



## Safety Data Sheet

### Section 1: Identification

#### Product identifier

- Product Name** • Nephrocaps® Softgels
- Product Code** • NDC 00187-5268-01; NDC 00187-5268-02

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

- Recommended use** • Vitamin and Mineral Supplement; To maintain vitamin levels when dietary intake is inadequate or excretion or loss is excessive.
- Restrictions on use** • This product is not intended to diagnose, treat, cure or prevent any disease. Use in accordance with product literature.

#### Details of the supplier of the safety data sheet

- Manufacturer** • Valeant Pharmaceuticals North America, LLC
- Bridgewater, NJ 08807  
United States  
valeant.com
- Telephone (General)** • 1-800-321-4576

#### 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

#### UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### Classification of the substance or mixture

- UN GHS** • Classification criteria not met

#### Label elements

**UN GHS**

#### Other hazards

- UN GHS** • 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	%	Classifications According to Regulation/Directive
Biotin	CAS:58-85-5 EINECS:200-399-3	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Folic acid	CAS:59-30-3 EINECS:200-419-0	< 1%	UN GHS: NDA
Lecithin	CAS:68910-52-1	< 5%	UN GHS: NDA
Niacin	CAS:98-92-0 EINECS:202-713-4	5% TO 10%	UN GHS: NDA
Pantothenic acid	CAS:137-08-6 EINECS:205-278-9	< 5%	UN GHS: NDA
Riboflavin	CAS:83-88-5 EINECS:201-507-1	< 1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A
Soybean oil	CAS:8001-22-7 EINECS:232-274-4	40% TO 50%	UN GHS: NDA
Thiamine, nitrate	CAS:532-43-4 EINECS:208-537-4	< 1%	UN GHS: NDA
Vitamin B12 (cyanocobalamin)	CAS:68-19-9 EINECS:200-680-0	< 1%	UN GHS: NDA
Vitamin B6 (pyridoxine hydrochloride)	CAS:58-56-0 EINECS:200-386-2	< 5%	UN GHS: NDA
Vitamin C (ascorbic acid)	CAS:50-81-7 EINECS:200-066-2	20% TO 30%	UN GHS: Skin Corr. 1; Skin Irrit. 2; Eye Dam. 1; Eye Irrit. 2A
Wax, yellow	CAS:8012-89-3 EINECS:232-383-7	< 5%	UN GHS: Classification criteria not met

Inactive ingredients in gelatin capsule shell: glycerin, gelatin, titanium dioxide.

*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, CO<sub>2</sub>, 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.

## Section 8 - Exposure Controls/Personal Protection

### Control parameters

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

### Exposure controls

- Engineering Measures/Controls**
- No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

### Personal Protective Equipment

#### Respiratory

- 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	#6 oval, black, soft gelatin capsule, imprinted with a white "n" on one side.
Color	Black	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	Not relevant	Melting Point/Freezing Point	No data available
Decomposition Temperature	Not relevant	pH	Not relevant
Specific Gravity/Relative Density	Not relevant	Water Solubility	Soluble
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
Environmental			
Octanol/Water Partition coefficient	No data available		

## 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.

### 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		
Vitamin C (ascorbic acid) (20% TO 30%)	50-81-7	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 11900 mg/kg; <i>Sense Organs and Special Senses:Eye:Lacrimation; Behavioral:Somnolence (general depressed activity); Gastrointestinal:Hypermotility, diarrhea</i>
Folic acid (< 1%)	59-30-3	<b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • 10 g/kg
Niacin (5% TO 10%)	98-92-0	<b>Acute Toxicity:</b> Ingestion/Oral-Mouse LD50 • 2500 mg/kg
Vitamin B6 (pyridoxine hydrochloride) (< 5%)	58-56-0	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • 4 g/kg; <i>Behavioral:Convulsions or effect on seizure threshold; Behavioral:Excitement</i>
Pantothenic acid (< 5%)	137-08-6	<b>Acute Toxicity:</b> Ingestion/Oral-Rat LD50 • >10 g/kg
Soybean oil (40% TO 50%)	8001-22-7	<b>Acute Toxicity:</b> Intravenous-Rat LD50 • 16500 mg/kg

GHS Properties	Classification
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met

<b>STOT-RE</b>	UN GHS • Classification criteria not met
<b>STOT-SE</b>	UN GHS • Classification criteria not met
<b>Toxicity for Reproduction</b>	UN GHS • Classification criteria not met
<b>Germ Cell Mutagenicity</b>	UN GHS • Classification criteria not met

## Potential Health Effects

### Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

### Skin

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

### Eye

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

### Ingestion

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Refer to the product insert and/or product prescribing information for comprehensive information regarding adverse reactions and other important symptoms and effects.

