

**Product Name:** Zemplar Capsules  
**Issued:** Jun-10-2013

## **SAFETY DATA SHEET**

### **Section 1. Identification of the substance/mixture and of the company/undertaking**

#### **1.1 Product Identifier**

**Product Name:** Zemplar Capsules  
**Synonyms:** Zemplar (Paricalcitol) Capsules 1 mcg; Zemplar (Paricalcitol) Capsules 2 mcg;  
Zemplar (Paricalcitol) Capsules 4 mcg  
**Trade name:** Zemplar  
**List Number:** 4317; 4314; 4315

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

**Recommended use:** Pharmaceuticals

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

**Supplier:** AbbVie Inc.  
1 North Waukegan Road  
North Chicago, IL 60064  
USA  
1-800-255-5162  
+1-847-937-7433  
**Customer Service Telephone:** 1-800-255-5162 (US and Canada only)  
+1-847-937-7433  
**E-mail Address:** AbbVie.SDS@abbvie.com

#### **1.4 Emergency telephone number**

**Emergency Telephone:** CHEMTREC: 1(800) 424-9300 (in USA and Canada)  
or +1-703-527-3887 (international)

### **Section 2. Hazards identification**

#### **2.1 Classification of the substance or mixture**

##### **Regulation (EC) No 1272/2008**

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

##### **Classification according to EU Directives 67/548/EEC or 1999/45/EC**

**Indication of danger:** Not classified

#### **2.2 Label elements**

Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

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## Section 2. Hazards identification

### 2.3 Other hazards

Not determined

## Section 3. Composition/information on ingredients

Chemical Name	Percent	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH No.
Neobee M-5 Oil 73398-61-5	95-100	Present		Not Hazardous*	No data available
Ethyl Alcohol 64-17-5	1-5	Present	F; R11	Flam. Liq. 3 (H226)	No data available
Paricalcitol 131918-61-1	< 0.01	NA	T+, R24, R28 R40 R63	Acute Tox. 2 (H300) Acute Tox. 3 (H311)	No data available

Not Hazardous\* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

**For the full text of the R-phrases mentioned in this Section, see Section 16**

**For the full text of the H-Statements mentioned in this Section, see Section 16**

## Section 4. First aid measures

### 4.1 Description of first aid measures

**Eye Contact:** Remove from source of exposure. Flush eyes with copious amounts of water. Seek immediate medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. Seek immediate medical attention. Provide symptomatic/supportive care.

**Inhalation:** Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Ingestion:** Remove from source of exposure. Seek immediate medical attention. Provide symptomatic/supportive care as necessary.

**Protection of First-aiders:** Use personal protective equipment

### 4.2 Most important symptoms and effects, both acute and delayed

**Signs and Symptoms:** No signs and symptoms from occupational exposure are known. Clinical data suggests the following: headaches, incoordination, vomiting, nausea, constipation, fast heart rate, sleep, muscle weakness, loss of appetite, alterations in blood chemistry, drowsiness, electrolyte imbalances, flushing, lightsensitive eyes, nasal discharge, cardiac changes, metallic taste, stupor. Ingestion may result in the following: alterations in serum lipid concentrations, anorexia, pruritus, altered libido, bone and joint pain, hypercalcemia, hyperphosphatemia.

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**Medical Conditions Aggravated by Exposure:** No medical conditions aggravated by occupational exposure are known. Data suggest any pre-existing ailments in the following organs: eyes, female reproductive system, cardiovascular system, bone. Hypersensitivity to the material and/or similar materials.

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

**Notes To Physician:** Maintain ventilation, electrolyte balance and monitor cardiovascular function, as necessary. If alert, induce vomiting. If alert, perform gastric lavage. If ingested and gastric lavage or emesis is not successful, administer mineral oil to promote fecal elimination.

