Not appropriate for regulatory submission. Please visit www.spectrumchemical.com or contact Tech Services for the most up-to-date information contained in this information package.
Dear Customer,

Thank you for your interest in Spectrum’s quality products and services.

Spectrum has been proudly serving the scientific community for over 45 years. It is our mission to manufacture and distribute fine chemicals and laboratory products with Quality and delivery you can count on every time.

To accomplish our mission, Spectrum utilizes our sourcing leverage and supplier qualification expertise in offering one of the industry’s most comprehensive line of fine chemical products under one brand, in packaging configurations designed to meet your research and production requirements. Our product grades include: USP, NF, BP, EP, JP, FCC, ACS, KSA, Reagent grade, as well as DEA controlled substances. We operate facilities in the United States on the East Coast, West Coast, as well as in Shanghai, China in order to provide the best logistical support for our customers.

At Spectrum, Quality is priority number one. Suppliers with the best qualifications are preferred and we employ full-functioning in-house analytical laboratories at each of our facilities. Our facilities and systems are USFDA registered and ISO certified. We frequently host customer audits and cherish opportunities for improvements. Quality is engrained into our culture. Quality is priority number one.

In the following pages, we have designed and prepared documented scientific information to aid you in your initial qualification or your continual use of our products. Please do not hesitate to contact us if further information or the most up-to-date documentation is desired from any of the covered areas.

We appreciate your business and we look forward to hearing from you.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com
Table of Contents

- Product Specification
- Safety Data Sheet (SDS)
- Manufacturer
- Certification of Quality Management System (QMS)
- Certification of current Good Manufacturing Practices (cGMP)
- Product BSE/TSE Statement
- Product Allergen Statement
- Product Aflatoxin Statement
- Product Certificate of Analysis Sample(s)
- General Label Information – Sample Label
- General Lot Numbering System Guidance
- Stability – Shelf Life Guidance
- Halal Certificate
## Specification for Phytonadione, USP (PH195)

<table>
<thead>
<tr>
<th>Item Number</th>
<th>PH195</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Phytonadione, USP</td>
</tr>
<tr>
<td>CAS Number</td>
<td>84-80-0</td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C(<em>{31})H(</em>{46})O(_{2})</td>
</tr>
<tr>
<td>Molecular Weight</td>
<td>450.70</td>
</tr>
<tr>
<td>MDL Number</td>
<td></td>
</tr>
<tr>
<td>Synonyms</td>
<td>3-Phythylmenadione ; Vitamin K1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASSAY (C(<em>{31})H(</em>{46})O(_{2}))</td>
<td>Min 97.0  Max 103.0 %</td>
</tr>
<tr>
<td>REFRACTIVE INDEX @ 25°C</td>
<td>Min 1.523  Max 1.526</td>
</tr>
<tr>
<td>REACTION MENADIONE</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>Z-ISOMER CONTENT</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>IDENTIFICATION</td>
<td>TO PASS TEST</td>
</tr>
<tr>
<td>EXPIRATION DATE</td>
<td></td>
</tr>
<tr>
<td>DATE OF MANUFACTURE</td>
<td></td>
</tr>
<tr>
<td>APPEARANCE</td>
<td></td>
</tr>
<tr>
<td>RESIDUAL SOLVENTS</td>
<td>TO PASS TEST</td>
</tr>
</tbody>
</table>

---

**Spectrum Chemical Mfg Corp**

**Corporate Headquarters:**
769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

**West Coast Facility:**
14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000
SAFETY DATA SHEET

Product code: PH195
Product Name: PHYTONADIONE, USP

1. IDENTIFICATION

Product code: PH195
Product Name: PHYTONADIONE, USP

Other means of identification
Synonyms:
- Antihemorrhagic vitamin; Aqua mephyton; Combinal K1; Kativ N; Kaywan; Kephton; Kinadion; Konakion; Mephyton;
- 2-Methyl-3-(3,7,11,15-tetramethyl-2-hexadecenyl)-1,4-naphthalenedione;
- 1,4-Naphthalenedione,
- 2-methyl-3-(2E,7R,11R)-3,7,11,15-tetramethyl-2-hexadecenyl)-;
- 1,4-Naphthoquinone, 2-methyl-3-phytyl-; Monodion; Mono-kay; Phyloquinone K1;
- alpha-Phyloquinone; trans-Phyloquinone; Phytomenadione; Phytonadione;
- Phytilymenadione; Phytilymenaquinone; Synthex P; 2',3'-trans-Vitamin K1; Vitamin K1 (20); Phyloquinone; Vitamin K1;

