
	<b>Sagent Pharmaceuticals, Inc.</b>			
	<b>Propofol Injectable Emulsion, USP 1%</b>		<b>Safety Data Sheet (SDS)</b>	
	SDS Issue Date: <b>Oct. 13, 2014</b>	SDS No.: <b>SDS 073</b>	SDS Version No.: <b>1.0</b>	Form No.: <b>R-SOP-009-F001</b>

### Section 1 - Identification

- (a) **Product Identifier:** Propofol Injectable Emulsion, USP 1%
- (b) **Product Code:** 20521-608
- Common/Trade Name:** Diprivan
- Chemical Name (Active Ingredient):** 2, 6-diisopropylphenol
- Chemical Family:** Anesthesia
- (c) **Product Use:** Pharmaceutical
- Product Type:** Regulated Prescription Drug
- Container Information:** Glass vial
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

### Section 2 - Hazards Identification

- (a) **Classification:** HMIS Classification  
Health hazard:2  
Fire Hazard: 1  
Reactivity: 1
- (b) **Signal Word,** Not available  
**Hazard statement(s),**  
**Symbol(s), and/or**  
**Precautionary**  
**statement(s):**
- (c) **Description of Hazards:** *Health hazards:* In the workplace may be harmful if swallowed. Known adverse effects by other routes are not known. In therapeutic use, this product may produce irregular heartbeat, reduced blood pressure, convulsions, swelling and sleepiness. Therapeutic use has been associated with both fatal and life-threatening anaphylactic and anaphylactoid reactions. It is not known if these effects are possible as a result of workplace exposure.
- Flammability Hazards:* This product is expected to be combustible. If heated to high temperatures for a prolonged

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period, the material may ignite. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds, including carbon and nitrogen oxides.

*Reactivity Hazards:* This product is not reactive.

*Environmental Hazards:* Release of large quantity may cause harm to animals and aquatic organisms if accidentally released to the environment.

*Emergency Recommendations:* Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

**(d) Unknown Acute Toxicity:** Not available


### Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% by weight	(c) CAS No.	(d) Impurities / Stabilizing Additives
2, 6-diisopropylphenol	Propofol	Proprietary	2078-54-8	N/A
Soybean Oil	Soybean Oil	Proprietary	8001-22-7	N/A
Glycerol	Glycerol	Proprietary	56-81-5	N/A
Egg Yolk Phospholipid	Egg Yolk Phospholipid	Proprietary	93685-90-6	N/A
Sodium Metabisulfite	Sodium Metabisulfite	Proprietary	7681-57-4	N/A
Water for Injection	Water for Injection	Proprietary	7732-18-5	N/A

### Section 4 - First Aid Measures

**Eye Exposure:**

If this material enters the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

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**Skin Exposure:** If skin contact with this material occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

**Ingestion:** If this material is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.


**Injection:** If this product is accidentally injected, flush injection site with water. Seek medical attention. Refer to Section 11.

**Inhalation:** If aerosols are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

**Notes to Physician:** See patient package insert in shipping carton for complete information.

#### Section 5 –Fire-fighting Measures

- (a) Extinguishing Media** Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, ‘ABC’ type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.
- (b) Hazardous Combustion Products:** This solution is not flammable or combustible. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon and nitrogen oxides).

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- (c) **Special Protective Equipment / Precautions:** Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

**Section 6 - Accidental Release Measures**

- Spill:** *Small Spills/Spills in Hoods:* Personnel wearing nitrile or other appropriate gloves, labcoat or other protective clothing and eye protection should immediately clean spills of less than 5 mL. *Large Spills:* Use proper protective equipment, including double nitrile or appropriate gloves, protective clothing (i.e., Tyvek coveralls), and full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.
- Release to Air:** N/A
- Release to Water:** N/A

**Section 7 - Handling and Storage**

- General Handling:** All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this product is used with adequate ventilation. Appropriate personal protective equipment must be worn (see section 8, Exposure Controls - Personal Protection). Minimize all exposures to this product. Avoid generation of aerosols.


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**Storage Conditions:** Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: 4° to 25°C (40° to 77°F). Do not allow product to freeze. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.

**Section 8 - Exposure Controls / Personal Protection**

**(a) Exposure Limits**

<b>Compound</b>	<b>Issuer</b>	<b>Type</b>	<b>Exposure Limit</b>
Propofol	OSHA	PEL	NE
	ACGIH	TLV	NE
Soybean Oil	OSHA	PEL	NE
	ACGIH	TLV	NE
Glycerol	OSHA	PEL	15 mg/m <sup>3</sup> (TWA) (total dust)
	ACGIH	TLV	NE
Egg Yolk Phospholipid	OSHA	PEL	NE
	ACGIH	TLV	NE
Sodium Metabisulfite	OSHA	PEL	NE
	ACGIH	TLV	5 mg/m <sup>3</sup> (TWA)
Water for Injection	OSHA	PEL	NE
	ACGIH	TLV	NE


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**(b) Engineering Controls**

Ventilation: General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

**(c) Individual Protection Measures**

Respiratory Protection:	Maintain airborne contaminant concentrations below exposure limits listed above. For materials without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998)
Eye Protection:	Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.
Skin Protection:	Use appropriate protective clothing for the task (e.g., lab coat, etc.). If necessary, refer to the U.S. OSHA Technical Manual (Section VII: Personal Protective Equipment) or other appropriate regulations.
Other Protective Equipment:	Wash hands and wrists before putting on and after removing gloves. During manufacture or other similar operations, wear the appropriate hand protection for the process. When used in medical administration of the product, double glove with nitrile or other appropriate gloves to avoid contact and/or absorption of the product. Use double gloves for spill response, as stated in Section 6 (Accidental Release Measures) of this SDS. Because all gloves are to some extent permeable and their permeability increases with time, they should be changed regularly (hourly is preferable) or immediately if torn or punctured. If necessary refer to appropriate regulations.

