Section 1. Identification

GHS product identifier : Propofol Injectable Emulsion

Other means of identification : Not available.

Product type : Liquid.

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

Product use : Pharmaceuticals. (For intended use only.)
Observe technical data sheet/instructions for use.
Specific Treatments: Anesthetic. / Sedative.

Area of application : Professional applications.

Supplier's details : Meitheal Pharmaceuticals, Inc.
8700 W. Bryn Mawr, Suite 600S
Chicago, IL 60631

Telephone: 224-443-4617
www.meithealpharma.com

e-mail address of person responsible for this SDS : info@meithealpharma.com

Emergency telephone number (with hours of operation) : 844-824-8426 (Monday - Friday, 08:00 - 18:00 CST)

Effective

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

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Section 2. Hazards identification

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Other means of identification : Not available.

Ingredient name	Other names	%	Identifiers
Water	-	≥75 - ≤90	CAS: 7732-18-5
Soybean oil	-	≥10 - ≤25	CAS: 8001-22-7
glycerol	Glycerin	≤3	CAS: 56-81-5
Lecithins	Sunflower lecithin	≤3	CAS: 8002-43-5
disoprofol	-	≤3	CAS: 2078-54-8
sodium hydroxide	-	≤0.1	CAS: 1310-73-2
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Edetate Disodium	≤0.1	CAS: 6381-92-6

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified and hence require reporting in this section.

Effective

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.

Ingestion : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

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Section 4. First aid measures

Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : Do not use water jet.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
phosphorus oxides

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Effective

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Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Dispose of via a licensed waste disposal contractor. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations.

Effective

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

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Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Water	None.
Soybean oil	None.
glycerol	**OSHA PEL (United States, 5/2018)** TWA 8 hours: 15 mg/m³. Form: Total dust. TWA 8 hours: 5 mg/m³. Form: Respirable fraction. **CAL OSHA PEL (United States, 5/2018)** TWA 8 hours: 5 mg/m³. Form: respirable fraction. TWA 8 hours: 10 mg/m³. Form: total dust.
Lecithins	None.
disoprofol	None.
sodium hydroxide	**ACGIH TLV (United States, 1/2024)** C: 2 mg/m³. **NIOSH REL (United States, 10/2020)** CEIL: 2 mg/m³. **OSHA PEL (United States, 5/2018)** TWA 8 hours: 2 mg/m³. **CAL OSHA PEL (United States, 5/2018)** C: 2 mg/m³.
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	None.

Effective

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

Skin protection

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Section 8. Exposure controls/personal protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

Effective

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

Appearance

Physical state : Liquid. [Homogeneous Emulsion.]

Color : White.

Odor : Not available.

Odor threshold : Not available.

pH : 4.5 to 8.5

Melting point : Not available.

Boiling point or initial boiling point and boiling range : Not available.

Flash point :

Ingredient name	Closed cup			Open cup		
	°C	°F	Method	°C	°F	Method
Soybean oil	281.85	539.3				

Evaporation rate : Not available.

Flammability : Not available.

Lower and upper explosion limit/flammability limit : Not available.

Vapor pressure :

Ingredient name	Vapor Pressure at 20˚C			Vapor pressure at 50˚C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Water	17.5	2.3		92.258	12.3	

Relative vapor density : Not available.

Relative density : 0.993 [Water = 1]

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Section 9. Physical and chemical properties

Density : 0.993 g/cm³ [25°C (77°F)]

Solubility(ies) :

Media	Result
water	Easily soluble

Miscible with water : Yes.

Partition coefficient: n-octanol/water : Not applicable.

Auto-ignition temperature :

Ingredient name	°C	°F	Method
Soybean oil	444.85	832.7	

Decomposition temperature : Not available.

SADT : Not available.

Viscosity : Dynamic (room temperature): Not available.
Kinematic (room temperature): Not available.
Kinematic (40°C (104°F)): Not available.

Flow time (ISO 2431) : Not available.

Particle characteristics

Median particle size : Not applicable.

Other information

Physical/chemical properties comments : No additional information.