**Additional Information:** Excessive repeated exposure to paracalcin may result in calcification of susceptible organs.

### **Section 5. Firefighting measures**

#### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Unsuitable Extinguishing Media:** Not determined

#### **5.2 Special hazards arising from the substance or mixture**

**Special Exposure Hazards:** Not determined

#### **5.3 Advice for firefighters**

**Protective Equipment and Precautions for Firefighters:** As in any fire, wear self-contained breathing apparatus and full protective gear

### **Section 6. Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

**Personal Precautions:** For personal protection see section 8

#### **6.2. Environmental precautions**

**Environmental Precautions:** Contain material and prevent release to waterways or soil.

#### **6.3. Methods and material for containment and cleaning up**

**Methods for Cleaning Up:** Recover product and place in an appropriate container for disposal. Clean with bleach.

#### **6.4. Reference to other sections**

Refer to Sections 8, 12, and 13 for further information.

### **Section 7. Handling and storage**

#### **7.1. Precautions for safe handling**

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Handle in accordance with good industrial hygiene and safety practice.

**7.2. Conditions for safe storage, including any incompatibilities**

Store according to label instructions

**7.3. Specific end use(s)**

**Recommended use:** Pharmaceuticals

**Section 8. Exposure controls/personal protection**

**8.1. Control parameters**

**Exposure limits:**

Chemical Name	Employee Exposure Limit	Skin Notation
Neobee M-5 Oil 73398-61-5	Not Applicable	None
Ethyl Alcohol 64-17-5	Not Applicable	None
Paricalcitol 131918-61-1	0.003 mcg/m <sup>3</sup> TWA	Skin Notation

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Ethyl Alcohol 64-17-5	1000 ppm TWA	STEL: 9500 mg/m <sup>3</sup> TWA: 1900 mg/m <sup>3</sup>	960 mg/m <sup>3</sup> TWA	1000 ppm (STEL)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethyl Alcohol 64-17-5	1900 mg/m <sup>3</sup> (STEL) 260 mg/m <sup>3</sup> (TWA)	1910 mg/m <sup>3</sup> (TWA)	960 mg/m <sup>3</sup> (TWA) 1920 mg/m <sup>3</sup> (STEL)	3000 ppm (STEL) 5760 mg/m <sup>3</sup> (STEL) 3000 ppm (STEL) 1000 ppm (TWA) 1920 mg/m <sup>3</sup> (TWA)

**8.2. Exposure controls**

**Engineering Controls:** No special precautions are required under normal conditions. Use inside a process enclosure when handling the bulk formulation.

**Respiratory Protection:** Respiratory protection is not needed during normal product use. When handling the bulk formulation, an approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.

**Gloves:** Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.

**Other PPE Data:** Not determined.

**Environmental Exposure Controls:** Not determined

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## **Section 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

<b>Appearance:</b>	Colorless Mixture Blend Pale Yellow Liquid in a Soft elastic capsule (SEC)
<b>Odor:</b>	Not determined.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	Not determined.
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Not determined.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	Not determined.

### **9.2. Other information**

Not determined

## **Section 10. Stability and reactivity**

### **10.1. Reactivity**

Not determined

### **10.2. Chemical stability**

Stable under normal conditions

### **10.3. Possibility of hazardous reactions**

**Hazardous reactions:** Not determined.

### **10.4. Conditions to avoid**

Not determined.

### **10.5 Incompatible materials**

Oxidizing agents, Hypochlorite Solutions

### **10.6 Hazardous decomposition products**

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Carbon oxides, Nitrogen oxides (NOx)

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

**Routes of Exposure:**

**Oral:** Clinical Route  
**Dermal:** Unlikely  
**Inhalation:** Unlikely

**Acute Toxicity - Oral:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LD50 =	3450-7060	mg/kg	Mice Rats
Paricalcitol 131918-61-1	LD50 =	0.62	mg/kg, for a similar material	Rats
	LD50 =	1.35		Mice

**Acute Toxicity - Dermal:** Data for component (s) given below.

Chemical Name	Acute Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LD50 =	20000	mg/kg	Rabbits
Paricalcitol 131918-61-1	LDLo =	15	mg/kg, for a similar material	Rats

**Acute Toxicity - Inhalation:** Data for component (s) given below.

Chemical Name	Test	Value	Units	Species
Ethyl Alcohol 64-17-5	LC 50 =	20000	ppm	Rats

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Paricalcitol 131918-61-1	ALD (iv) >	16	mcg/kg	Mice Rats	I.V. administration
	LD Lo (der) =	15	mg/kg	Rats	By analogy to a similar material.

