SAFETY DATA SHEET

Product Name: Propofol Injectable Emulsion

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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

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. HAZARD(S) IDENTIFICATION

Emergency Overview
Propofol Injectable Emulsion is an oil:water mixture 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 nervous system, respiratory system, and cardiovascular system.

U.S. OSHA GHS Classification

Physical Hazards Hazard Class Hazard Category
Not Classified Not Classified

Health Hazards Hazard Class Hazard Category
STOT – SE 3

Label Element(s)

Pictogram

Signal Word Warning

Hazard Statement(s)
May cause drowsiness or dizziness

Precautionary Statement(s)

Prevention
Do not breathe vapor or spray
Use only outdoors or in a well-ventilated area
Wash hands thoroughly after handling

Response
Get medical attention if you feel unwell.

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.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.
Product Name: Propofol Injectable Emulsion

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propofol</td>
<td>1.0</td>
<td>2078-54-8</td>
<td>SL0810000</td>
</tr>
</tbody>
</table>

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

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 emulsion product.

Fire & Explosion Hazard: None anticipated for this emulsion product.

Extinguishing Media: As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

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 control 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/PERSOAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propofol</td>
<td>8 hr TWA: Not Established</td>
<td>8 hr TWA: Not Established</td>
<td>8-hour TWA: Not Established</td>
<td>8 hr TWA: Not Established</td>
</tr>
</tbody>
</table>

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.

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>A sterile, non-pyrogenic white, oil-in-water emulsion for intravenous administration</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless or a slight phenolic odor</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>7 to 8.5</td>
</tr>
<tr>
<td>Melting point/Freezing Point</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range</td>
<td>NA</td>
</tr>
<tr>
<td>Flash Point</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density (Air =1)</td>
<td>NA</td>
</tr>
<tr>
<td>Relative Density</td>
<td>0.955</td>
</tr>
<tr>
<td>Solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Partition Coefficient: n-octanol/water</td>
<td>6761:1 at a pH of 6 to 8.5</td>
</tr>
<tr>
<td>Auto-ignition Temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>NA</td>
</tr>
<tr>
<td>Viscosity</td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: Propofol Injectable Emulsion

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
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 active ingredient is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propofol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>500</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1100</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Propofol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>42</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>50</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>30</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
</tbody>
</table>

LD 50: Dosage that produces 50% mortality.

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
None anticipated from normal handling of this product. 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.

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
None anticipated from normal handling of this product. Female Wistar rats 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 performed in rats and rabbits at intravenous dosages of 15 mg/kg/day have revealed no evidence of harm to the fetus due to propofol.
Product Name: Propofol Injectable Emulsion

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects: continued However, propofol 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.

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

Specific Target Organ Toxicity – Single Exposure NA

Specific Target Organ Toxicity – Repeat Exposure Based on clinical use, possible target organs may include the 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:

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.
Product Name: Propofol Injectable Emulsion

14. TRANSPORTATION INFORMATION

<table>
<thead>
<tr>
<th>ADR/ADG/ DOT STATUS</th>
<th>Not regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Class</td>
<td>NA</td>
</tr>
<tr>
<td>UN Number</td>
<td>NA</td>
</tr>
<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
<tr>
<td>ICAO/IATA STATUS</td>
<td>Not regulated</td>
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<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Class</td>
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<tr>
<td>UN Number</td>
<td>NA</td>
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<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
<tr>
<td>IMDG STATUS</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
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<tr>
<td>Hazard Class</td>
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<td>UN Number</td>
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<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
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</table>

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>US TSCA Status</th>
<th>Exempt</th>
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</thead>
<tbody>
<tr>
<td>US CERCLA Status</td>
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<tr>
<td>US SARA 302 Status</td>
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<td>US SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


GHS/CLP 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.

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Pictogram</th>
<th>Signal Word</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
</tbody>
</table>

Prevention

Do not breathe vapor or spray
Use only outdoors or in a well-ventilated area
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

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.

IF INHALED: Remove person to fresh air and keep comfortable for breathing.
15. REGULATORY INFORMATION: continued

<table>
<thead>
<tr>
<th>Classification*</th>
<th>*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification(s)</td>
<td>NA</td>
</tr>
<tr>
<td>Symbol</td>
<td>NA</td>
</tr>
<tr>
<td>Indication of Danger</td>
<td>NA</td>
</tr>
<tr>
<td>Risk Phrases</td>
<td>NA</td>
</tr>
</tbody>
</table>
| 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  
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  
STOT - SE Specific Target Organ Toxicity – Single Exposure  
STOT - RE Specific Target Organ Toxicity – Repeated Exposure  
TSCA Toxic Substance Control Act  
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS  
Date Prepared: October 19, 2012  
Date Revised: June 02, 2014

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