

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Cyclosporine capsule premix  
**Synonyms:** Premix for Cyclosporine Capsules  
**Drug Code Number:** 74848

#### **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**

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

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

**Risk Phrases:** R45 - May cause cancer  
R60 - May impair fertility  
R61 - May cause harm to the unborn child

#### **2.2 Label elements**

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

## Section 2. Hazards identification



**Signal Word:** Danger

**Hazard Statements:** H350 - May cause 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.
Castor Oil 8001-79-4	30-50	Present		Not Hazardous*	No data available
Sorbitan Monooleate 1338-43-8	5-20	Present		Not Hazardous*	No data available
Cyclosporine 59865-13-3	5-20	NA	Xn, R22 R45 R60, R61	Acute Tox. 4 (H302) Carc 1B (H350) Repr. 1B (H360)	No data available
Ethanol 64-17-5	5-20	Present	F; R11	Flam. Liq. 2 (H225)	No data available
Polyethylene Glycols 25322-68-3	5-20	NA		Not Hazardous*	No data available
Propylene Glycol 57-55-6	5-20	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:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

**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:** Clinical data suggests the following: abnormal kidney function, tremor, hirsutism (abnormal hairiness), gastrointestinal upset, rash, increased blood pressure, abnormal liver function, excessive urination, convulsion, alterations in blood chemistry.

**Medical Conditions Aggravated by Exposure:** Data suggest any pre-existing ailments in the following organs: immune system, kidney, central nervous system, cardiovascular system, liver. Pregnancy.

#### **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 water spray, alcohol-resistant foam, dry chemical or carbon dioxide

**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:** Use personal protective equipment identified in Section 8. Remove all sources of ignition.

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

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

**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:** Keep away from ignition sources. 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. Keep away from open flames, hot surfaces and sources of ignition. Bond and ground containers during transfer operations..

### **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:**

<b>Chemical Name</b>	<b>Employee Exposure Limit</b>	<b>Skin Notation</b>
Castor Oil 8001-79-4	Not Applicable	None
Sorbitan Monooleate 1338-43-8	Not Applicable	None
Cyclosporine 59865-13-3	0.2 mg/m <sup>3</sup> TWA	None
Ethanol 64-17-5	1,900 mg/m <sup>3</sup>	None
Polyethylene Glycols 25322-68-3	Not Applicable	None
Propylene Glycol 57-55-6	Not Applicable	None

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>France</b>	<b>German MAK</b>	<b>Ireland</b>	<b>Italy</b>
Ethanol 64-17-5	1000 ppm STEL	STEL: 9500 mg/m <sup>3</sup> TWA: 1900 mg/m <sup>3</sup>	960 mg/m <sup>3</sup> TWA	1000 ppm (STEL)	
Polyethylene Glycols 25322-68-3			1000 mg/m <sup>3</sup> TWA		
Propylene Glycol 57-55-6				150 ppm (TWA) 470 mg/m <sup>3</sup> (TWA) 10 mg/m <sup>3</sup> (TWA)	

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Ethanol 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)
Polyethylene Glycols 25322-68-3			1000 ppm (TWA)	
Propylene Glycol 57-55-6				450 ppm (STEL) 1422 mg/m <sup>3</sup> (STEL) 30 mg/m <sup>3</sup> (STEL) 150 ppm (TWA) 474 mg/m <sup>3</sup> (TWA) 10 mg/m <sup>3</sup> (TWA)

## 8.2. Exposure controls

**Engineering Controls:** Local exhaust ventilation as necessary to maintain exposures to within applicable limits.

**Respiratory Protection:** An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

**Eyes:** Wear eye protection appropriate to handling activities.

**Gloves:** Impervious gloves.

**Other PPE Data:** Wear appropriate body coverings if contact may occur.

**Environmental Exposure Controls:** Not determined

## Section 9. Physical and chemical properties

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

**Appearance:** Off-White Mixture Blend Yellow Viscous solution

**Odor:** Alcohol odor.

**Odor Threshold:** Not determined

**pH:** Not determined.

**Boiling Pt. @ 760 mm Hg (°C):** Not determined.

**Melting/Freezing Point (°C):** Not determined

**Flash Point (°C):** 29.4

**Flash Point Method:** Tag Closed Cup (TCC)

**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.

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

**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

Keep away from open flames, hot surfaces and sources of ignition

### 10.5 Incompatible materials

Not determined

### 10.6 Hazardous decomposition products

Carbon oxides, Nitrogen oxides (NO<sub>x</sub>)

