium, no data for free acid were identified

Oral LD50 (mouse) = 1100 mg/kg      IV LD50 (dog) = 30 mg/kg      IP LD50 (mouse) = 170 mg/kg  
IV LD50 (rat) = 42 mg/kg      IV LD50 (mouse) = 50 mg/kg

Suspected Cancer Agent: No long-term cancer studies in laboratory animals were identified. It has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: This product is irritating to contaminated skin, eyes and other tissues.

Sensitization to the Product: Rare instances of hypersensitive reactions in patents taking this drug have been reported.

Reproductive Toxicity Information: Listed below is information concerning the effects of Propofol on human and animal reproductive systems. This material is classified as a Pregnancy Category B (No Evidence of Risk).

Mutagenicity: Not a mutagen based on a battery of studies.

Embryotoxicity/Teratogenicity/Reproductive Toxicity: Not a teratogen in rats and rabbits. Not a reproductive toxicant in male or female rats.

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

### 12. ECOLOGICAL INFORMATION

All work practices must be aimed at eliminating environmental contamination.

Environmental Stability: This product will be relatively stable under ambient environmental conditions.

Effect of Materials on Plants or Animals: No specific information is available on the effect of Propofol on plants or animals in the environment.

Effect of Chemicals on Aquatic Life: No specific information is available on the effect of Propofol on plants or animals in the aquatic environment.

### 13. DISPOSAL CONSIDERATIONS

Preparing Wastes for Disposal: This material, if discarded as produced, is not a RCRA "listed" or "characteristic" hazardous waste. Use resulting in chemical or physical change or contamination may subject it to regulation as a hazardous waste. Along with properly characterizing all waste materials consult state and local regulations regarding the proper disposal of this material.

U.S. EPA Waste Number: None



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Propofol Injectable Emulsion, 1%

### 14. TRANSPORTATION INFORMATION

This Materials is not Hazardous as Defined by 49 CFR 172.101 by the U. S. Department of Transportation

Proper Shipping Name: Not applicable

Hazard Class Number and Description: Not applicable

UN Identification Number: Not applicable

Packing Group: Not applicable

DOT Label(s) Required: Not applicable

North American Emergency Response Guidebook Number (1996): Not applicable.

MARINE POLLUTANT: No component of this product is listed as a Marine Pollutant (49 CFR 172.101, Appendix B)

Transport Canada Transportation of Dangerous Goods Regulations: Not applicable

### 15. REGULATORY INFORMATION

#### U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304 and 313 of Title II of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity: Not applicable

U.S. CERCLA Reportable Quantities (RQ): Not applicable

U.S. TSCA Inventory Status: Propofol is a "drug" as defined by the Federal Food, Drug and Cosmetic Act and is therefore not a chemical substance under TSCA.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): This product does not contain a chemical known to the State of California to cause cancer, developmental and reproductive effects.

Other U.S. Federal Regulations: Based on this product's use, the requirements of the OSHA Bloodborne pathogen Standard (29 CFR 1910.1030) are applicable.

ANSI Labeling (Based on 129.1, Provided to Summarize Occupational Exposure Hazards):

Propofol should be administered under the supervision of a qualified physician. Avoid over-exposure. Avoid breathing vapor. Avoid contact with eyes, skin and clothing. Do not eat, drink or smoke when handling Propofol. Do not taste or swallow. Wash thoroughly after handling. Clean up spills promptly.

#### CANADIAN REGULATIONS:

Canadian DSL/NDSL Status: Propofol is regulated by the Food and Drug Administration of Health Canada and is therefore exempt from the requirements of CEPA.



TEVA PARENTERAL MEDICINES

## Material Safety Data Sheet

# Propofol Injectable Emulsion, 1%

### 16. OTHER INFORMATION

Issue Date: 08/07/07

Previous Issue Date: 01/29/99

The information in this document is believed to be correct as of the date issued. **HOWEVER, NO WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE, OR ANY OTHER WARRANTY IS EXPRESSED OR IS TO BE IMPLIED REGARDING THE ACCURACY OR COMPLETENESS OF THIS INFORMATION, THE RESULTS TO BE OBTAINED FROM THE USE OF THIS INFORMATION OR THE PRODUCT, THE SAFETY OF THIS PRODUCT, OR THE HAZARDS RELATED TO ITS USE.** This information and product are furnished on the condition that the person receiving them shall make his own determination as to the suitability of the product for his particular purpose and on the condition that he assume the risk of his use thereof.