SAFETY DATA SHEETS

This SDS packet was issued with item:

078906608

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078863657 078907765 078907766 078908331

*(Bad file name or number)***ANIMAL HEALTH**

SAFETY DATA SHEET

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1 Product Identifier

Product Name: PropoFlo

Synonyms: Propofol ES; Propofol Injectable Emulsion, 10 mg/mL

Trade name: PropoFlo

List Number: 3919; 5206; 6059

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended use: Pharmaceuticals

1.3 Details of the supplier of the safety data sheet

Supplier: Abbott Laboratories
Animal Health
100 Abbott Park Road
Abbott Park Illinois 60064

Customer Service Telephone: 1 - 888 - 299 - 7416 (Abbott Animal Health 8:00 am - 5:00 pm CST)

E-mail Address: Abbott.SDS@abbott.com

1.4 Emergency telephone number

Emergency Telephone: 1 (800) 424-9300 CHEMTREC (USA)
1 (703) 527 3887 CHEMTREC (INTERNATIONAL)

Section 2. Hazards identification

2.1 Classification of the substance or mixture

Regulation (EC) No 1272/2008

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System. EU notification not required.

Classification according to EU Directives 67/548/EEC or 1999/45/EC

2.2 Label elements

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System. EU notification not required.

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Water 7732-18-5	85 - 86	Present		Not Hazardous*	No data available
Soybean Oil 8001-22-7	10	Present		Not Hazardous*	No data available
Glycerol 56-81-5	2 - 3	Present		Not Hazardous*	No data available
Egg Phosphatide L-02-3139	1 - 2	NA			No data available
2,6-Diisopropylphenol 2078-54-8	1	Present	Xi; R36/37/38	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

Section 4. First aid measures

4.1 Description of 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.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms: No signs and symptoms from occupational exposure are known. Clinical data suggests the following: headaches, vomiting, nausea, slow heart rate, decreased blood pressure, sedation, anaphylatic reactions, sleep. Similar product: Injection in normal volunteers produced psychoactive effects that could be construed as pleasant.

Medical Conditions Aggravated by Exposure: No medical conditions aggravated by occupational exposure are known. Clinical data suggests any pre-existing ailments of the following organs: respiratory system, central nervous system, cardiovascular system. Hypersensitivity to the material and/or similar materials.

4.3 Indication of any immediate medical attention and special treatment needed

Notes To Physician: Monitor central nervous system and cardiovascular function, as necessary.

Additional Information: Injection of propofol in normal volunteers produced psychoactive effects that could be construed as pleasant.

Section 5. Firefighting measures

5.1 Extinguishing Media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not determined

5.2 Special hazards arising from the substance or mixture

Special Exposure Hazards: Avoid inhalation of combustion products.

5.3 Advice for firefighters

Protective Equipment and Precautions for Firefighters: Wear self-contained breathing apparatus and protective suit

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: Use personal protective equipment identified in Section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Clean up promptly. Absorb with suitable material. Clean with suitable cleaning materials. Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

Section 7. Handling and storage

7.1. Precautions for safe handling

Handle according to label instructions..

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions. Should not be used beyond the indicated expiration date..

7.3. Specific end use(s)

Recommended use: Pharmaceuticals

Section 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Water 7732-18-5	Not Applicable	None
Soybean Oil 8001-22-7	Not Applicable	None
Glycerol 56-81-5	Not Applicable	None
Egg Phosphatide L-02-3139	Not Applicable	None
2,6-Diisopropylphenol 2078-54-8	2 mg/m^3 for 8-hr TWA : 10 mg/m^3 for 15-min STEL	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Glycerol 56-81-5	10 mg/m^3 (total mist)	TWA: 10 mg/m^3	50 mg/m^3 TWA	10 mg/m^3 (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Glycerol 56-81-5		10 mg/m^3 (TWA)	50 mg/m^3 (TWA) 100 mg/m^3 (STEL)	30 mg/m^3 (STEL) 10 mg/m^3 (TWA)

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: Respiratory protection is not needed during normal product use.

Eyes: Eye protection not required during typical product use conditions. Wear eye protection appropriate to handling activities.

Gloves: If skin contact is anticipated: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: White to off-white
Odor: Odorless.
Odor Threshold: Not determined

pH:	6.0 - 8.5
Boiling Pt. @ 760 mm Hg (°C):	Not determined.
Melting/Freezing Point (°C):	Not determined
Flash Point (°C):	Not determined.
Evaporation Rate at 20°C:	Not determined.
Flammability (Solid):	Not determined.
Lower Explosive Limit:	Not determined.
Upper Explosive Limit:	Not determined.
Vapor Pressure (mm Hg):	Not determined.
Vapor Density (Air = 1):	Not determined.
Bulk Density at 20°C:	0.996 g/mL
Specific Gravity:	Not determined.
Solubility(ies):	Slightly soluble in: water (11.2 grams/l)
Partition coefficient: n-octanol/water	Not determined.
Autoignition Temp. (°C):	Not determined.
Decomposition temperature (°C):	Not determined.
Viscosity (centipoise):	1.54cps at 25 deg. C
Explosion Severity:	Not determined.
Oxidizer Properties:	Not determined.

