SAFETY DATA SHEET

Phytonadione Injectable Emulsion USP 10mg/mL

Section 1: IDENTIFICATION OF THE SUBSTANCE

1.1. Product identifier

Product Name Phytonadione Injectable Emulsion, USP

1.2. Details of the supplier of the safety data sheet

Caplin Steriles Ltd.
Survey No 895 & 897
Guruvarajakandigai
Sirupuzhalpettai (post)
Gummidipoondi Taluk,
Thiruvallur District
601201.
India.

Section 2: HAZARDS IDENTIFICATION

2.1. Emergency overview

Phytonadione Injectable Emulsion, USP is an aqueous dispersion for parenteral injection. Clinically, it is indicated for coagulation disorders caused by vitamin K deficiency or interference with vitamin K activity. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract and a potential sensitizer. Based on clinical use, possible target organs include the lungs, cardiovascular system and blood.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified
Health Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Label element (s)

Pictogram	NA
Signal Word	NA
Hazard statemet(s)	NA
Precautionary statement(s)	
Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention if you feel unwell If in EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Phytonadione

Chemical Formula C31H46O2

Component	Qty/mL	CAS Number	EU EINECS/ELINCS LIST
Phytonadione	10.0 mg	84-80-0	201-564-2
Polyoxyl 35 castor oil (Polyoxyehylated fatty acid derivative)	70.0 mg	61791-12-6	Not Listed
Dextrose	37.50 mg	5996-10-1	Not Listed
Benzyl alcohol	9.0 mg	100-51-6	202-859-9
Hydrochloric acid	q.s. to pH	231-595-7	231-595-7

Section 4: FIRST AID MEASURES

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

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.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Section 5: FIRE-FIGHTING MEASURES

Flammability	None anticipated for this aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous product.
Extinguishing Media	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
Specific hazards arising from the chemical	Fine particles (such as dust and mists) may fuel fires/explosions.

Section 6: ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Section 7: HANDLING AND STORAGE

Handling No special handling required for hazard control under conditions of normal product use.

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.

Special Precautions No special precautions required for hazard control.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**EEL**
Phytonadione Polyoxyl 35 castor oil (Polyoxyethylated fatty acid derivative)	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average

Engineering controls	Engineering controls are normally not needed during the normal use of this product.
Eye protection	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.
Skin and body protection	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Respiratory protection	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance/Physical State	A yellow, sterile, nonpyrogenic aqueous dispersion
Odor	NA
Odor Threshold	NA
pH	3.5 to 7.0
Melting point / freezing point	No data available
Initial Boiling point / boiling point range	NA
Flash point	NA
Evaporation rate	NA
Flammability (solid, gas)	NA
Upper/Lower flammability or Explosive limits:	NA
Vapor pressure	NA
Vapor density	NA

Relative density	NA
Solubility	NA
Solubility	NA
Partition coefficient: n-octanol/water	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
Viscosity	NA

Section 10: STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Conditions to Avoid	Not determined.
Incompatibilities	Not determined.
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides.
Hazardous Polymerization	Not anticipated to occur with this product.

Section 11: TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Phytonadione	100	LD50	Oral	>33, 487 25,000	mg/kg mg/kg	Rat Mouse
Phytonadione	100	LD50	Intravenous	>6570	mg/kg	Mouse
Polyoxyl 35 castor oil NF (Polyoxyehylated fatty acid derivative)	100	LD50	Oral	>6.400	mg/kg	Rat
Polyoxyl 35 castor oil NF (Polyoxyehylated fatty acid derivative)	100	LD50	Dermal	>5.000	mg/kg	Rat
Benzyl alcohol	100	LD50	Inhalation	>4178	mg/m^3	Rat

LD 50: Dosage that produces 50% mortality.

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, Phytonadione is relatively nontoxic; however, severe reactions have occurred rarely during or immediately after intravenous administration. These reactions resemble hypersensitivity or anaphylaxis with symptoms that include cramp-like pains, convulsive movements, cardiac irregularities, chest pains, cyanosis, dulled consciousness, flushing of the face, a sense of chest constriction, circulatory collapse, bronchospasm, hyperhidrosis, dyspnea, alteration of taste, dizziness, rapid and weak pulse, brief hypotension, shock, cardiac and/or respiratory arrest, and death. It is not known whether these adverse reactions are caused by the drug or the injection vehicle. Skin lesions have also been reported following intramuscular administration of Phytonadione. They are described as localized red, tender, infiltrated plaques.
Aspiration Hazard	None anticipated from normal handling of this product
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, severe reactions, including fatalities, have occurred during and immediately after intravenous administration of this product. These severe reactions have resembled hypersensitivity or anaphylaxis, including shock and cardiac and/or respiratory arrest. Some patients have exhibited these severe reactions on receiving Phytonadione for the first time.
Reproductive Effects	None anticipated from normal handling of this product
Mutagenicity	Studies to evaluate the mutagenic potential have not been conducted with Vitamin K1 Injection
Carcinogenicity	Studies to evaluate the carcinogenic potential have not been conducted with Vitamin K1 Injection.

Section 12: ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Section 13: DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

Section 14: TRANSPORT INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

Section 15: REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65.

GHS/CLP Classification*	*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user
Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.
EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

Section 16: OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

Revision Date	Not applicable.
Revision Note	New SDS.

Disclaimer

Caplin Steriles Ltd. considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the product and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals.

Caplin Steriles Ltd. shall not be held liable for any loss, injury or damage from contact with the product.

End of Safety Data Sheet