

MATERIAL SAFETY DATA SHEET

Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency 224-212-2000

Product Name Vitamin K1 Injection - Phytonadione Injectable Emulsion

Synonyms 2-methyl-3-phytyl-1, 4-naphthoquinone

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Phytonadione

Chemical Formula C₃₁H₄₆O₂

Preparation Non-hazardous ingredients include Water for Injection and dextrose. Hazardous ingredients present at less than 1% include benzyl alcohol. Hydrochloric acid may be used to adjust the pH.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Cremophor EL	7	61791-12-6	GO5661000
Phytonadione	≤1	84-80-0	QJ5800000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Cremophor EL	Not Listed	Not Listed	Not Listed
Phytonadione	Not Listed	Not Listed	Not Listed

Emergency Overview Vitamin K1 Injection - Phytonadione Injectable Emulsion is an aqueous dispersion of vitamin K1 (phytonadione) 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.

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 known from workplace exposures. 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

Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion



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.

Medical Conditions Aggravated by Exposure	Pre-existing hypersensitivity to this or similar materials; pre-existing respiratory, cardiovascular, or blood disorders.
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4. FIRST AID MEASURES

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.
Inhalation	Remove from source of exposure. If 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.

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.
Special Fire Fighting Procedures	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill 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.
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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.

Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion**Special Precautions**

No special precautions required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Exposure Guidelines**

Component	Exposure limits				
	Type	mg/m3	ppm	µg/m3	Note
Cremophor EL	Not Applicable	N/A	N/A	N/A	None Established
Phytonadione	Not Applicable	N/A	N/A	N/A	None Established

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.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

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.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Yellow, sterile
Odor	NA
Odor Threshold:	NA
pH:	6.3 (5.0 to 7.0)
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	NA
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

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 (COx).
Hazardous Polymerization	Not anticipated to occur with this product.

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
*Cremophor EL	100	LD50	Oral	>6400	mg/kg	Rat
Cremophor EL	100	LD50	Intravenous	6500 640	mg/kg mg/kg	Mouse Dog
*Cremophor EL	100	LD50	Dermal	>5000	mg/kg	Rat

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. 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	Studies to evaluate the effects on fertility or fetal development have not been conducted with Vitamin K1 Injection.
Mutagenicity	Studies to evaluate the mutagenic potential have not been conducted with Vitamin K1 Injection.

Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion



Carcinogenicity	Studies to evaluate the carcinogenic potential have not been conducted with Vitamin K1 Injection.
Target Organ Effects	Based on clinical use, possible target organs include the lungs, cardiovascular system and blood.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. Information for ingredients follows: <i>Leuciscus idus</i> /LC50 (24 h): 713 mg/l for Cremophor EL <i>Leuciscus idus</i> /LC50 (48 h): 448 mg/l for Cremophor EL <i>Daphnia magna</i> /EC50 (48 h): > 100 mg/l for Cremophor EL
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

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.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:	Not regulated
IMDG STATUS:	Not regulated
ICAO/IATA STATUS:	Not regulated
Transport Comments:	None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Cremophor EL	Listed	Not Listed	Not Listed	Not Listed	Not Listed
Phytonadione	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status	Not Listed
U.S. OSHA Classification	Possible Sensitizer Target Organ Toxin Possible Irritant

GHS 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:
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Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion



Hazard Class	Not Applicable
Hazard Category	Not Applicable
Signal Word	Not Applicable
Symbol	Not Applicable
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapours/spray.
Hazard Statement	Not Applicable
Response:	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. Wash hands after handling. Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Phytonadione

Classification(s):	Not Applicable
Symbol:	Not Applicable
Indication of Danger:	Not Applicable
Risk Phrases:	Not Applicable
Safety Phrases:	S23 - Do not breathe vapor. S24/25 - Avoid contact with skin and eyes. S37/39 - Wear suitable gloves and eye/face protection.

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
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion



MSDS Coordinator: Hospira GEHS

Date Prepared: 10/19/2012

Obsolete Date: 11/08/2011

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