



SAFET DATA SHEET (SDS)

Propofol Injectable Emulsion USP, 10 mg/mL (20 mL), 10 mg/mL (50 mL), 10 mg/mL (100 mL)

• SECTION – 1: IDENTIFICATION

Product Name	Propofol Injectable Emulsion USP, 10 mg/mL (20 mL), 10 mg/mL (50 mL), 10 mg/mL (100 mL)
Name of the organization	Amneal Pharmaceuticals Pvt. Ltd. Amneal Parenteral Unit, Pipan, Taluka –Sanand, District –
Use of the Substance/Mixture	Pharmaceuticals
Emergency contact numbers	Phone: +91 2717 684300

• SECTION - 2: HAZARDS IDENTIFICATION

Principal Hazards of the product	Not classified as hazardous
Harmful Effect of the drug on Health	Eye: Causes eye irritation. Skin: Causes skin irritation. May be harmful if absorbed through the skin. Ingestion: Harmful if swallowed. May cause irritation of the digestive tract. Inhalation: Causes respiratory tract irritation. May be harmful if inhaled. Chronic: Prolonged or repeated skin contact may cause dermatitis. Effects may be delayed. Individuals with Wilson's disease are unable
Effects on the Environment	Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.
Physical & Chemical Hazards	None under normal processing

• SECTION – 3: COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	CAS Number
Propofol, USP	2078-54-8
Sodium Hydroxide NF	1310-73-2
Soybean Oil USP	8001-22-7
Egg Lecithin NF	8002-43-5
Glycerol USP	56-81-5



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Edetate Disodium USP	6381-92-6
Water for Injection USP	7732-18-5

Note: The exact percentage composition of this mixture has been withheld as a trade secret

• SECTION - 4: FIRST-AID MEASURES

Contact With Skin	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention
Contact With Eyes	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention.
Inhalation	Remove to fresh air. Seek immediate medical attention/advice.
Instruction for the physician	Treat symptomatically and supportively.
Protection for first aiders	Use a mask, safety glasses and gloves. Wash the hand with plenty of water.

• SECTION - 5: FIRE-FIGHTING MEASURES

Flammability	Fine particles (such as mists) may fuel fires/explosions. Formation of toxic gases is possible during heating or fire.
Fire & Explosion Hazard	None anticipated for this aqueous product.
Fire extinguishing media	Dry chemical, CO ₂ , alcohol-resistant foam or water spray
Protection equipment	Firefighters should wear self-contained breathing apparatus and full firefighting. Turnout gear. Use personal protection equipment.

• SECTION – 6: ACCIDENTAL RELEASE MEASURES

Personal precautions	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
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Precautions for Environmental Protection	Place waste in an appropriately labelled, sealed container for disposal. Care should be taken to avoid environmental release.
Cleaning methods	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Dispose of spill materials according to the applicable federal, state, or local regulations.

• **SECTION -7: HANDLING AND STORAGE**

Handling Appropriate technical measures	Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Recommended 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.
Recommended packaging materials	Injection/Vials in Carton in Corrugated boxes (or As per label instructions)

• **SECTION - 8: EXPOSURE CONTROL/PERSONAL PROTECTION**

Technical measures	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.
Respiratory protection	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.
Hand protection	Wear impervious gloves.
Eye protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.



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Body and skin protection	Wear appropriate protective gloves and clothing to prevent skin exposure.
Specific safety protection	Do not drink or eat during handling.

• SECTION - 9: PHYSICAL AND CHEMICAL PROPERTIES

Colour description of the vials or Appearance	White Milky Emulsion
Form	Liquid
Odor	No data Available
Water Solubility	Soluble in water
Boiling Point	No data Available
Melting Point	No data Available
Specific gravity	No data Available
Percent Volite	No data Available

• SECTION - 10: STABILITY AND REACTIVITY

Stability	Stable under standard use and storage conditions
Conditions to avoid	Not determined
Materials to avoid	Not determined.
Hazardous decomposition Products	No data available
Incompatibility	As a precautionary measure, keep away from strong oxidizers
Hazardous Polymerization	No data available

• SECTION - 11: TOXICOLOGICAL INFORMATION

Routes of Entry: Propofol USP	Information on the absorption of this product via inhalation or skin contact is no available. Avoid liquid aerosol generation and skin contact.
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Toxicity to Animals: Acute	Propofol Rat Oral LD50 500 mg/kg Mouse Oral LD50 1100 mg/kg Rabbit Dermal LD50 > 2000 mg/kg Sodium hydroxide Mouse IP LD50 40 mg/kg Glycerol, USP Mouse Oral LD50 4090 mg/kg Rat Oral LD50 12.6 g/kg Rabbit Dermal LD50 > 10 g/kg Rat Inhalation LC50 1hr > 570 mg/m ³ Rat Dermal LD 50 > 21.9 g/kg Lecithin Rat Oral LD50 > 8 ml/kg Edetate disodium Rat Oral LD50 2000-2200 mg/kg
Effects on Humans	The following information is available for the individual ingredients. Short term May cause eye and skin irritation (based on components) Known Clinical Effects: Clinical use of this drug has caused slow heart rate (bradycardia), decrease in blood pressure (hypotension), respiratory depression, skin rash, cough, drowsiness, sleepiness, dizziness, sedation, and gastrointestinal disturbance
Special Remarks on Chronic Effects on Humans:	No known significant effects or critical hazards.

• SECTION - 12: ECOLOGICAL INFORMATION

Persistence / degradation of The Product	No information available.
Bioaccumulation	No information available
Aquatic Toxicity	No information available

• SECTION - 13: DISPOSAL CONSIDERATIONS

Product disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
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• SECTION - 14: TRANSPORT INFORMATION

IATA/ICAO – Not Regulated IATA Proper shipping Name: N/A IATA UN/ID No: N/A IATA Hazard Class: N/A IATA Packaging Group: N/A IATA Label: N/A	IMDG - Not Regulated IMDG Proper shipping Name: N/A IMDG UN/ID No: N/A IMDG Hazard Class: N/A IMDG Flash Point: N/A IMDG Label: N/A
DOT - Not Regulated DOT Proper shipping Name: N/A DOT UN/ID No: N/A DOT Hazard Class: N/A DOT Flash Point: N/A DOT Packing Group: N/A DOT Label: N/A	

• SECTION - 15: REGULATORY INFORMATION

This Section Contains Information relevant to compliance with other Federal and/or state laws.

• SECTION - 16: OTHER INFORMATION

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

• Revision History: -

Issue date	23-May-2024
Revision date	NA
Version #	000
Further information if any,	No

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