Effective

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerization will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

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Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
glycerol	LD50 Dermal	Rabbit	>18700 mg/kg	-
	LD50 Oral	Rat	12600 mg/kg	-
disoprofol	LD50 Oral	Rat	500 mg/kg	-
sodium hydroxide	LD50 Oral	Rat	325 mg/kg	-
Glycine, N, N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	LD50 Oral	Rat	2214.37 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
glycerol	Eyes - Mild irritant	Rabbit	-	24 hours 500 mg	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 mg	-
sodium hydroxide	Eyes - Mild irritant	Rabbit	-	400 ug	-
	Eyes - Severe irritant	Rabbit	-	1 %	-
	Eyes - Severe irritant	Rabbit	-	0.5 minutes 1 mg	-
	Eyes - Severe irritant	Rabbit	-	24 hours 50 ug	-
	Skin - Severe irritant	Rabbit	-	24 hours 500 mg	-

Effective

Sensitization

Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

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Section 11. Toxicological information

Name	Category	Route of exposure	Target organs
disoprofol	Category 3	-	Respiratory tract irritation
sodium hydroxide	Category 3	-	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Name	Category	Route of exposure	Target organs
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Category 2	inhalation	respiratory tract

Aspiration hazard

Not available.

Effective

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Potential chronic health effects

General : No known significant effects or critical hazards.

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Section 11. Toxicological information

Carcinogenicity : No known significant effects or critical hazards.

Mutagenicity : No known significant effects or critical hazards.

Reproductive toxicity : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Product/ingredient name	Oral (mg/kg)	Dermal (mg/kg)	Inhalation (gases) (ppm)	Inhalation (vapors) (mg/l)	Inhalation (dusts and mists) (mg/l)
Propofol Injectable Emulsion	44400.2	N/A	N/A	N/A	N/A
glycerol	12600	N/A	N/A	N/A	N/A
disoprofol	500	N/A	N/A	N/A	N/A
sodium hydroxide	325	N/A	N/A	N/A	N/A
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	2214.37	N/A	N/A	11	N/A

Effective

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
sodium hydroxide	Acute EC50 40.38 mg/l Fresh water	Crustaceans - *Ceriodaphnia dubia* - Neonate	48 hours
	Acute LC50 125 ppm Fresh water	Fish - *Gambusia affinis* - Adult	96 hours
Glycine, N,N'-1,2-ethanediylbis [N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	Chronic NOEC 25 mg/l Fresh water	Daphnia	21 days

Conclusion/Summary : Not available.

Persistence and degradability

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
glycerol	-	-	Readily

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Water	-1.38	-	Low
glycerol	-1.76	-	Low
disoprofol	3.79	-	Low

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Section 12. Ecological information

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.

Additional information

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to IMO instruments : Not available.

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Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

United States inventory (TSCA 8b): All components are active or exempted.

Clean Water Act (CWA) 311: sodium hydroxide

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Classification
glycerol	≤3	EYE IRRITATION - Category 2B
Lecithins	≤3	COMBUSTIBLE DUSTS
disoprofol	≤3	ACUTE TOXICITY (oral) - Category 4 SKIN IRRITATION - Category 2 EYE IRRITATION - Category 2A SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3
sodium hydroxide	≤0.1	CORROSIVE TO METALS - Category 1 ACUTE TOXICITY (oral) - Category 4 SKIN CORROSION - Category 1A SERIOUS EYE DAMAGE - Category 1 SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3 HNOC - Corrosive to digestive tract [severe]
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, sodium salt, hydrate (1:2:2)	≤0.1	ACUTE TOXICITY (inhalation) - Category 4 SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) - Category 2

SARA 313

Not applicable.

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Section 15. Regulatory information

State regulations

Massachusetts : The following components are listed: GLYCERINE MIST

New York : None of the components are listed.

New Jersey : The following components are listed: GLYCERIN

Pennsylvania : The following components are listed: SOYBEAN OIL; 1,2,3-PROPANETRIOL

California Prop. 65

This product does not require a Safe Harbor warning under California Prop. 65.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Effective

Section 16. Other information

Hazardous Material Information System (U.S.A.)

Health	/	0
Flammability		0
Physical hazards		0

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings and the associated label are not required on SDSs or products leaving a facility under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered trademark and service mark of the American Coatings Association, Inc.

The customer is responsible for determining the PPE code for this material. For more information on HMIS® Personal Protective Equipment (PPE) codes, consult the HMIS® Implementation Manual.

National Fire Protection Association (U.S.A.)



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Section 16. Other information

Procedure used to derive the classification

Classification	Justification
Not classified.	

History

Date of issue/Date of revision : 09/20/2024

Date of previous issue : No previous validation

Version : 1.0

Prepared by : Sphera Solutions

Key to abbreviations :
ATE = Acute Toxicity Estimate
AMP = Acceptable maximum peak above the acceptable ceiling concentration for an 8-hr shift
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
N/A = Not available
UN = United Nations

References : HCS (U.S.A.)- Hazard Communication Standard
International transport regulations

Indicates information that has changed from previously issued version.

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

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