CAS #: 84-80-0
RTECS #: QJ5800000
CI#: Not available

Recommended use of the chemical and restrictions on use
Recommended use: For manufacturing, processing, or repacking.
Uses advised against: No information available

Supplier:
Spectrum Chemical Mfg. Corp
14422 South San Pedro St.
Gardena, CA 90248
(310) 516-8000.

Order Online At: https://www.spectrumchemical.com
Emergency telephone number: Chemtrec 1-800-424-9300
Contact Person: Martin LaBenz (West Coast)
Contact Person: Ibad Tirmiz (East Coast)

2. HAZARDS IDENTIFICATION

Classification
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)
Not a dangerous substance or mixture according to the Globally Harmonized System (GHS)

Label elements
Not classified
Hazard not otherwise classified (HNOC)
Not Applicable

Other hazards
Not available

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>100</td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

**First aid measures**

**General Advice:** National Capital Poison Center in the United States can provide assistance if you have a poison emergency and need to talk to a poison specialist. Call 1-800-222-1222.

**Skin Contact:** Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes. Get medical attention if irritation develops. Consult a physician if necessary.

**Eye Contact:** Flush eyes with water for 15 minutes. Get medical attention if irritation occurs. If symptoms persist, call a physician.

**Inhalation:** Move to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention.

**Ingestion:** Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Consult a physician if necessary.

**Most important symptoms and effects, both acute and delayed**

**Symptoms** Health injuries are not known or expected under normal use.

**Indication of any immediate medical attention and special treatment needed**

**Notes to Physician:** Treat symptomatically.

**Protection of first-aiders**

First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

### 5. FIRE-FIGHTING MEASURES

**Extinguishing Media**

**Suitable Extinguishing Media:** Dry chemical. Carbon dioxide (CO2). Water spray, mist, or foam.

**Unsuitable Extinguishing Media:** No information available.

**Specific hazards arising from the chemical**

**Hazardous Combustion Products:** Carbon Dioxide, Carbon Monoxide.

**Product code:** PH195  
**Product name:** PHYTONADIONE, USP
Specific hazards: May be combustible at high temperatures

Special Protective Actions for Firefighters

Specific Methods: No information available.

Special Protective Equipment for Firefighters: As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions: Ensure adequate ventilation. Use personal protective equipment. Avoid contact with skin, eyes and clothing. Remove all sources of ignition.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers.

Methods and material for containment and cleaning up

Methods for containment: Absorb spill with inert material (e.g. vermiculite, dry sand or earth).

Methods for cleaning up: Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Technical Measures/Precautions: Provide sufficient air exchange and/or exhaust in work rooms. Keep away from incompatible materials.

Safe Handling Advice: Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Keep away from heat and sources of ignition. Do not ingest. Do not breathe vapors or spray mist. Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities


Incompatible Materials: Strong oxidizing agents Strong bases

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

National occupational exposure limits

United States

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>OSHA</th>
<th>NIOSH</th>
<th>ACGIH</th>
<th>AIHA WHEEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Product code: PH195  Product name: PHYTONADIONE, USP
Canada

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Canada - Alberta</th>
<th>Canada - British Columbia</th>
<th>Canada - Ontario</th>
<th>Canada - Quebec</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Australia and Mexico

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Australia</th>
<th>Mexico</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

Appropriate engineering controls

Engineering measures to reduce exposure: Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels below recommended exposure limits. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Individual protection measures, such as personal protective equipment

Personal Protective Equipment

Eye protection: Goggles or Safety glasses with side-shields

Skin and body protection: Gloves. Chemical resistant apron. Long sleeved clothing.