9.2. Other information

Not determined

Section 10. Stability and reactivity

10.1. Reactivity

Not determined

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: None under normal processing

10.4. Conditions to avoid

Not determined.

10.5 Incompatible materials

Oxidizing agents

10.6 Hazardous decompostion products

Not determined.

Section 11. Toxicological information

11.1. Information on toxicological effects

Routes of Exposure:

Oral: Unlikely
Dermal: Unlikely
Inhalation: Unlikely

Acute Toxicity - Oral: LD50 not determined for product. Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	4090	mg/kg	Animals
2,6-Diisopropylphenol 2078-54-8	LD50 =	518-1230	mg/kg	Rats Mice

Acute Toxicity - Dermal: LD50 not determined for product. Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	10,000	mg/kg	Rabbits
2,6-Diisopropylphenol 2078-54-8	LD50 >	2000	mg/kg	Rabbits

Acute Toxicity - Inhalation: LC50 not determined for product. Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Glycerol 56-81-5	LC 50 >	0.57	mg/L , 1 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined for product. Active Ingredient : Reported to produce skin irritation in humans.

Eye Irritation: Not determined for product. Active Ingredient : Produced mild eye irritation in animal testing.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Not determined for this mixture. Active Ingredient : In clinical use target organ effects include: central nervous system.

In clinical use, propofol depresses the central nervous system with the rapid induction of anesthesia. Anesthesia is of short duration. Sedative doses can elicit psychoactive effects that could be construed as pleasant. In a dog study, animals were given single intravenous dose of 7.5, 11.5 and 19.5 mg/kg of propofol emulsion. There were dose related increase in anesthesia in animals; and at the high dose animals had difficulty walking normally. In an cat study, animals were given intravenous infusion of 13.5 mg/kg and 19.5 mg/kg in two intervals over 20 days with week recovery after each interval. Some animals were observed with apnea after induction. Some vomiting and gastronintestinal discomfort was observed in animals during recovery. In large amounts, glycerol has potential to produce and increase in urine output and cause hemolysis due to changes in osmolality.

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Glycerol 56-81-5	No Data.	Negative	No Data.	No Data.
2,6-Diisopropylphenol 2078-54-8	Negative	Negative	No Data.	No Data.

Aspiration hazard: Not determined

Notes:
1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

Section 12. Ecological information

12.1. Toxicity

Not determined.

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Not determined

12.4. Mobility in soil

Not determined.

12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

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. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

Section 13. Disposal considerations

13.1 Waste treatment methods

Waste Disposal Methods: All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices. This material, as supplied, is not a hazardous waste according to Federal regulations (40 CFR 261)

Section 14. Transport information

ADR, DOT, ICAO/IATA, IMDG/IMO
Status: Not regulated

14.1. UN Number: Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special Provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

Section 15. Regulatory Information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Water 7732-18-5	Present	X	X	Not listed.	X
Soybean Oil 8001-22-7	Present	X	X	Not listed.	X
Glycerol 56-81-5	Present	X	X	Not listed.	X
Egg Phosphatide L-02-3139	-	-	-	Not listed.	-
2,6-Diisopropylphenol 2078-54-8	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Water 7732-18-5	-	2-(4)-1220	X	X	Present	
Soybean Oil 8001-22-7	-	-	X	X	Present	
Glycerol 56-81-5	Present	-	X	X	Present	
Egg Phosphatide L-02-3139	-	-	-	-	-	
2,6-Diisopropylphenol 2078-54-8	Present	-	X	X	Present	HSR003281

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Water	85 - 86	Not Listed	Not Listed	Not Listed
Soybean Oil	10	Not Listed	Not Listed	Not Listed
Glycerol	2 - 3	Not Listed	Not Listed	Not Listed
Egg Phosphatide	1 - 2	Not Listed	Not Listed	Not Listed
2,6-Diisopropylphenol	1	Not Listed	Not Listed	Not Listed

SARA 313 Information

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	85 - 86	No	Not Applicable	Not applicable
Soybean Oil	10	No	Not Applicable	Not applicable
Glycerol	2 - 3	No	Not Applicable	Not applicable
Egg Phosphatide	1 - 2	No	Not Applicable	Not applicable
2,6-Diisopropylphenol	1	No	Not Applicable	Not applicable

Immediate Health: No
Delayed Health: No
Fire: No
Sudden Pressure: No
Reactivity: No

RCRA Status: Not a RCRA Hazardous Waste.

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Not determined.

Health: 0
Fire: 0
Reactivity: 0

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

Section 16. Other information

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