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 USA 60045
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224-212-2000
Product Name	Propofol Injectable Emulsion
Synonyms	2,6-diisopropylphenol; 2,6-DIP

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name	Propofol
Chemical Formula	$C_{12}H_{18}O$
Preparation	Non-hazardous ingredients include Water for Injection, egg lecithin, soybean oil and glycerin. Hazardous ingredients present at less than 1% include benzyl alcohol; sodium hydroxide is added to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Propofol	1	2078-54-8	SL0810000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Propofol	Not Listed	Not Listed	Not Listed

Emergency Overview	Propofol Injectable Emulsion is a solution containing 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. This product may cause eye and skin irritation following inadvertent contact. During clinical use, adverse effects may include slowed heart rate, decreased blood pressure, transient apnea, nausea, rash and cough.

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.

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	None anticipated for this aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous 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 firefighting 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.

7. HANDLING AND STORAGE

Handling	No special handling required for hazard control under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions	No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure limits				
Component	**Type**	**mg/m3**	**ppm**	**µg/m3**	**Note**
Propofol	Hospira EEL	2	N/A	N/A	8hr TWA
Propofol	Hospira STEL	10	N/A	N/A	STEL

Respiratory protection

Respiratory protection is normally not needed during intended 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 (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. 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.

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	Liquid
Color	White
Odor	Odorless or a slight phenolic odor
Odor Threshold:	NA
pH:	6 to 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:	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 1100	mg/kg mg/kg	Rat Mouse
Propofol	100	LD50	Intravenous	42 50 30	mg/kg mg/kg mg/kg	Rat Mouse Dog

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.
Mutagenicity	Propofol was not mutagenic in the in vitro bacterial reverse mutation assay (Ames test) using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and TA 1538. Propofol was not mutagenic in either the gene mutation/gene conversion test using *Saccharomyces cerevisiae*, or *in vitro* cytogenetic studies in Chinese hamsters. In the *in vivo* 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

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.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:	Not regulated
IMDG STATUS:	Not regulated
ICAO/IATA STATUS:	Not regulated
Transport Comments:	None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Propofol	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed

U.S. OSHA Classification Target Organ Toxin
Possible Irritant

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.:

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

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.

Get medical attention if you feel unwell.

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

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Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24 - Avoid contact with 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
LD50	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: Hospira GEHS
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