Respiratory protection: Respiratory protection is not necessary for normal handling. Good room ventilation or use of local exhaust (fume hood) is sufficient. Use a vapor respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentrations of mist or vapor, inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hygiene measures: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. When using, do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical state:</th>
<th>Appearance:</th>
<th>Color:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Odor:</th>
<th>Taste</th>
<th>Formula:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odorless</td>
<td>No information available</td>
<td>C31H46O2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Molecular/Formula weight:</th>
<th>Flammability:</th>
<th>Flashpoint (°C/°F):</th>
</tr>
</thead>
<tbody>
<tr>
<td>431.92</td>
<td>No information available</td>
<td>&gt; 113°C (&gt; 235°F)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Flash Point Tested according to:</th>
<th>Autoignition Temperature (°C/°F):</th>
<th>Lower Explosion Limit (%):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed cup</td>
<td>No information available</td>
<td>No information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Upper Explosion Limit (%):</th>
<th>Melting point/range(°C/°F):</th>
<th>Decomposition temperature(°C/°F):</th>
</tr>
</thead>
<tbody>
<tr>
<td>No information available</td>
<td>-20°C (-4°F)</td>
<td>No information available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Boiling point/range(°C/°F):</th>
<th>Bulk density:</th>
<th>Density (g/cm3):</th>
</tr>
</thead>
<tbody>
<tr>
<td>140°C (284°F)</td>
<td>No information available</td>
<td>0.984 g/cm3 @ 20°C (68°F)</td>
</tr>
</tbody>
</table>

Product code: PH195  Product name: PHYTONADIONE, USP
10. STABILITY AND REACTIVITY

Reactivity
Reactive with oxidizing agents

Chemical stability

Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: Hazardous polymerization does not occur

Conditions to avoid: Heat. Incompatible materials.

Incompatible Materials: Strong oxidizing agents
Strong bases

Hazardous decomposition products: Carbon oxides.

Other Information
Corrosivity: No information available

Special Remarks on Corrosivity: No information available

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Principal Routes of Exposure:
Skin. Eyes. Inhalation. Ingestion.

Acute Toxicity

Component Information

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS-No.</th>
<th>LD50/oral/rat (mg/kg)</th>
<th>LD50/oral/mouse</th>
<th>LD50/dermal/rabbit (mg/kg)</th>
<th>LC50/dermal/rabbit (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>&gt; 33487</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Oral LD50 Rat</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Product code: PH195  Product name: PHYTONADIONE, USP
Other LD50 or LC50 information = No information available

Product Information

LD50/oral/rat = VALUE- Acute Tox Oral = No information available

LD50/oral/mouse = Value - Acute Tox Oral = > 33487 mg/kg Oral LD50 Rat

LD50/dermal/rabbit VALUE-Acute Tox Dermal = No information available

LD50/dermal/rat VALUE -Acute Tox Dermal = >33487mg/kg Oral LD50 Rat

LC50/inhalation/rat VALUE-Vapor = No information available
VALUE-Gas = No information available
VALUE-Dust/Mist = No information available

LC50/Inhalation/mouse VALUE-Vapor = No information available
VALUE - Gas = No information available
VALUE - Dust/Mist = No information available

Symptoms

Skin Contact: May cause skin irritation.
Eye Contact: May cause eye irritation.
Inhalation May cause irritation of respiratory tract.
Ingestion Health injuries are not known or expected under normal use.
Aspiration hazard No information available.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chronic Toxicity No information available.
Sensitization: No information available.

Mutagenic Effects: No information available

Carcinogenic effects: Not considered carcinogenic.

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>IARC</th>
<th>ACGIH - Carcinogens</th>
<th>NTP</th>
<th>OSHA HCS - Carcinogens</th>
<th>Australia - Notifiable Carcinogenic Substances</th>
<th>Australia - Prohibited Carcinogenic Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Monograph 76 [2000] Vitamin K substances</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

ACGIH (American Conference of Governmental Industrial Hygienists)

IARC (International Agency for Research on Cancer)

Product code: PH195
Product name: PHYTONADIONE, USP
Reproductive toxicity
No data is available

Reproductive Effects: No information available
Developmental Effects: No information available
Teratogenic Effects: No information available

Specific Target Organ Toxicity
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Target Organs: No information available.

12. ECOLOGICAL INFORMATION

Ecotoxicity
Ecotoxicity effects: No data available.

Persistence and degradability: No information available
Bioaccumulative potential: No information available.
Mobility: No information available.

13. DISPOSAL CONSIDERATIONS

Disposal Methods
Waste from residues / unused products:
Waste must be disposed of in accordance with Federal, State and Local regulation.

