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.
Section 2. Hazards identification

2.3 Other hazards

Not determined

Section 3. Composition/information on ingredients

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

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.
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
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:**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Employee Exposure Limit</th>
<th>Skin Notation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neobee M-5 Oil 73398-61-5</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
<tr>
<td>Ethyl Alcohol 64-17-5</td>
<td>Not Applicable</td>
<td>None</td>
</tr>
<tr>
<td>Paricalcitol 131918-61-1</td>
<td>0.003 mcg/m³ TWA</td>
<td>Skin Notation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>France</th>
<th>German MAK</th>
<th>Ireland</th>
<th>Italy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol 64-17-5</td>
<td>1000 ppm TWA</td>
<td>STEL: 9500 mg/m³ TWA: 1900 mg/m³</td>
<td>960 mg/m³ TWA</td>
<td>1000 ppm (STEL)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>The Netherlands</th>
<th>Spain</th>
<th>Switzerland</th>
<th>UK OEL/MEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol 64-17-5</td>
<td>1900 mg/m³ (STEL)</td>
<td>1910 mg/m³ (TWA)</td>
<td>960 mg/m³ (TWA)</td>
<td>5760 mg/m³ (STEL)</td>
</tr>
<tr>
<td></td>
<td>260 mg/m³ (TWA)</td>
<td></td>
<td>1920 mg/m³ (STEL)</td>
<td>3000 ppm (STEL)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1000 ppm (TWA)</td>
<td>1920 mg/m³ (TWA)</td>
</tr>
</tbody>
</table>

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

9.1. Information on basic physical and chemical properties

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>LD50 =</td>
<td>3450-7060</td>
<td>mg/kg</td>
<td>Mice Rats</td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paricalcitol</td>
<td>LD50 =</td>
<td>0.62</td>
<td>mg/kg, for a similar material</td>
<td>Rats</td>
</tr>
<tr>
<td>331918-61-1</td>
<td>LD50 =</td>
<td>0.35</td>
<td></td>
<td>Mice</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Acute Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>LD50 =</td>
<td>20000</td>
<td>mg/kg</td>
<td>Rabbits</td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paricalcitol</td>
<td>LD50 =</td>
<td>15</td>
<td>mg/kg, for a similar material</td>
<td>Rats</td>
</tr>
<tr>
<td>331918-61-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>LC 50</td>
<td>20000</td>
<td>ppm</td>
<td>Rats</td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Test Type</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paricalcitol</td>
<td>ALD (iv)</td>
<td>16</td>
<td>mcg/kg</td>
<td>Mice Rats</td>
<td>I.V. administration</td>
</tr>
<tr>
<td>331918-61-1</td>
<td>LD Lo (der) =</td>
<td>15</td>
<td>mcg/kg</td>
<td>Rats</td>
<td>By analogy to a similar material.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Target Organs:</th>
<th>Species</th>
<th>Dosage</th>
<th>Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paricalcitol</td>
<td>Endocrine System</td>
<td>Rats</td>
<td>0.1</td>
<td>mcg/kg</td>
<td>Intravenous</td>
<td>6 months</td>
</tr>
<tr>
<td>331918-61-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Product Name: Zemplar Capsules  
Issued: Jun-10-2013  

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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Species</th>
<th>Dosage Units</th>
<th>Route</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paricalcitol 131918-61-1</td>
<td>Rats</td>
<td>3 mcg/kg</td>
<td>Intravenous</td>
<td>During Gestation</td>
</tr>
<tr>
<td></td>
<td>Rabbits</td>
<td>0.5 mcg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Carcinogenicity:  
Data for component(s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Site of Tumors</th>
<th>Species</th>
<th>Dosage Units</th>
<th>Route</th>
<th>Units</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paricalcitol 131918-61-1</td>
<td>Adrenal Gland</td>
<td>Rats</td>
<td>1.5 mcg/kg</td>
<td>Subcutaneous</td>
<td></td>
<td>2 years</td>
</tr>
</tbody>
</table>

Mutagenicity:  
Data for component(s) given below.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Micronucleus Assay</th>
<th>Ames Test</th>
<th>Mouse Lymphoma Assay</th>
<th>Chromosomal Abbr. Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paricalcitol 131918-61-1</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>EINECS/ELINCS</th>
<th>TSCA</th>
<th>DSL</th>
<th>NDSL</th>
<th>PICCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neobee M-5 Oil</td>
<td>Present</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>X</td>
</tr>
<tr>
<td>73398-61-5</td>
<td></td>
<td>X</td>
<td>X</td>
<td>Not listed.</td>
<td>X</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Present</td>
<td>X</td>
<td>X</td>
<td>Not listed.</td>
<td>X</td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paricalcitol</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>Not listed.</td>
<td>-</td>
</tr>
<tr>
<td>131918-61-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ENCS</th>
<th>ISHL</th>
<th>IECSC</th>
<th>AICS</th>
<th>KECL</th>
<th>New Zealand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neobee M-5 Oil</td>
<td>Present</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>73398-61-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>Present</td>
<td>-</td>
<td>X</td>
<td>X</td>
<td>Present</td>
<td></td>
</tr>
<tr>
<td>64-17-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>HSR001144</td>
<td></td>
</tr>
<tr>
<td>Paricalcitol</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>131918-61-1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

**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:**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>NTP:</th>
<th>IARC:</th>
<th>ACGIH:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neobee M-5 Oil</td>
<td>95-100</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>1-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Paricalcitol</td>
<td>&lt; 0.01</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**SARA 313 Information**

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>SARA 313 Chemical:</th>
<th>CERCLA RQ/SARA EHS RQ (lbs):</th>
<th>SARA EHS TPQ (lbs):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neobee M-5 Oil</td>
<td>95-100</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>1-5</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Paricalcitol</td>
<td>&lt; 0.01</td>
<td>No</td>
<td>Not Applicable</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**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.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Percent</th>
<th>Proposition 65 Listed Materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethyl Alcohol</td>
<td>1-5</td>
<td>Developmental toxicity (when in alcoholic beverages); initial date 10/1/87.</td>
</tr>
</tbody>
</table>

**WHMIS Hazard Class:** Not determined.  
**NFPA Rating:**  
- Health: 1  
- Fire: 1  
- Reactivity: 0

**Notes:**

1. SARA = Superfund Amendments and the Reauthorization Act.  
4. TSCA = Toxic Substances Control Act.  
5. EC = European Community.  

**15.2. Chemical safety assessment**

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

**Section 16. Other information**

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