



Material Safety Data Sheet

MSDS Number: 1093108
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1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MSDS Number: 1093108
Product name: Propofol Injectable Emulsion 1%
Product Codes: NDC 10019-013-06, NDC 10019-013-01, NDC 10019-013-02, NDC 10019-013-03, NDC 66758-025-02, NDC 66758-025-04, NDC 10019-213-01, NDC 10019-213-02, NDC 10019-213-03
Synonyms: None
Chemical Family: Anesthetic
Product Type: Regulated Prescription Drug
Container Information: Vials and infusion vials
Product Use: Pharmaceutical.

Supplier

BAXTER HEALTHCARE CORPORATION
DEERFIELD, ILLINOIS 60015
(800) 422-9837 or (847) 948-4770

Emergency telephone number PROSAR: USA (888) 990-0996 OUTSIDE USA (615)917-6114
CHEMTREC: USA (800) 424-9300 OUTSIDE USA (743)741-6089

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component	Weight %	UN Number:	Classification:
Propofol 2078-54-8	1	None	None
Soybean Oil 8001-22-7	9-11	None	None
Egg Yolk Phospholipid 93685-90-6	1-2	None	None
Glycerin 56-81-5	1-5	None	None
Sodium Metabisulfite 7681-57-4	<0.1	None	Xn; R22 R31 Xi; R41
Water 7732-18-5	>85	None	None

3. HAZARDS IDENTIFICATION

Emergency overview: CAUTION! MAY BE HARMFUL IF SWALLOWED. Do not ingest. Avoid skin contact. Avoid eye contact.

Principle routes of exposure: Absorbed through skin. Eye contact. Ingestion.

Inhalation: Inhalation not likely under normal use conditions. May cause respiratory tract irritation.

3. HAZARDS IDENTIFICATION

Ingestion:	May be harmful if swallowed. Gastrointestinal effects (may include nausea, upset stomach, loss of appetite). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness).
Skin contact:	May cause skin irritation.
Eye contact:	May cause eye irritation.

4. FIRST AID MEASURES

Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.
Skin contact:	In case of contact, immediately flush skin with plenty of water. Get medical attention.
Ingestion:	Do NOT induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. If large quantities of this material are swallowed, call a physician immediately.
Eye contact:	Flush with plenty of water for at least 15 minutes, occasionally lifting the upper and lower eyelids. Get medical attention.
Notes to physician:	See patient package insert in shipping carton for complete information.

5. FIRE FIGHTING MEASURES

Suitable extinguishing media:	Use foam or all purpose dry chemicals to extinguish.
Special protective equipment for firefighters:	Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.
Specific methods:	No information available
Flash point:	Not determined
Autoignition temperature:	Not available.
Flammable limits	Not available.
in air-lower (%):	
Flammable limits	
in air-upper (%):	Not available.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5).
Environmental precautions:	No information available.
Methods for cleaning up:	If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) scoop up material and place in a sealed, liquid-proof container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal.

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: Do not ingest. Wash thoroughly after handling.

Storage:**Technical measures****/Storage conditions:**

Keep containers tightly closed in a dry, cool and well-ventilated place. Store between 4 to 22°C (39.2 to 71.6°F). Avoid freezing.

Incompatible products:

No special restrictions on storage with other products.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

Component	OSHA- Time Weighted Average:	OSHA- Short Term Exposure Limit:	OSHA- Ceiling Limits	ACGIH- Time Weighted Average:	ACGIH- Short Term Exposure Limit:	ACGIH- Ceiling Limit Value:
Propofol 2078-54-8	None	None	None	None	None	None
Soybean Oil 8001-22-7	None	None	None	None	None	None
Egg Yolk Phospholipid 93685-90-6	None	None	None	None	None	None
Glycerin 56-81-5	15 mg/m ³	None	None	10 mg/m ³	None	None
Sodium Metabisulfite 7681-57-4	None	None	None	5 mg/m ³	None	None
Water 7732-18-5	None	None	None	None	None	None

Engineering measures:

No special containment is required. Good general ventilation should be sufficient to control airborne levels.

Personal protective equipment:**Respiratory protection:**

No personal respiratory protective equipment normally required.

Hand protection:

Use chemical resistant, impervious gloves.

Skin and body protection:

Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits).

Eye protection:

Eye protection not required for normal final product use. Safety glasses with side-shields are recommended for laboratory and manufacturing use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:

Liquid

Appearance:

Aqueous solution.

Color:

White.

Odor:

Odorless

pH:

4.5 - 6.6

Molecular weight:

Not applicable.

Boiling point/range:

Not available.

Melting point/range:

Not available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Density:	Not available.
Vapor pressure:	Not available.
Evaporation rate:	Not available.
Solubility:	Soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Viscosity:	Not available.
% Volatile by Volume:	Not available.

10. STABILITY AND REACTIVITY

Stability:	Stable under recommended storage conditions.
Polymerization:	Not applicable
Hazardous decomposition products:	Not available.
Materials to avoid:	Not available.

