

Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • **Phytonadione 5 mg Tablets**

Product Code • 368682170054; NDC 68682-170-05

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Finished Pharmaceutical Product; Phytonadione 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.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals International, Inc.
100 LifeSciences Parkway
Steinbach R5G 1Z7
Canada
valeant.com

Telephone (General) • 1-800-321-4576

Supplier • Oceanside Pharmaceuticals, a division of Valeant Pharmaceuticals N. America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

United States (US)

According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012 • Classification criteria not met

Label elements

OSHA HCS 2012

Other hazards

OSHA HCS 2012 • No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition		
Chemical Name	Identifiers	%
Arabic gum	CAS:9000-01-5 EINECS:232-519-5	N/A
Colloidal silicone dioxide	CAS:112945-52-5	N/A
Corn starch	CAS:9005-25-8 EINECS:232-679-6	N/A
Dibasic calcium phosphate dihydrate	CAS:7789-77-7	N/A
Lactose monohydrate	CAS:5989-81-1	N/A
Magnesium stearate	CAS:557-04-0 EINECS:209-150-3	N/A
Phytonadione (Vitamin K1)	CAS:84-80-0 EINECS:201-564-2	3.85%
Talc	CAS:14807-96-6 EINECS:238-877-9	N/A

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention if cough or other symptoms develop.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- 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 advice/attention.

Ingestion

- No specific treatment is necessary since this material is not hazardous by ingestion when used in accordance with product literature. If quantities exceeding the recommended intake are accidentally ingested, get medical attention immediately.

Most important symptoms and effects, both acute and delayed

- Refer to Section 11 - Toxicological Information.

Indication of any immediate medical attention and special treatment needed

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- LARGE FIRE: Water spray, fog or regular foam.
 - SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.

- Unsuitable Extinguishing Media**
- No data available

- Firefighting Procedures**
- As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- No data available

- Hazardous Combustion Products**
- No data available.

Advice for firefighters

- No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

- Emergency Procedures**
- No emergency procedures are expected to be necessary if material is used under ordinary conditions as recommended. For bulk material spills, keep unauthorized personnel away. Isolate spill area and stop source of release if safe to do so. Ensure adequate ventilation.

Environmental precautions

- No data available on the environmental impact of this product. Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- For bulk material spills: Contain spilled product. For small spills, scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

- Prohibited Materials**
- None known.

Section 7 - Handling and Storage

Precautions for safe handling

- Handling**
- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Wash thoroughly with warm water and soap after handling.

Conditions for safe storage, including any incompatibilities

- Storage**
- Keep tightly closed. Store at controlled room temperature 25°C/77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container. Protect from light.

Section 8 - Exposure Controls/Personal Protection

Control parameters

- Exposure Limits/Guidelines**
- Refer to the occupational exposure limits / guidelines for the individual product

components.

Exposure Limits/Guidelines					
	Result	ACGIH	Canada Quebec	NIOSH	OSHA
Talc (14807-96-6)	TWAs	2 mg/m ³ TWA (particulate matter containing no asbestos and <1% crystalline silica, respirable fraction)	3 mg/m ³ TWAEV (respirable dust)	2 mg/m ³ TWA (containing no Asbestos and <1% Quartz, respirable dust)	Not established
Corn starch (9005-25-8)	TWAs	10 mg/m ³ TWA	10 mg/m ³ TWAEV (containing no Asbestos and <1% Crystalline silica, total dust)	10 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable dust)	15 mg/m ³ TWA (total dust); 5 mg/m ³ TWA (respirable fraction)

Exposure Control Notations**ACGIH**

- Corn starch (9005-25-8): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen)
- Talc (14807-96-6): **Carcinogens:** (A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers))

Exposure Limits Supplemental**OSHA**

- Talc (14807-96-6): **Mineral Dusts:** (20 mppcf TWA (if 1% Quartz or more, use Quartz limit))

ACGIH

- Corn starch (9005-25-8): **TLV Basis - Critical Effects:** (dermatitis)
- Talc (14807-96-6): **TLV Basis - Critical Effects:** (pulmonary fibrosis (containing no asbestos fibers); pulmonary function (containing no asbestos fibers))

Exposure controls**Engineering****Measures/Controls****Personal Protective Equipment****Respiratory**

- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.
- No special controls or personal protection required under conditions of intended use. In the event of a bulk spill, a NIOSH-certified air-purifying respirator equipped with HEPA -organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits and when adequate oxygen is present. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

- No special personal protection required under conditions of intended use. In the event of a bulk spill, appropriate eye protection should be worn.

Hands

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear rubber or nitrile gloves.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties****Material Description**

Physical Form	Solid	Appearance/Description	Yellow, round, scored tablets coded VRX 405 on one side and MEPHYTON on the other.
Color	Yellow	Odor	Not relevant

General Properties

Boiling Point	No data available	Melting Point/Freezing Point	No data available
Decomposition Temperature	No data available	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	No data available
Viscosity	Not relevant		

Volatility

Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		

Flammability

Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		

Environmental

Octanol/Water Partition coefficient	No data available		
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Section 10: Stability and Reactivity**Reactivity**

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available.

