

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Prometrium capsules  
**Synonyms:** Utrogestan Capsules; Prometrium Capsules, 100 mg; Prometrium Capsules, 200 mg; Utrogestan Capsules, 100 mg; Utrogestan Capsules, 200 mg  
**Trade name:** Prometrium; Utrogestan  
**List Number:** 1072; 1074; 1708; 1711

#### **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:** Manufactured for:  
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**

**Reproductive toxicity** Category 1A  
**Carcinogenicity** Category 2

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

**Risk Phrases:** R40 - Limited evidence of a carcinogenic effect  
R61 - May cause harm to the unborn child

#### **2.2 Label elements**

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

## Section 2. Hazards identification



**Signal Word:** Danger

**Hazard Statements:**

H351 - Suspected of causing cancer  
H360 - May damage fertility or the unborn child

P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P281 - Use personal protective equipment as required  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P405 - Store locked up  
P501 - Dispose of contents/container to an approved waste disposal plant

### 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.
Peanut oil 8002-03-7	40-60	Present		Not Hazardous*	No data available
Progesterone 57-83-0	10-30	Present	R40 R61	Carc. 2 (H351) Repr. 1A (H360)	No data available
Gelatin 9000-70-8	10-30	Present		Not Hazardous*	No data available
Glycerol 56-81-5	5-20	Present		Not Hazardous*	No data available
Titanium Dioxide 13463-67-7	0.1-1	Present		Not Hazardous*	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

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**Skin Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**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. If signs of toxicity occur, seek 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:** Available information support the following: headaches, bone and joint pain, depression, dizziness, bloating, abdominal pain, nausea, vomiting, chest pain, diarrhea, constipation.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity to the material and/or similar materials. Medical conditions exacerbated due to exposure to the following organs: cardiovascular system.

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

**Notes To Physician:** Treat symptomatically

### **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.

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

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

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

**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:**

Chemical Name	Employee Exposure Limit	Skin Notation
Peanut oil 8002-03-7	Not Applicable	None
Progesterone 57-83-0	10 mcg/m <sup>3</sup>	None
Gelatin 9000-70-8	Not Applicable	None
Glycerol 56-81-5	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Glycerol 56-81-5	10 mg/m <sup>3</sup> (total mist)	TWA: 10 mg/m <sup>3</sup>	50 mg/m <sup>3</sup> TWA	10 mg/m <sup>3</sup> (TWA)	
Titanium Dioxide 13463-67-7	10 mg/m <sup>3</sup> TWA	TWA: 10 mg/m <sup>3</sup>		10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Glycerol 56-81-5		10 mg/m <sup>3</sup> (TWA)	50 mg/m <sup>3</sup> (TWA) 100 mg/m <sup>3</sup> (STEL)	30 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)
Titanium Dioxide 13463-67-7		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	30 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)

**8.2. Exposure controls**

<b>Product Name:</b>	<b>Prometrium capsules</b>
<b>Issued:</b>	<b>Jun-14-2013</b>
<b>Engineering Controls:</b>	No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.
<b>Respiratory Protection:</b>	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.
<b>Eyes:</b>	Eye protection not needed during typical product use conditions. Wear eye protection as appropriate when handling the bulk formulation.
<b>Gloves:</b>	Gloves not required during normal product use conditions. Wear impervious gloves when handling the bulk formulation.
<b>Other PPE Data:</b>	Wear appropriate body coverings if contact may occur.
<b>Environmental Exposure Controls:</b>	Not determined

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

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

<b>Appearance:</b>	White Paste in a Capsule
<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

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

### 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

Not determined

### 10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NOx)

## **Section 11. Toxicological information**

### 11.1. Information on toxicological effects

#### **Routes of Exposure:**

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

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

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	4090	mg/kg	Animals

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

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	10,000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Glycerol 56-81-5	LC 50 >	0.57	mg/L , 1 hour	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Progesterone 57-83-0	LD50 (ip) =	327	mg/kg	Rats	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

**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
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

**Reproductive Effects:** Active Ingredient : In humans adverse reproductive effects include: fetal abnormalities.

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

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Progesterone 57-83-0	Mammary Gland Ovaries Uterus	Mice	0.018 - 2.5	Subcutaneous	mg/kg	Variable exposure periods
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

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

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Glycerol 56-81-5	No Data.	Negative	No Data.	No Data.

**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.

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

### 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.

#### 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
Peanut oil 8002-03-7	Present	X	X	Not listed.	X
Progesterone 57-83-0	Present	X	-	X	X
Gelatin 9000-70-8	Present	X	X	Not listed.	X
Glycerol 56-81-5	Present	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X



**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Peanut oil 8002-03-7	-	Present	X	X	Present	HSR002734
Progesterone 57-83-0	-	Present	-	X	Present	HSR003883
Gelatin 9000-70-8	Present	-	X	X	Present	
Glycerol 56-81-5	Present	-	X	X	Present	
Titanium Dioxide 13463-67-7	Present	-	X	X	Present	

### 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

**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:
Peanut oil	40-60	Not Listed	Not Listed	Not Listed
Progesterone	10-30	Not Listed	Not Listed	Not Listed
Gelatin	10-30	Not Listed	Not Listed	Not Listed
Glycerol	5-20	Not Listed	Not Listed	Not Listed
Titanium Dioxide	0.1-1	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):
Peanut oil	40-60	No	Not Applicable	Not applicable
Progesterone	10-30	No	Not Applicable	Not applicable
Gelatin	10-30	No	Not Applicable	Not applicable
Glycerol	5-20	No	Not Applicable	Not applicable
Titanium Dioxide	0.1-1	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
Progesterone	10-30	Cancer. Listed January 1988.

**WHMIS Hazard Class:** Not determined.

### NFPA Rating:

Health: 1

Fire: 1

**Product Name:** Prometrium capsules  
**Issued:** Jun-14-2013

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**

**Risk Phrases:** R40 - Limited evidence of a carcinogenic effect , R61 - May cause harm to the unborn child

**Full text of H-Statements referred to under sections 2 and 3**

H351 - Suspected of causing cancer if inhaled, H360 - May damage fertility or the unborn child if inhaled

**Document Authored By:** Global Occupational Toxicology (D-03QC)

**Issued:** Jun-14-2013

**Supersedes the SDS dated:** Dec-08-2011

**Disclaimer:**

*The information and recommendations contained herein are based upon tests believed to be reliable. However, AbbVie Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. AbbVie 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.*