11. TOXICOLOGICAL INFORMATION

Component	LD50 Dermal	LC50 Inhalation	LD50 Oral
Propofol 2078-54-8	-	-	500 mg/kg (rat)
Soybean Oil 8001-22-7	-	-	-
Egg Yolk Phospholipid 93685-90-6	-	-	-
Glycerin 56-81-5	21900 mg/kg (rat)	-	12600 mg/kg (rat)
Sodium Metabisulfite 7681-57-4	2 g/kg (rat)	-	1131 mg/kg (rat)
Water 7732-18-5	-	-	90 mL/kg (rat)

Acute toxicity:	Gastrointestinal effects (may include nausea/vomiting, abdominal pain, diarrhea, dry mouth, colic). Cardiovascular effects (may include fluctuations in heart rate, changes in blood pressure, chest pain). Dermatologic effects (may include exfoliative dermatitis, photosensitivity, rash, itching). Respiratory effects (may include shortness of breath, bronchospasms, laryngospasms, respiratory depression). Nervous System effects (may include ataxia, tremor, disturbance of speech, lethargy, headache, dizziness, blurred vision).
Chronic toxicity:	No data is available on the product itself.
Carcinogenic effects:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH. No data is available on the product itself.
Mutagenic effects:	Not mutagenic in a standard battery of genetic toxicological tests.
Reproductive toxicity:	No impairment to fertility based on animal data. Teratogenic at maternally toxic doses.
FDA Pregnancy Catagory	B

12. ECOLOGICAL INFORMATION

Environmental properties:

Component	Ecotoxicity - Water Flea Data	Fish Species Ecotoxicity	Ecotoxicity - Freshwater Algae Data	Ecotoxicity - Microtox Data
Propofol 2078-54-8	None.	None.	None.	None.
Soybean Oil 8001-22-7	None.	None.	None.	None.
Egg Yolk Phospholipid 93685-90-6	None.	None.	None.	None.
Glycerin 56-81-5	500 mg/L EC50 24 h	51 - 57 mL/L LC50 Oncorhynchus mykiss 96 h	None.	None.
Sodium Metabisulfite 7681-57-4	89 mg/L EC50 24 h	32 mg/L LC50 Lepomis macrochirus 96 h	40 mg/L 96 h 48 mg/L 72 h	56mg/LEC50Pseudomonas putida17h
Water 7732-18-5	None.	None.	None.	None.

Ecotoxicity effects: No data available

Bioaccumulation: No data available

13. DISPOSAL CONSIDERATIONS

Waste Classification: Not regulated.

Waste from residues / unused products: Waste disposal must be in accordance with appropriate Federal, State, and local regulations.

14. TRANSPORT INFORMATION

DOT:

DOT shipping name:	None
UN Number:	None
DOT Packing Group:	None
DOT Hazard class:	None

TDG (Canada):

TDG Proper shipping name:	None
TDG UN/NA Number:	None
TDG Packing Group:	None
TDG Hazard class:	None

ADR/RID:

ADR Official Transport Name:	None
ADR Proper shipping name:	None
ADR UN/NA number:	None
ADR Hazard Class:	None

ICAO / IATA:

IATA Proper shipping name:	None
IATA UN Number:	None

14. TRANSPORT INFORMATION

IATA Primary Hazard: None
IATA Packing group: None
ICAO ERG Code: None

IMO / IMDG:

IMDG Proper Shipping Name: None
IMDG Hazard Class and Division: None
IMDG Packing Group: None
IMDG Subsidiary Risks: None

15. REGULATORY INFORMATION

U.S. Regulations:

TSCA Inventory List -

The product is exempt from TSCA, it is FDA Regulated

OTHER REGULATIONS:

Japanese Inventory (ENCS)

This product does not comply with JPENCS

Component	Weight %	RCRA Status:	CERCLA Reportable Quantity:	CERCLA/SARA - 302 Ext. haz. substances:	Listed as Sara 313 title III:
Propofol	1	Not Listed	Not Listed	Not Listed	Not Listed
Soybean Oil	9-11	Not Listed	Not Listed	Not Listed	Not Listed
Egg Yolk Phospholipid	1-2	Not Listed	Not Listed	Not Listed	Not Listed
Glycerin	1-5	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Metabisulfite	<0.1	Not Listed	Not Listed	Not Listed	Not Listed
Water	>85	Not Listed	Not Listed	Not Listed	Not Listed

STATE REGULATIONS:

Component	California Prop. 65	Minnesota Right-To - Know:	Florida Right-to-Know Reporting List:	Rhode Island Right-to-Know List:	Massachusetts Right-to-Know List:	Pennsylvania Right-to-Know:	New Jersey Right-to-Know:
Propofol	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Soybean Oil	Not Listed	Not Listed	Not Listed	Present	Not Listed	Present	Not Listed
Egg Yolk Phospholipid	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Glycerin	Not Listed	Present	Not Listed	Present	Present	Present	Present
Sodium Metabisulfite	Not Listed	Present	Not Listed	Present	Present	Present	Present
Water	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed

CANADIAN REGULATIONS:

Canada DSL Inventory List -

This product does not comply with DSL

EU EINECS List -

This product does not comply with EINECS

Risk Phrases:

NONE

Safety Phrases:

NONE

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s)?:

Additional product codes. New MSDS format. Changes to Section 8. Changes to Section 9.

Additional information:

Not Available.

Prepared by:

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End of safety data sheet: