



Section 1. Product and Company Identification

Product Name Vitamin K1
CAS Number 84-80-0

Parchem - fine & specialty chemicals
415 Huguenot Street
New Rochelle, NY 10801
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EMERGENCY RESPONSE NUMBER
CHEMTEL
Toll Free US & Canada: 1 (800) 255-3924
All other Origins: 1 (813) 248-0585
Collect Calls Accepted

Section 2. Hazards Identification

Classification of the substance or mixture

Not a hazardous substance or mixture

GHS Label Elements

Pictograms: N/A

Signal word: N/A

Hazard and precautionary statements

None

NFPA Rating

Health: 2

Fire: 1

Reactivity: 0

HMIS Rating

Health: 2

Flammability: 1

Reactivity: 0

Personal Protection: J

Potential Acute Health Effects: Hazardous in case of eye contact (irritant), of ingestion, of inhalation.

Potential Chronic Health Effects: Hazardous in case of eye contact (irritant), of ingestion, of inhalation.

Carcinogenic Effects: Not available

Mutagenic Effects: Not available

Teratogenic Effects: Not available

Developmental Toxicity: Not available



The substance is toxic to mucous membranes.
Repeated or prolonged exposure to the substance can produce target organs damage.

Section 3. Composition / Information on Ingredients

Common Name Vitamin K1
Synonym(s) Phytomenadione
Formula $C_{31}H_{46}O_2$
CAS Number 84-80-0

| COMPONENT | CAS NUMBER | CONCENTRATION |
|------------|------------|---------------|
| Vitamin K1 | 84-80-0 | 97 - 103% |

Section 4. First Aid Measures

Persons using these products should consult a physician or other medical professional if an accident involving these products in injury. Specific first-aid measures are as follows:

Eye Contact: Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.

Skin Contact: No known effect on skin contact, rinse with water for a few minutes.

Inhalation: Allow the victim to rest in a well ventilated area. Seek immediate medical attention.

Ingestion: Do not induce vomiting. Loosen tight clothing such as a collar, tie, belt, or waistband. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek immediate medical attention.

Serious Ingestion: Not available.

Section 5. Firefighting Measures

Flammability: May be combustible at high temperature.

Auto-Ignition Temperature: Not applicable

Flash Point: Not applicable

Flammable Limits: Not applicable

Products of Combustion: Carbon oxides (CO, CO₂)

Fire Hazards in Presence of Various Substances: Not available

Explosion Hazards in Presence of Various Substances

Risks of explosion of the product in presence of mechanical impact: Not available

Risks of explosion of the product in presence of static discharge: Not available

Fire Fighting Media and Instructions

Small Fire: Use DRY chemical powder

Large Fire: Use water spray, fog, or foam. Do not use water jet.

Special Remarks on Fire Hazard: Not available

Special Remarks on Explosion Hazard: Not available



Section 6. Accidental Release Measures

Small Spill: Absorb with an inert material and put the spilled material in an appropriate waste disposal.

Large Spill: Absorb with an inert material and put the spilled material in an appropriate waste disposal. Finish cleaning by spreading water on the contaminated surface and allow evacuation through the sanitary system.

Section 7. Handling and Storage

Precautions: Keep away from heat. Keep away from sources of ignition. Empty containers pose a fire risk; evaporate the residue under a fume hood. Ground all equipment containing material. Do not ingest. Do not breathe gas/fumes/vapor/spray.

Avoid contact with eyes. Wear suitable protective clothing. In case of insufficient ventilation, wear suitable respiratory equipment. If ingested, seek medical advice immediately and show the container or the label.

Drug Interactions: Temporary resistance to prothrombin-depressing anticoagulants may result, especially when larger doses of Phytonadione are used. If relatively large doses have been employed, it may be necessary when reinstating anticoagulant therapy to use somewhat larger doses of the prothrombin-depressing anticoagulant, or to use one which acts on a different principle, such as heparin sodium.

Laboratory Tests: Prothrombin time should be checked regularly as clinical conditions indicate. Carcinogenesis, Mutagenesis, Impairment of Fertility Studies of carcinogenicity, mutagenesis, or impairment of fertility have not been conducted with Vitamin K1 Injection (Phytonadione Injectable Emulsion, USP).

Pregnancy: Pregnancy Category C: Animal reproduction studies have not been conducted with Vitamin K1 Injection. It is also not known whether Vitamin K1 Injection can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Vitamin K1 Injection should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Vitamin K1 injection is administered to a nursing woman.

Pediatric Use: Hemolysis, jaundice, and hyperbilirubinemia in neonates, particularly those that are premature, may be related to the dose of Vitamin K1 Injection. Therefore, the recommended dose should not be exceeded (see ADVERSE REACTIONS and DOSAGE AND ADMINISTRATION).

Storage: Keep container dry. Keep in a cool place. Ground all equipment containing material. Keep container tightly closed. Keep in a cool, well-ventilated place. Combustible materials should be stored away from extreme heat and away from strong oxidizing agents.

Indications and Usage for Vitamin K1: Vitamin K1 Injection (Phytonadione Injectable Emulsion, USP) is indicated in the following coagulation disorders which are due to faulty formation of factors II, VII, IX, and X when caused by vitamin K deficiency or interference with vitamin K activity. Vitamin K1 Injection is indicated in: anticoagulant-induced prothrombin deficiency caused by coumarin or indanedione derivatives; prophylaxis and therapy of hemorrhagic disease of the newborn; hypoprothrombinemia due to antibacterial therapy; hypoprothrombinemia secondary to



factors limiting absorption or synthesis of vitamin K, e.g., obstructive jaundice, biliary fistula, sprue, ulcerative colitis, celiac disease, intestinal resection, cystic fibrosis of the pancreas, and regional enteritis; other drug-induced hypoprothrombinemia where it is definitely shown that the result is due to interference with vitamin K metabolism.

Section 8. Exposure Controls / Personal Protection

Engineering Controls: Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection: Splash goggles; lab coat; vapor respirator. Be sure to use an approved/certified respirator or equivalent.

Personal Protection in Case of a Large Spill: Splash goggles; full suit; vapor respirator; boots; gloves. A self-contained breathing apparatus should be used to avoid inhalation of the product. Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.

Exposure Limits: Not available.

Section 9. Physical and Chemical Properties

Physical State & Appearance: Viscous liquid

Odor: Odorless or almost odorless

Taste: Not available

Molecular Weight: Not available

Density: 0.97 g/cm³

Color: Yellow to orange

pH (1% solution/water): Not available

Boiling Point: 140 - 145°C

Melting Point: -20°C

Critical Temperature: Not applicable

Vapor Pressure: Not applicable

Vapor Density: Not available

Volatility: Not available

Odor Threshold: Not available

Water/Oil Dist. Coefficient: Not available

Ionicity (in water): Not available

Dispersion Properties: Not available

Viscosity: General

Solubility: Insoluble in water

Section 10. Stability and Reactivity

Stability: This product is stable.

Instability Temperature: Not available



Conditions of Instability: Not available
Incompatibility with Various Substances: Not available
Corrosivity: Not available
Special Remarks on Reactivity: Not available
Special Remarks on Corrosivity: Not available
Polymerization: Will not occur

Section 11. Toxicological Information

Routes of Entry: Eye contact, inhalation, ingestion.
Toxicity to Animal: Acute oral toxicity (LD50): 25,000 mg/kg [Rat].
Chronic Effects: The substance is toxic to mucous membranes.
Other Toxic Effects on Humans: Hazardous in case of ingestion, of inhalation.
Special Remarks on Toxicity to Animals: Not available
Special Remarks on Chronic Effects on Humans: Passes through the placental barrier in animal.
Adverse Reactions: Deaths have occurred after intravenous and intramuscular administration. (See Box Warning). Transient "flushing sensations" and "peculiar" sensations of taste have been observed, as well as rare instances of dizziness, rapid and weak pulse, profuse sweating, brief hypotension, dyspnea, and cyanosis. Pain, swelling, and tenderness at the injection site may occur. The possibility of allergic sensitivity including an anaphylactic reaction, should be kept in mind. Infrequently, usually after repeated injection, erythematous, indurated, pruritic plaques have occurred; rarely, these have progressed to scleroderma-like lesions that have persisted for long periods. In other cases, these lesions have resembled erythema perstans. Hyperbilirubinemia has been observed in the newborn following administration of Phytonadione. This has occurred rarely and primarily with doses above those recommended. (See PRECAUTIONS, Pediatric Use.)
Special Remarks on Other Toxic Effects on Humans: Not available

Section 12. Ecological Information

Ecotoxicity: Not available
BOD5 and COD: Not available
Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
Toxicity of the Products of Biodegradation: The products of degradation are more toxic.
Special Remarks on the Products of Biodegradation: Not available

Section 13. Disposal Considerations

Waste Treatment Methods: Dispose of product and contaminated packaging in accordance with all local, state, and federal environmental control regulations.



Section 14. Transport Information

DOT Regulations: Not Regulated

Land Transport ADR/RID (Cross-Border): Not regulated

Maritime Transport IMDG: Not regulated

Marine Pollutant: Not listed in Appendix B to 49CFR172.101

Air Transport ICAO-TI and IATA-DGR: Not regulated

Packaging: 10 kg/carton; 10 x 1 kg tin/carton

Section 15. Regulatory Information

SARA

Section 355 (extremely hazardous substances): None of the ingredient is listed.

Section 313 (specific toxic chemical listing): None of the ingredient is listed.

TSCA (toxic substance control act): None of the ingredient is listed.

Proposition 65

Chemical Known to Cause Cancer: None of the ingredient is listed.

Chemical Known to Cause Reproductive Toxicity for Females: None of the ingredient is listed.

Chemical Known to Cause Reproductive Toxicity for Males: None of the ingredient is listed.

Chemical Known to Cause Developmental Toxicity: None of the ingredient is listed.

Carcinogenicity Categories

EPA (Environmental Protection Agency): None of the ingredient is listed.

IARC (International Agency for Research on Cancer): None of the ingredient is listed.

NTP (National Toxicology Program): None of the ingredient is listed.

TLV (Threshold Limit Value Established by ACGIH): None of the ingredient is listed.

OSHA-Ca (Occupational Safety & Health Administration): None of the ingredient is listed.

Section 16. Other Information

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

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