Contaminated packaging:
Empty containers should be taken for local recycling, recovery or waste disposal

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

14. TRANSPORT INFORMATION

DOT
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Class: No information available
Packing group: No information available
Emergency Response Guide Number: No information available
Marine Pollutant: No data available
DOT RQ (lbs): No information available
Special Provisions: No Information available

Product code: PH195 Product name: PHYTONADIONE, USP
Symbol(s): No information available
Description: No information available

TDG (Canada)
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No Information available
Description: No information available

ADR
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Packing Group: No information available
Subsidiary Risk: No information available

IMO / IMDG
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
Marine Pollutant: No information available

RID
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

ICAO
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available

IATA
UN-No: Not Regulated
Proper Shipping Name: No information available
Hazard Class: No information available
Subsidiary Risk: No information available
Packing Group: No information available
ERG Code: No information available
Special Provisions: No information available

15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>U.S. TSCA</th>
<th>KOREA KECL</th>
<th>Philippines (PICCS)</th>
<th>Japan ENCS</th>
<th>CHINA</th>
<th>Australia (AICS)</th>
<th>EINECS-No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Present</td>
<td>Present KE-24853</td>
<td>Present</td>
<td>Not present</td>
<td>Present</td>
<td>Present</td>
<td>Present 201-564-2</td>
</tr>
</tbody>
</table>

Product code: PH195  Product name: PHYTONADIONE, USP
U.S. Regulations

*Phytonadione*

**Massachusetts RTK:** Present

**California Prop. 65: Safe Drinking Water and Toxic Enforcement Act of 1986.**

**Chemicals Known to the State of California to Cause Cancer:**
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

**Chemicals Known to the State of California to Cause Reproductive Toxicity:**
This product does not contain a chemical requiring a warning under California Prop. 65. (See table below)

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Carcinogen</th>
<th>Developmental Toxicity</th>
<th>Male Reproductive Toxicity</th>
<th>Female Reproductive Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**CERCLA/SARA**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CERCLA - Hazardous Substances and their Reportable Quantities</th>
<th>Section 302 Extremely Hazardous Substances and TPQs</th>
<th>Section 302 Extremely Hazardous Substances and RQs</th>
<th>Section 313 - Chemical Category</th>
<th>Section 313 - Reporting de minimis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
</tbody>
</table>

**U.S. TSCA**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>TSCA Section 5(a)2 - Chemicals With Significant New Use Rules (SNURS)</th>
<th>TSCA 8(d) - Health and Safety Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

**Canada**

**WHMIS hazard class:**
Non-controlled

**Canada Controlled Products Regulation:**
This product has been classified according to the hazard criteria of the CPR (Controlled Products Regulation) and the MSDS contains all of the information required by the CPR.

**Inventory**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Canada (DSL)</th>
<th>Canada (NDSL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Present</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CEPA Schedule I - Toxic Substances</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>CEPA - 2010 Greenhouse Gases Subject to Mandatory Reporting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phytonadione</td>
<td>84-80-0</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

**EU Classification**

**R-phrase(s)**
not determined (not applicable)

**S-phrase(s)**
none

**Product code:** PH195  
**Product name:** PHYTONADIONE, USP
The product is classified in accordance with Annex VI to Directive 67/548/EEC

Indication of danger:
None.

16. OTHER INFORMATION

Preparation Date: 09/28/2016
Revision Date: Not Applicable
Prepared by: Roumann Pangilinan

Disclaimer: All chemicals may pose unknown hazards and should be used with caution. This Safety Data Sheet (SDS) applies only to the material as packaged. If this product is combined with other materials, deteriorates, or becomes contaminated, it may pose hazards not mentioned in this SDS. The physical properties reported in this SDS are obtained from the literature and do not constitute product specifications. Information contained herein does not constitute a warranty, whether expressed or implied, as to the safety, merchantability or fitness of the goods for a particular purpose. Spectrum Chemicals & Laboratory Products, Inc. assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied. It shall be the user's responsibility to develop proper methods of handling and personal protection based on the actual conditions of use. While this SDS is based on technical data judged to be reliable, Spectrum assumes no responsibility for the completeness or accuracy of the information contained herein.

End of Safety Data Sheet
Manufacturer

Product Covered: PH195, Phytonadione, USP

Spectrum takes ownership as the manufacturer for the Spectrum product listed above and provides full quality assurance, customer service, and technical product support.