Conditions to avoid

- Extreme heat or cold. Do not freeze. Protect from light.

Incompatible materials

- None known.

Hazardous decomposition products

- None known.

Section 11 - Toxicological Information**Information on toxicological effects**

- Other Material Information**
- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Phytonadione (Vitamin K1) (3.85%)	84-80-0	Acute Toxicity: Ingestion/Oral-Rat LD50 • >33487 mg/kg

GHS Properties	Classification
Acute toxicity	OSHA HCS 2012 • Classification criteria not met
Skin corrosion/Irritation	OSHA HCS 2012 • Classification criteria not met
Serious eye damage/Irritation	OSHA HCS 2012 • Classification criteria not met
Skin sensitization	OSHA HCS 2012 • Classification criteria not met
Respiratory sensitization	OSHA HCS 2012 • Classification criteria not met

Aspiration Hazard	OSHA HCS 2012 • Classification criteria not met
Carcinogenicity	OSHA HCS 2012 • Classification criteria not met
Germ Cell Mutagenicity	OSHA HCS 2012 • Classification criteria not met
Toxicity for Reproduction	OSHA HCS 2012 • Classification criteria not met
STOT-SE	OSHA HCS 2012 • Classification criteria not met
STOT-RE	OSHA HCS 2012 • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available

Skin

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available

Eye

- Acute (Immediate)** • Exposure to dust may cause irritation. Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available

Ingestion

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • No data available

Carcinogenic Effects			
	CAS	IARC	NTP
Arabic gum	9000-01-5	Not Listed	Evidence of Carcinogenicity
Talc	14807-96-6	Group 3-Not Classifiable	Evidence of Carcinogenicity
Phytonadione (Vitamin K1)	84-80-0	Group 3-Not Classifiable	Not Listed
Colloidal silicone dioxide	112945-52-5	Group 3-Not Classifiable	Not Listed

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available.

Mobility in Soil

- No data available.

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • No data available

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Phytonadione (Vitamin K1)	84-80-0	Yes	Yes	Yes
Lactose monohydrate	5989-81-1	No	No	No
Arabic gum	9000-01-5	Yes	Yes	Yes
Dibasic calcium phosphate dihydrate	7789-77-7	Yes	No	No
Corn starch	9005-25-8	Yes	Yes	Yes
Colloidal silicone dioxide	112945-52-5	Yes	No	No
Magnesium stearate	557-04-0	Yes	Yes	Yes
Talc	14807-96-6	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS 1988 - Classifications of Substances

• Magnesium stearate	557-04-0	Not Listed
• Arabic gum	9000-01-5	D2A
• Dibasic calcium phosphate dihydrate	7789-77-7	Not Listed
• Talc	14807-96-6	D2A
• Corn starch	9005-25-8	Uncontrolled product according to WHMIS

		classification criteria
• Lactose monohydrate	5989-81-1	Not Listed
• Phytonadione (Vitamin K1)	84-80-0	Not Listed
• Colloidal silicone dioxide	112945-52-5	Not Listed

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

• Magnesium stearate	557-04-0	Not Listed
• Arabic gum	9000-01-5	Not Listed
• Dibasic calcium phosphate dihydrate	7789-77-7	Not Listed
• Talc	14807-96-6	Not Listed
• Corn starch	9005-25-8	Not Listed
• Lactose monohydrate	5989-81-1	Not Listed
• Phytonadione (Vitamin K1)	84-80-0	Not Listed
• Colloidal silicone dioxide	112945-52-5	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Magnesium stearate	557-04-0	Not Listed
• Arabic gum	9000-01-5	Not Listed
• Dibasic calcium phosphate dihydrate	7789-77-7	Not Listed
• Talc	14807-96-6	Not Listed
• Corn starch	9005-25-8	Not Listed
• Lactose monohydrate	5989-81-1	Not Listed
• Phytonadione (Vitamin K1)	84-80-0	Not Listed
• Colloidal silicone dioxide	112945-52-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Magnesium stearate	557-04-0	Not Listed
• Arabic gum	9000-01-5	Not Listed
• Dibasic calcium phosphate dihydrate	7789-77-7	Not Listed
• Talc	14807-96-6	Not Listed
• Corn starch	9005-25-8	Not Listed
• Lactose monohydrate	5989-81-1	Not Listed
• Phytonadione (Vitamin K1)	84-80-0	Not Listed
• Colloidal silicone dioxide	112945-52-5	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Magnesium stearate	557-04-0	Not Listed
• Arabic gum	9000-01-5	Not Listed
• Dibasic calcium phosphate dihydrate	7789-77-7	Not Listed
• Talc	14807-96-6	Not Listed
• Corn starch	9005-25-8	Not Listed
• Lactose monohydrate	5989-81-1	Not Listed
• Phytonadione (Vitamin K1)	84-80-0	Not Listed
• Colloidal silicone dioxide	112945-52-5	Not Listed

Section 16 - Other Information

Revision Date • 02/November/2016

Last Revision Date • 02/November/2016

Preparation Date

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- 02/November/2016
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