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Paricalcitol 131918-61-1	Endocrine System	Rats	0.1	mcg/kg	Intravenous	6 months

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**Reproductive Effects:** Active Ingredient : In animals adverse reproductive effects include: fetal toxicity. Based on these experimental results, protection against maternal toxicity will provide adequate protection against potential embryo-fetal toxicity and teratogenicity Animal testing did not show any effects on fertility  
Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Paricalcitol 131918-61-1	Rats Rabbits	3 0.5	mcg/kg	Intravenous	During Gestation

**Carcinogenicity:** Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Paricalcitol 131918-61-1	Adrenal Gland	Rats	1.5	Subcutaneous	mcg/kg	2 years

**Mutagenicity:** Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Paricalcitol 131918-61-1	Negative	Negative	Negative	Negative

**Aspiration hazard:** Not determined

**Notes:**

1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

## Section 12. Ecological information

### 12.1. Toxicity

Not determined.

### 12.2. Persistence and degradability

Not determined.

### 12.3. Bioaccumulative potential

Not determined

### 12.4. Mobility in soil

Not determined.

### 12.5. Results of PBT or vPvB assessment

Chemical safety report is not required for this substance/product.

### 12.6. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

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**Notes:**

1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.

**Section 13. Disposal considerations**

**13.1 Waste treatment methods**

**Waste Disposal Methods:** Disposal should be made in accordance with country, federal, state and local regulations.

**Section 14. Transport information**

**ADR, DOT, ICAO/IATA, IMDG/IMO**

**Status:** Not regulated

- 14.1. UN Number: Not applicable  
 14.2. Proper shipping name: Not applicable  
 14.3. Hazard class: Not applicable  
 14.4. Packing group: Not applicable  
 14.5. Environmental hazard: Not applicable  
 14.6. Special Provisions: Not applicable  
 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

**Section 15. Regulatory Information**

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

**International Inventories**

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Neobee M-5 Oil 73398-61-5	Present	X	X	Not listed.	X
Ethyl Alcohol 64-17-5	Present	X	X	Not listed.	X
Paricalcitol 131918-61-1	-	-	-	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Neobee M-5 Oil 73398-61-5	Present	-	X	X	Present	
Ethyl Alcohol 64-17-5	Present	-	X	X	Present	HSR001144
Paricalcitol 131918-61-1	-	-	-	-	-	

**Legend**

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
 TSCA - United States Toxic Substances Control Act Section 8(b) Inventory  
 DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List  
 PICCS - Philippines Inventory of Chemicals and Chemical Substances



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ENCS - Japan Existing and New Chemical Substances  
ISHL - Japan Industrial Safety and Health Law  
IECSC - China Inventory of Existing Chemical Substances  
AICS - Australian Inventory of Chemical Substances  
KECL - Korean Existing and Evaluated Chemical Substances

**Carcinogenicity Rating:**

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Neobee M-5 Oil	95-100	Not Listed	Not Listed	Not Listed
Ethyl Alcohol	1-5	Not Listed	Not Listed	Not Listed
Paricalcitol	< 0.01	Not Listed	Not Listed	Not Listed

**SARA 313 Information**

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Neobee M-5 Oil	95-100	No	Not Applicable	Not applicable
Ethyl Alcohol	1-5	No	Not Applicable	Not applicable
Paricalcitol	< 0.01	No	Not Applicable	Not applicable

**Immediate Health:** Yes  
**Delayed Health:** No  
**Fire:** No  
**Sudden Pressure:** No  
**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Chemicals known to the State of California to cause cancer or reproductive harm listed below.

Chemical Name	Percent	Proposition 65 Listed Materials
Ethyl Alcohol	1-5	Developmental toxicity (when in alcoholic beverages); initial date 10/1/87.

**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**  
Health: 1  
Fire: 1  
Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

**15.2. Chemical safety assessment**

Chemical safety assessment has not been conducted on the substance/product.

**Section 16. Other information**

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