While information concerning the raw material manufacturer of our starting materials is considered proprietary, such information can be made available upon request contingent on demonstration of business volume justification and successful execution of confidential disclosure agreement (CDA).

Requests for disclosure of proprietary raw material manufacturer information may be submitted to the assigned account representative for consideration.

Sincerely,

Alan Wang, MSQA, ASQ CQA
Director of Technical Services
techservices@spectrumchemical.com
This is to certify that the quality management system of:

Spectrum Chemicals and Laboratory Products, Inc.

Main Site: 14422 South San Pedro Street, Gardena, California, 90248, USA,
Additional sites: 13915 South Main Street, Los Angeles, California, 90061, USA
769 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
755 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
777 Jersey Avenue, New Brunswick, New Jersey, 08901, USA
400 N. Oracle, Suite 221, Tucson, Arizona, 85704, USA, USA

has been assessed and registered by Intertek as conforming to the requirements of:

ISO 9001:2015

The quality management system is applicable to:

Main Site: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

Certificate Number:
94-316m-03
Initial Certification Date:
27 December 1994
Certificate Issue Date:
31 July 2017
Certificate Expiry Date:
28 January 2019

Authorized Signature
Calin Moldovean
President Business Assurance
Intertek Testing Services NA, Inc. dba Intertek
900 Chelmsford Street, Lowell, MA, USA

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request.
This appendix identifies the locations by the management system of

**Spectrum Chemicals and Laboratory Products, Inc.**

755 and 769 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.

777 Jersey Avenue: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for Compounding Pharmacies.

7400 N. Oracle: The manufacture and distribution of specialty fine chemicals, solutions, equipment, supplies and products for the laboratory, pharmaceutical, food, healthcare, cosmetic, fragrance, biotechnology, environmental and process industries.
Certificate of Registration

Intertek Certification Limited is a UKAS accredited body under schedule of accreditation no. 014.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.

Certificate of Registration

Intertek

This is to certify that the quality management system of

Spectrum China Ltd.

Building A20, No. 3802, Shengang Road, Songjiang District, Shanghai, China

has been assessed and registered by Intertek as conforming to the requirements of

ISO 9001: 2008

The quality management system is applicable to:

Provision of service of purchase, testing and sales for chemical products, repacking of non-hazardous chemical products.

Organization Code: 77762704-8
Certificate Number: 111310001-01
Certificate Issue Date: 17 November 2015
Certificate Expiry Date: 14 September 2018

Authorised Signature: Calin Moldovean – President, Business Assurance
Intertek Certification Limited, 10A Victory Park, Victory Road, Derby DE24 8ZF, United Kingdom

In the issuance of this certificate, Intertek assumes no liability to any party other than to the client, and then only in accordance with the agreed upon Certification Agreement. This certificate’s validity is subject to the organization maintaining their system in accordance with Intertek’s requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone.

The annual validity of the certificate can also be checked through the website http://www.cnca.gov.cn of CNCA in China.

The certificate remains the property of Intertek, to whom it must be returned upon request.
Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that our USP, NF, FCC, EP, BP, JP and food grade products are produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632
Spectrum-New Brunswick, NJ: 2246824
Spectrum-Shanghai, China: 3006174778

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist
Certification of Compliance with current Good Manufacturing Practices

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>PH195</td>
<td>Phytonadione, USP</td>
</tr>
</tbody>
</table>

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

- Spectrum-Gardena, CA: 2020632
- Spectrum-New Brunswick, NJ: 2246824
- Spectrum-Shanghai, China: 3006174778

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at qualityassurance@spectrumchemical.com

Sincerely,

Oralia Chavez
Quality Assurance Specialist
May 25, 2016

Re: Phytonadione, USP- PH195

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding Bovine Spongiform Encephalopathy (BSE). Please be assured that the chemical Phytonadione, USP- PH195 is BSE/TSE free.

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
June 22, 2016

Re: Phytonadione, USP- PH195

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfr. Corp. understand the concern regarding the presence of allergens in raw materials. Please be assured that the following chemical does not contain (Milk; Egg; Fish; Shellfish; Lupin; Tree nuts; Mollusks; Wheat; Peanuts; Soy; Cereals containing Gluten; Celery; Mustard; Sesame Seed).