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Additional Exposure Precautions:	N/A
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### Section 9 - Physical and Chemical Properties

(a)	<b>Appearance</b>	White
(b)	<b>Odor</b>	Odorless
(c)	<b>Odor Threshold</b>	N/A
(d)	<b>pH</b>	4.5 – 6.6
(e)	<b>Melting Point:</b>	N/A
(f)	<b>Initial Boiling Point:</b>	N/A
(g)	<b>Flash Point</b>	N/A
(h)	<b>Evaporation Rate:</b>	N/A
(i)	<b>Flammability</b>	N/A
(j)	<b>Upper Lower Flammability or Explosion Limits</b>	Not available
(k)	<b>Vapor Pressure:</b>	N/A
(l)	<b>Vapor Density:</b>	N/A
(m)	<b>Relative Density</b>	N/A
(n)	<b>Solubility(ies)</b>	Very Slightly soluble in water
(o)	<b>Partition Coefficient: n-octanol/water</b>	N/A
(p)	<b>Auto-ignition Temperature</b>	Not available
(q)	<b>Decomposition Temperature</b>	Not available
(r)	<b>Viscosity</b>	N/A

### Section 10 - Stability and Reactivity

(a)	<b>Reactivity</b>	None known.
(b)	<b>Chemical Stability</b>	Normally stable. The Propofol component is air sensitive. This product can decompose in the presence of air and is therefore supplied with a blanket of nitrogen in each vial.

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(c)	<b>Possibility of Hazardous Reactions</b>	None known
(d)	<b>Conditions to Avoid</b>	Exposure to or contact with extreme temperatures, incompatible chemicals.
(e)	<b>Incompatible Materials</b>	Strong acids and bases. Avoid materials that are incompatible with water.
(f)	<b>Hazardous Decomposition Products</b>	Combustion: Products of thermal decomposition may include carbon and nitrogen oxides. Hydrolysis: None known

**Section 11 - Toxicological Information**

(a)	<b>Likely Routes of Exposure</b>	Inhalation of aerosols, eye and skin contact.
(b)	<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	During therapeutic use by intravenous route, this material can cause adverse effects on the nervous system, may produce irregular heartbeat, reduced blood pressure, convulsions, swelling and sleepiness. Therapeutic use has been associated with both fatal and life-threatening anaphylactic and anaphlactoid reactions. These effects may be possible as a result of workplace exposure. The actual risk in the workplace is not known. Please refer to the patient package insert for more details.
(c)	<b>Delayed and immediate effects and also chronic effects from short and long term exposure</b>	It is anticipated that for Occupational Exposure the target organs are: <i>Acute:</i> Skin, eyes, respiratory system. <i>Chronic:</i> None known from workplace exposure.

**(d) Acute Toxicity**

Component	Type	Route	Species	Dosage
Propofol disodium	LD <sub>50</sub>	Oral	Mouse	1100 mg/kg
Propofol disodium	LD <sub>50</sub>	Intravenous	Rat	42 mg/kg

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<b>Component</b>	<b>Type</b>	<b>Route</b>	<b>Species</b>	<b>Dosage</b>
Propofol disodium	LD <sub>50</sub>	Intravenous	Dog	30 mg/kg
Propofol disodium	LD <sub>50</sub>	Intravenous	Mouse	50 mg/kg
Propofol disodium	LD <sub>50</sub>	Interperitoneal	Mouse	170 mg/kg

**(e) Hazardous Chemical Listings**

NTP: Not listed

IARC: Not listed

OSHA: Not listed

**Section 12 - Ecological Information**


<b>(a) Ecotoxicity</b>	No information available
<b>(b) Persistence and degradability</b>	No information available
<b>(c) Bioaccumulative potential</b>	No information available
<b>(d) Mobility in soil</b>	No information available
<b>(e) Other Adverse Effects</b>	The components of this product are not listed as having ozone depletion potential.

**Section 13 - Disposal Considerations**

Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures and/or regulated medical waste requirements.

**Section 14 - Transport Information**

<b>(a) UN Number</b>	N/A
<b>(b) UN Proper Shipping Name</b>	N/A
<b>(c) Transport Hazard Class(es)</b>	N/A
<b>(d) Packing Group</b>	N/A

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<b>(e)</b>	<b>Environmental Hazards</b>	This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations, and the components are not specifically listed in Annex III under MARPOL 73/78.
<b>(f)</b>	<b>Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)</b>	N/A
<b>(g)</b>	<b>Special Precautions</b>	N/A

Per U.S. DOT regulations, under 49 CFR 172.101, this product is NOT classified as dangerous goods nor is any component of this product listed as a Marine Pollutant.

This product does not meet the criteria as Dangerous Goods, per rules of IATA.

**Section 15 - Regulatory Information**

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.


**U.S. Regulations:**

- TSCA: No
- CERCLA: Not on this list
- SARA 302: Not on this list
- SARA 313: Not on this list

**Section 16 - Other Information**


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:  
 Sagent Pharmaceuticals, Inc.  
 1901 N. Roselle Rd, Suite 700  
 Schaumburg, IL 60195  
 847-908-1600

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**Glossary:** This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IDLH	Immediately Dangerous To Life Or Health
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)

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RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SCBA	Self Contained Breathing Apparatus
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System