



MATERIAL SAFETY DATA SHEET

Product Name: Propofol Injectable Emulsion

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira, Inc.
275 North Field Drive
Lake Forest, Illinois 60045
USA

Emergency Telephone CHEMTREC: 800-424-9300
Hospira, Inc. , Non-Emergency 224 212-2055

Product Name Propofol Injectable Emulsion

Synonyms 2,6-diisopropylphenol; 2-6-DIP

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Propofol
Chemical Formula C₁₂H₁₈O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Propofol	1.0	2078-54-8	SL0810000

Non-hazardous ingredients include water, egg lecithin, soybean oil and glycerin. Hazardous ingredients present at less than 1% include benzyl alcohol; sodium hydroxide is added to adjust the pH.

3. HAZARD INFORMATION

Emergency Overview Propofol Injectable Emulsion contains propofol, an intravenous sedative-hypnotic agent for use in the induction and maintenance of anesthesia or sedation. In the workplace, this product should be considered potentially irritating to the eyes and respiratory tract, and may cause an allergic reaction in persons with pre-existing allergies to egg or soy products. Based on clinical use, possible target organs include the central nervous system, respiratory system, and cardiovascular system.

Occupational Exposure Potential The active ingredient in this product may be absorbed via inhalation and possibly through the skin. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms No signs or symptoms from occupational exposure are known. During clinical use, adverse effects may include slowed heart rate, decreased blood pressure, transient apnea, nausea, rash and cough. The product may cause eye and skin irritation.

Medical Conditions Aggravated by Exposure Pre-existing hypersensitivity to the active ingredient propofol; pre-existing allergies to eggs, egg products, soybeans or soy products; pre-existing central nervous system, respiratory system, or cardiovascular system ailments.

Carcinogen Lists: **IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed

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.

5. FIRE FIGHTING MEASURES

Flammability	Not determined for product.
Fire & Explosion Hazard	Not determined for product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.
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7. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions	In general, protect from freezing and extreme heat.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Exposure limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Propofol	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hour TWA: Not Established	8 hr TWA: 2.0 mg/m ³ STEL: 10.0 mg/m ³

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 : Workplace Environmental Exposure Level
 EEL: Employee Exposure Limit.
 TWA: 8 hour Time Weighted Average.
 STEL: 15-minute Short Term Exposure Limit.

Respiratory Protection Respiratory protection is not needed during normal product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (P100 or equivalent) is recommended. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended. The use of double-gloves is also recommended.

Eye Protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	A sterile, non-pyrogenic white, oil-in-water emulsion for intravenous administration.
Odor	Odorless or a slight phenolic odor
Odor Threshold:	NA
pH:	7.0-8.5
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Evaporation Rate	NA
Specific Gravity	0.955
Solubility	Soluble in water.
Partition coefficient: n-octanol/water:	6761:1
Auto-ignition temperature	NA
Decomposition temperature	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Propofol	100	LD50	Oral	500	mg/kg	Rat
				1100	mg/kg	Mouse
Propofol	100	LD50	Intravenous	42	mg/kg	Rat
				50	mg/kg	Mouse
				30	mg/kg	Dog
Propofol	100	LD50	Intraperitoneal	170	mg/kg	Mouse

LD 50: Dosage that produces 50% mortality.

Aspiration Hazard	None anticipated from normal handling of this product. This product contains soybean oil. Inadvertent aspiration of vegetable oils may lead to lipoid pneumonia and difficulty breathing.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce redness and discomfort. Based on a study in animals, the active ingredient may have some potential for skin absorption.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation, redness, and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, in clinical use, rash, pruritis, and life-threatening and/or fatal anaphylactic and anaphylactoid reactions have been reported. This product may cause allergic reactions in persons with known allergies to egg or soy products.
Reproductive Effects	Female Wistar rats were administered either 0, 10, or 15 mg/kg/day propofol intravenously from 2 weeks before pregnancy to day 7 of gestation did not show impaired fertility. Male fertility in rats was not affected in a dominant lethal study at intravenous dosages up to 15 mg/kg/day for 5 days. Reproduction studies have been performed in rats and rabbits at intravenous dosages of 15 mg/kg/day and have revealed no evidence of impaired fertility or harm to the fetus due to propofol. Propofol, however, has been shown to cause maternal deaths in rats and rabbits and decreased pup survival during the lactating period in dams treated with dosages of 15 mg/kg/day. The pharmacological activity of the drug on the dam may be responsible for the adverse effects seen in the offspring.

11. TOXICOLOGICAL INFORMATION: continued

Mutagenicity	Propofol was not mutagenic in the <i>in vitro</i> bacterial reverse mutation assay (Ames test) using <i>Salmonella typhimurium</i> strains TA98, TA100, TA1535, TA1537, and TA 1538. Propofol was not mutagenic in either the gene mutation/gene conversion test using <i>Saccharomyces cerevisiae</i> , or <i>in vitro</i> cytogenetic studies in Chinese hamsters. In the <i>in vivo</i> mouse micronucleus assay with Chinese Hamsters propofol administration did not produce chromosome aberrations.
Carcinogenicity	Long-term studies in animals have not been conducted to evaluate the carcinogenic potential of propofol.
Target Organ Effects	Based on clinical use, possible target organs may include the central nervous system, respiratory system, and the cardiovascular system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

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. EC50: Concentration in water that produces 50% inhibition of growth in algae.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

Notes: DOT - US Department of Transportation Regulations

14. TRANSPORTATION INFORMATION

DOT STATUS: Not regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

ICAO/IATA STATUS Not regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

IMDG STATUS Not regulated
Proper Shipping Name: NA
Hazard Class: NA
UN Number: NA
Packing Group: NA
Reportable Quantity: NA

15. REGULATORY INFORMATION


TSCA Status Exempt.
CERCLA Status Not listed
SARA 302 Status Not listed
SARA 313 Status Not listed
RCRA Status Not listed
PROP 65 (Calif.) Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

U.S. OSHA Classification Possible Irritant
Target Organ Toxin

15. REGULATORY INFORMATION: continued

GHS Classification



Hazard Class	Acute Oral Toxicity	Eye Irritation	Target Organ Toxicity
Hazard Category	Unclassified	2B	2
Symbol	NA		
Signal Word	NA	Warning	Warning
Hazard Statement	NA	Causes eye irritation	May cause damage to the central nervous system, respiratory system, and cardiovascular system through prolonged or repeated exposure.

Prevention: Do not breath mist or spray
Wear protective gloves and eye/face protection

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance propofol.

Classification(s):	Irritant	Harmful
Symbol:		
Indication of Danger	Xi	Xn

Risk Phrases: R22 – Harmful if swallowed
R36/37 - Irritating to eyes and respiratory system

Safety Phrases: S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD ₅₀	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Global Occupational Toxicology
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