Phytonadione, USP- PH195

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature.
June 22, 2016

Re: Phytonadione, USP- PH195

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

We at Spectrum Chemical Mfg. Corp. understand the concern regarding Aflatoxins in raw materials. To the best of our knowledge, the product listed below is not contaminated with Aflatoxins. Aflatoxins are not used in production. The following product does not come in contact with Aflatoxins at any stage of production.

Phytonadione, USP- PH195

If you have any further questions, please contact Tech Services at (310) 516-8000 Extension 5471, or by email at techservices@spectrumchemical.com.

Sincerely,

Darlene Dagdag-Lyudmirskiy
Technical Services
Spectrum Chemical Mfr. Corp.

This document has been produced electronically and is valid without a signature
## Certificate Of Analysis

<table>
<thead>
<tr>
<th>Item Number</th>
<th>PH195</th>
<th>Lot Number</th>
<th>1GE0756</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td>Phytonadione, USP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAS Number</td>
<td>84-80-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Molecular Formula</td>
<td>C₃₁H₄₆O₂</td>
<td>Molecular Weight</td>
<td>450.70</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Specification</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>min</td>
<td>max</td>
</tr>
<tr>
<td><strong>ASSAY (C₃₁H₄₆O₂)</strong></td>
<td>97.0</td>
<td>103.0 %</td>
</tr>
<tr>
<td><strong>REFRACTIVE INDEX @ 25°C</strong></td>
<td>1.523</td>
<td>1.526</td>
</tr>
<tr>
<td><strong>REACTION</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>MENADIONE</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>Z-ISOMER CONTENT</strong></td>
<td>21.0 %</td>
<td>12.6 %</td>
</tr>
<tr>
<td><strong>IDENTIFICATION</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td><strong>EXPIRATION DATE</strong></td>
<td></td>
<td>04-DEC-2018</td>
</tr>
<tr>
<td><strong>DATE OF MANUFACTURE</strong></td>
<td></td>
<td>05-DEC-2016</td>
</tr>
<tr>
<td><strong>APPEARANCE</strong></td>
<td></td>
<td>CLEAR YELLOW LIQUID</td>
</tr>
<tr>
<td><strong>RESIDUAL SOLVENTS</strong></td>
<td>TO PASS TEST</td>
<td>PASSES TEST</td>
</tr>
<tr>
<td>CLASS 2 (SOLVENT) / METHANOL</td>
<td></td>
<td>&lt;3000 ppm</td>
</tr>
<tr>
<td>CLASS 3 (solvent) / ACETONE</td>
<td></td>
<td>&lt;5000 ppm</td>
</tr>
<tr>
<td>CLASS 3 (solvent) / ETHANOL</td>
<td></td>
<td>&lt;5000 ppm</td>
</tr>
</tbody>
</table>

Spectrum Chemical Mfg Corp
14422 South San Pedro Street
Gardena 90248 CA

[Signature]
Adan Hernandez
Quality Control Manager
Spectrum Chemicals & Laboratory Products

All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.

Read and understand label and MSDS/SDS before handling any chemicals. All Spectrum’s chemicals are for manufacturing, processing, repacking or research purposes by experienced personal only. The customer must ensure to provide its users adequate hazardous material training and appropriate protective gears before handling our chemicals.
Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

USE CARE: This material has been evaluated per GHS/OSHA criteria and is not classified as hazardous. All chemicals may pose unknown hazards and must be used with caution. Use personal protection and safe handling methods consistent with proper workplace safety practices. Consult SDS for additional properties and precautions. If adverse reaction occurs seek medical attention.

KEEP FROM CHILDREN

Assay ........................................ 97.0-103.0%
Refractive Index @ 25°C ........... 1.523-1.526
Reaction .................................... To pass test
MAXIMUM LIMITS
Menadione .................................. To pass test
Z-Isomer Content ............................... 21.0%
Residual Solvents ..................... To pass test
LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.
FLUSHED WITH NITROGEN

Phytonadione
(3-Phythylmenadione; Vitamin K\textsubscript{1})

U.S.P.

