Emcure

# Safety Data Sheet
# Propofol Injectable Emulsion

## 1. PRODUCT AND COMPANY IDENTIFICATION

**Common name** : Propofol Injectable Emulsion

**Category** : Intravenous (IV) sedative-hypnotic agent

**Product Use** : Pharmaceutical product

**Manufacturer** : Emcure Pharmaceuticals Limited
Plot No. SM 14, 15 & 16/1, GIDC, Sanand-II, Charal,
Tal- Sanand, Dist- Ahmedabad - 382 110,
Gujarat, India.

## 2. HAZARDS IDENTIFICATION

**Signal word** : Not classified

**Hazard statements** : Non-hazardous in accordance with international standards for workplace safety.

**Other hazards** : An Occupational Exposure Value has been established for one or more of the ingredients
(see Section 8).

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

| Ingredient | Quantity/mL | CAS No. |
|---|---|---|
| Propofol | 10.0 mg | 2078-54-8 |
| Soybean oil | 100.0 mg | 8001-22-7 |
| Glycerine | 22.5 mg | 56-81-5 |
| Egg Phospholipid | 12.0 mg | 93685-90-6 |
| Edetate Disodium | 0.055 mg | 6381-92-6 |
| Sodium Hydroxide | q.s. to adjust pH | 1310-73-2 |

## 4. FIRST AID MEASURES

**Eye Contact** : Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.
Consult a physician.

**Skin Contact** : Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek
medical attention.

**Inhalation** : Remove to fresh air. Seek immediate medical attention/advice.

**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 immediately.

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## 5. FIRE FIGHTING MEASURES

| | | |
|---|---|---|
| **Specific hazards arising from the chemical** | : | Fine particles (such as mists) may fuel fires/explosions. |
| **Extinguishing media** | : | Dry chemical, CO2, alcohol-resistant foam or water spray. |
| **Hazardous combustion products** | : | Formation of toxic gases is possible during heating or fire. |
| **Special protective equipment for fire-fighters** | : | Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment. |

## 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| **Personal precautions** | : | Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure. |
| **Environmental Precautions** | : | Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release. |

**Methods and materials for containment and cleaning up**

| | | |
|---|---|---|
| **Methods for containment** | : | Prevent further leakage or spillage if safe to do so. |
| **Methods for cleaning up** | : | Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. |
| **Prevention of secondary hazards** | : | Clean contaminated objects and areas thoroughly observing environmental regulations. |

## 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| **Precautions for Safe Handling** | : | 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** | : | Store as directed by product packaging. |

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

| | | |
|---|---|---|
| **Engineering controls** | : | 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. Keep airborne contamination levels below the exposure limits listed above in this section. |
| **Personal Protective Equipment** | : | Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes. |
| **Hands** | : | Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent). |
| **Skin and body protection** | : | Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.). |
| **Eye protection** | : | Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.). |
| **Respiratory protection** | : | Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter).<br>(Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.). |

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## 9. PHYSICAL AND CHEMICAL PROPERTIES

| | | |
|---|---|---|
| **Physical state** | : | Oily emulsion |
| **Color** | : | White |
| **Molecular Weight** | : | Mixture |
| **Odor** | : | None |
| **Odor Threshold** | : | Not available. |
| **pH** | : | 7-8.5 |
| **Melting Point** | : | Not available |
| **Freezing Point** | : | Not available |
| **Boiling Point** | : | 242°C (468°F) |
| **Water Solubility** | : | Soluble |
| **Upper Flammable Limit** | : | Not available |
| **Lower Flammable Limit** | : | Not available |
| **Vapor Pressure** | : | Not available |
| **Vapor Density** | : | Not available |
| **Relative density** | : | Not available |
| **Partition Coefficient** | : | (Method, pH, Endpoint, Value)<br>**Propofol**<br>Measured Log P 3.8 |
| **Viscosity** | : | Not available |

## 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| **Reactivity** | : | No data available |
| **Chemical Stability** | : | Stable under normal conditions. |
| **Possibility of hazardous reaction** | : | No information available. |
| **Conditions to avoid.** | : | Fine particles (such as mists) may fuel fires/explosions. |
| **Incompatible materials** | : | As a precautionary measure, keep away from strong oxidizers. |
| **Hazardous Decomposition Products** | : | No data available. |

## 11. TOXICOLOGICAL INFORMATION

**Acute toxicity**

| Component | Test Type | Route of Administration | Species | Dosage |
|---|---|---|---|---|
| **Propofol** | LD50 | Oral<br>Oral<br>Dermal | Rat<br>Mouse<br>Rabbit | 500 mg/ kg<br>1100 mg/ kg<br>>2000 mg/ kg |

| | | |
|---|---|---|
| **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 |
| **Carcinogenicity** | : | None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. |

## 12. ECOLOGICAL INFORMATION

| | | |
|---|---|---|
| **Toxicity** | : | **Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**<br>**Glycerin, USP**<br>*Oncorhynchus mykiss* (Rainbow Trout) N/A LC50 96 hours 50 mg/l<br>*Daphnia magna* (Water Flea) N/A EC50 24 hours > 500 mg/L |
| **Persistence and degradability** | : | No information available. |
| **Bioaccumulation potential** | : | **Partition Coefficient: (Method, pH, Endpoint, Value)**<br>**Propofol**<br>Measured Log P 3.8 |
| **Mobility in soil** | : | No information available. |
| **Other adverse effects** | : | No information available. |

## 13. DISPOSAL CONSIDERATIONS

**Waste Disposal** : Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## 14. TRANSPORT INFORMATION

**The following refers to all modes of transportation unless specified below.**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## 15. REGULATORY INFORMATION

**Propofol**

| | | |
|---|---|---|
| TSCA: | : | Present |
| CERCLA | : | Not Listed |
| EINECS | : | 218-206-6 |

| | | |
|---|---|---|
| SARA 313 | : | Not Listed |
| AICS | : | Present |
| Standard for Uniform Scheduling of Medicines and Poisons (SUSMP) | : | Schedule 4 |

## 16. OTHER INFORMATION

**Date of Preparation:** 14 Mar 2022

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