Carcinogenic Effects		
	CAS	NTP
Vitamin C (ascorbic acid)	50-81-7	Evidence of Carcinogenicity

- Reproductive Effects** • No data available for the product.

## 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
Biotin	58-85-5	Yes	Yes	Yes
Vitamin B12 (cyanocobalamin)	68-19-9	Yes	Yes	Yes
Wax, yellow	8012-89-3	Yes	Yes	Yes
Folic acid	59-30-3	Yes	Yes	Yes
Vitamin C (ascorbic acid)	50-81-7	Yes	Yes	Yes
Lecithin	68910-52-1	Yes	No	Yes
Niacin	98-92-0	Yes	Yes	Yes
Pantothenic acid	137-08-6	Yes	Yes	Yes
Vitamin B6 (pyridoxine hydrochloride)	58-56-0	Yes	Yes	Yes
Riboflavin	83-88-5	Yes	Yes	Yes
Soybean oil	8001-22-7	Yes	Yes	Yes
Thiamine, nitrate	532-43-4	Yes	Yes	Yes

## Canada

### Labor

#### Canada - WHMIS - Classifications of Substances

• Vitamin C (ascorbic acid)	50-81-7	Uncontrolled product according to WHMIS classification criteria
• Lecithin	68910-52-1	Not Listed
• Folic acid	59-30-3	Uncontrolled product according to WHMIS

• Wax, yellow	8012-89-3	classification criteria Not Listed
• Soybean oil	8001-22-7	Uncontrolled product according to WHMIS classification criteria
• Riboflavin	83-88-5	Not Listed
• Vitamin B6 (pyridoxine hydrochloride)	58-56-0	Not Listed
• Biotin	58-85-5	Not Listed
• Niacin	98-92-0	Uncontrolled product according to WHMIS classification criteria
• Vitamin B12 (cyanocobalamin)	68-19-9	Not Listed
• Pantothenic acid	137-08-6	Not Listed
• Thiamine, nitrate	532-43-4	Not Listed

## United States - California

### Environment

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

• Vitamin C (ascorbic acid)	50-81-7	Not Listed
• Lecithin	68910-52-1	Not Listed
• Folic acid	59-30-3	Not Listed
• Wax, yellow	8012-89-3	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Riboflavin	83-88-5	Not Listed
• Vitamin B6 (pyridoxine hydrochloride)	58-56-0	Not Listed
• Biotin	58-85-5	Not Listed
• Niacin	98-92-0	Not Listed
• Vitamin B12 (cyanocobalamin)	68-19-9	Not Listed
• Pantothenic acid	137-08-6	Not Listed
• Thiamine, nitrate	532-43-4	Not Listed

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

• Vitamin C (ascorbic acid)	50-81-7	Not Listed
• Lecithin	68910-52-1	Not Listed
• Folic acid	59-30-3	Not Listed
• Wax, yellow	8012-89-3	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Riboflavin	83-88-5	Not Listed
• Vitamin B6 (pyridoxine hydrochloride)	58-56-0	Not Listed
• Biotin	58-85-5	Not Listed
• Niacin	98-92-0	Not Listed
• Vitamin B12 (cyanocobalamin)	68-19-9	Not Listed
• Pantothenic acid	137-08-6	Not Listed
• Thiamine, nitrate	532-43-4	Not Listed

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

• Vitamin C (ascorbic acid)	50-81-7	Not Listed
• Lecithin	68910-52-1	Not Listed
• Folic acid	59-30-3	Not Listed
• Wax, yellow	8012-89-3	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Riboflavin	83-88-5	Not Listed
• Vitamin B6 (pyridoxine hydrochloride)	58-56-0	Not Listed
• Biotin	58-85-5	Not Listed

• Niacin	98-92-0	Not Listed
• Vitamin B12 (cyanocobalamin)	68-19-9	Not Listed
• Pantothenic acid	137-08-6	Not Listed
• Thiamine, nitrate	532-43-4	Not Listed

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

• Vitamin C (ascorbic acid)	50-81-7	Not Listed
• Lecithin	68910-52-1	Not Listed
• Folic acid	59-30-3	Not Listed
• Wax, yellow	8012-89-3	Not Listed
• Soybean oil	8001-22-7	Not Listed
• Riboflavin	83-88-5	Not Listed
• Vitamin B6 (pyridoxine hydrochloride)	58-56-0	Not Listed
• Biotin	58-85-5	Not Listed
• Niacin	98-92-0	Not Listed
• Vitamin B12 (cyanocobalamin)	68-19-9	Not Listed
• Pantothenic acid	137-08-6	Not Listed
• Thiamine, nitrate	532-43-4	Not Listed

**Section 16 - Other Information**

<b>Revision Date</b>	• 30/July/2015
<b>Last Revision Date</b>	• 30/July/2015
<b>Preparation Date</b>	• 30/July/2015
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