CAS 84-80-0

C\textsubscript{31}H\textsubscript{46}O\textsubscript{2} F.W. 450.70

Assay ........................................ 97.0-103.0%
Refractive Index @ 25°C ........... 1.523-1.526
Reaction .................................... To pass test
MAXIMUM LIMITS
Menadione .................................. To pass test
Z-Isomer Content ............................... 21.0%
Residual Solvents ..................... To pass test
LIGHT SENSITIVE: Keep tightly closed in light-resistant containers.
FLUSHED WITH NITROGEN

Bar Code
GHS Hazard Pictograms
Warning, Safety Data and Precautionary Information
Product Catalog Number
Item Name, Form, Grade
Storage Color Band

Size/Quantity
Chemical Abstracts Service (CAS) Registry Number
Caution Information
DOT Shipping Information
Toll-Free 24-Hour Chemical Emergency Telephone Number

Empirical Formula, Formula Weight and Technical Specifications Panel
Expiration Information
Lot Number
Kosher Certified by Kosher Supervision of America (KSA).

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

Spectrum Chemical Mfg Corp

Corporate Headquarters: 769 Jersey Ave.
New Brunswick, NJ 08901
732.214.1300

West Coast Facility: 14422 S. San Pedro St.
Gardena, CA 90248
310.516.8000
January 26, 2016

**RE: Lot Numbering System**

Dear Valued Customer:

This letter is to inform you of Spectrum Chemicals and Laboratory Products’ Lot Numbering System. The system is based on an alpha-numerical sequence which provides the month, year and location of production.

The lot numbering system utilized until 2010 is a sequence of **six characters**, two letters followed by four numbers. The first letter represents the year, for example, Y denotes 2009 and Z denotes 2010. The second letter represents the month and site, for example, A-L denotes January through December at Spectrum’s Gardena, CA facility, while M-X denotes January through December at the New Brunswick, NJ facility. The following four numbers are sequentially assigned.

**Example:** ZI0928 = The 928\textsuperscript{th} material produced in California in September 2010

The lot numbering system utilized for 2011 and forward, is a sequence of **seven characters**. The first character, a number, represents the production facility:

1 = Gardena, CA Facility  
2 = New Brunswick, NJ Facility  
3 = China Facility

The second character, a letter, represents the year. For example, A denotes 2011 and B denotes 2012. The third character, a letter, represents the month, with A denoting January and L denoting December. The following four numbers are sequentially assigned.

**Example:** 2AA0706 = The 706\textsuperscript{th} material produced in New Jersey in January 2011

Thank you for your interest with Spectrum products. Please feel free to contact us at 310-516-8000 or via email at qualityassurance@spectrumchemical.com if we may be of further assistance.

Sincerely,

Michael Dang  
Manager, GMP Compliance
Stability – Shelf Life Guidance

Product Covered: PH195, Phytonadione, USP

Spectrum Chemical’s manufacturing partner has assigned the following shelf life guidance for the product listed above.

The product, PH195, Phytonadione, USP, is assigned a 24 months shelf life from date of manufacturing. The quality and integrity of the chemical depends on the handling and storage conditions. Please refer to the Safety Data Sheet for proper storage and handling procedures.

Adan R. Hernandez
Quality Control Manager

Corporate Headquarters
769 Jersey Avenue
New Brunswick, NJ 08901-3605

20. September 2017
This is to certify that the following product(s) have been produced under the supervision of the Islamic Food and Nutrition Council of America (IFANCA®). The production facility as well as component ingredients have been reviewed and approved. The product(s) are in compliance with the halal requirements under Islamic laws.

Date: September 05, 2017
Document #: 11205.11206.I170667

<table>
<thead>
<tr>
<th>Company Name &amp; Address:</th>
<th>Spectrum Laboratory Products, Inc. 769- Jersey Avenue New Brunswick, New Jersey 08901 USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plant Name &amp; Address:</td>
<td>Spectrum Laboratory Products, Inc. 769-Jersey Ave New Brunswick, New Jersey 08901 USA</td>
</tr>
<tr>
<td>Product Name</td>
<td>Phytonadione, USP</td>
</tr>
<tr>
<td>Product Code</td>
<td>PH195</td>
</tr>
<tr>
<td>Halal-ID</td>
<td>C22934</td>
</tr>
<tr>
<td>Product Certificate #</td>
<td>HC-17SPYA52</td>
</tr>
</tbody>
</table>

This certificate is valid until August 31, 2018 and subject to renewal at that time.