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 (02) 8014 4880

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 C$_{31}$H$_{46}$O$_{2}$

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cremophor EL</td>
<td>7</td>
<td>61791-12-6</td>
<td>GO5661000</td>
</tr>
<tr>
<td>Phytonadione</td>
<td>$\leq$1</td>
<td>84-80-0</td>
<td>QJ5800000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cremophor EL</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Phytonadione</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

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
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.

4. FIRST AID MEASURES

<table>
<thead>
<tr>
<th>Condition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye contact</td>
<td>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.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>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.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.</td>
</tr>
</tbody>
</table>

5. FIRE FIGHTING MEASURES

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Fire &amp; Explosion Hazard</td>
<td>None anticipated for this aqueous product.</td>
</tr>
<tr>
<td>Extinguishing media</td>
<td>As with any fire, use extinguishing media appropriate for primary cause of fire.</td>
</tr>
<tr>
<td>Special Fire Fighting</td>
<td>No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.</td>
</tr>
<tr>
<td>Procedures</td>
<td></td>
</tr>
</tbody>
</table>

6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spill Cleanup and Disposal</td>
<td>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.</td>
</tr>
</tbody>
</table>

7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling</td>
<td>No special handling required for hazard control under conditions of normal product use.</td>
</tr>
<tr>
<td>Storage</td>
<td>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.</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>mg/m3</td>
</tr>
<tr>
<td>Cremophor EL</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
<tr>
<td>Phytonadione</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;33, 487</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>25,000</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Phytonadione</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>&gt;6570</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>*Cremophor EL</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;6400</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>Cremophor EL</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>6500</td>
<td>mg/kg</td>
<td>Mouse</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>640</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>*Cremophor EL</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>&gt;5000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
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</table>

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: Leuciscus idus/LC50 (24 h): 713 mg/l for Cremophor EL Leuciscus idus/LC50 (48 h): 448 mg/l for Cremophor EL Daphnia magna/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

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cremophor EL</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Phytonadione</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
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</table>

RCRA Status  
Not Listed

U.S. OSHA Classification  
Possible Sensitizer

Target Organ Toxicity  
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:
Product Name: Vitamin K1 Injection - Phytonadione Injectable Emulsion

Hazard Class: Not Applicable
Hazard Category: Not Applicable
Signal Word: Not Applicable
Symbol: Not Applicable
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: 11/08/2011
Obsolete Date: 10/21/2008

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