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

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

**Oral:** Unlikely  
**Dermal:** Yes  
**Inhalation:** Unlikely

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

<b>Chemical Name</b>	<b>Acute Test</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Sorbitan Monooleate 1338-43-8	LD50 >	15,000	mg/kg	Rats
Cyclosporine 59865-13-3	LD50 =	1480	mg/kg	Rats
		2329		Mice
	LD50 >	1000		Rabbits
		1000		Hamsters
Ethanol 64-17-5	LD50 =	3450	mg/kg	Mice
		6300		Rabbits
		7060		Rats
		5560		Guinea Pigs
Polyethylene Glycols 25322-68-3	LD50 =	33,750	mg/kg	Rats
Propylene Glycol 57-55-6	LD50 =	10,000-33,700	mg/kg	Animals

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

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

Chemical Name	Acute Test	Value	Units	Species
Polyethylene Glycols 25322-68-3	LD50 >	20,000	mg/kg	Rabbits
Propylene Glycol 57-55-6	LD50 =	20,800	mg/kg	Rabbits

**Acute Toxicity - Inhalation:** Not determined.

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

Chemical Name	Test Type	Value	Units	Species	Comments
Cyclosporine 59865-13-3	LD50 (sc) =	286	mg/kg	Rats	
	LD 50 (iv) >	10-148	mg/kg	Mice Rabbits Rats	

**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
Cyclosporine 59865-13-3	Kidney	Rats	45	mg/kg	Oral	13 weeks
	Gastrointestinal Tract Liver	Monkeys Dogs	60 45			52 weeks
	Lymphatic system Bone Marrow Immune System					

**Reproductive Effects:** Active Ingredient : In clinical use target organ effects include: reduced fetal growth. In animals adverse reproductive effects include: testicular atrophy, embryo toxicity, Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Cyclosporine 59865-13-3	Rats Rabbits	15	mg/kg	Oral	Premating in Males During Gestation

**Carcinogenicity:** Active ingredient : In clinical use produced tumors in the following tissue (s): lymphatic system. In animals produced tumors in the following tissue (s): lymphatic system, kidney. Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Cyclosporine 59865-13-3	Lymphatic system Kidney	Mice Rats	7.5	Oral	mg/kg	Lifetime

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

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

<b>Chemical Name</b>	<b>Micronucleus Assay</b>	<b>Ames Test:</b>	<b>Mouse Lymphoma Assay</b>	<b>Chromosomal Abbr. Assay</b>
Cyclosporine 59865-13-3	Negative	Negative	No Data.	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.

**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:** Regulated



**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

**14.1. UN Number:** UN1170  
**14.2. Proper shipping name:** Ethanol mixture  
**14.3. Hazard class:** 3  
**14.4. Packing group:** III  
**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
Castor Oil 8001-79-4	Present	X	X	Not listed.	X
Sorbitan Monooleate 1338-43-8	Present	X	X	Not listed.	X
Cyclosporine 59865-13-3	-	-	X	Not listed.	-
Ethanol 64-17-5	Present	X	X	Not listed.	X
Polyethylene Glycols 25322-68-3	-	X	X	Not listed.	X
Propylene Glycol 57-55-6	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Castor Oil 8001-79-4	Present	-	X	X	Present	
Sorbitan Monooleate 1338-43-8	Present	-	X	X	Present	
Cyclosporine 59865-13-3	-	-	X	-	-	
Ethanol 64-17-5	Present	-	X	X	Present	HSR001144
Polyethylene Glycols 25322-68-3	Present	-	X	X	Present	
Propylene Glycol 57-55-6	Present	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:
Castor Oil	30-50	Not Listed	Not Listed	Not Listed

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

Chemical Name	Percent	NTP:	IARC:	ACGIH:
Sorbitan Monooleate	5-20	Not Listed	Not Listed	Not Listed
Cyclosporine	5-20	Not Listed	Listed	Not Listed
Ethanol	5-20	Not Listed	Not Listed	Not Listed
Polyethylene Glycols	5-20	Not Listed	Not Listed	Not Listed
Propylene Glycol	5-20	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):
Castor Oil	30-50	No	Not Applicable	Not applicable
Sorbitan Monooleate	5-20	No	Not Applicable	Not applicable
Cyclosporine	5-20	No	Not Applicable	Not applicable
Ethanol	5-20	No	Not Applicable	Not applicable
Polyethylene Glycols	5-20	No	Not Applicable	Not applicable
Propylene Glycol	5-20	No	Not Applicable	Not applicable

**Immediate Health:** Yes  
**Delayed Health:** Yes  
**Fire:** Yes  
**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
Cyclosporine	5-20	Cancer

**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**  
 Health: 1  
 Fire: 3  
 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:** R45 - May cause cancer, R60 - May impair fertility, R61 - May cause harm to the unborn child

**Product Name:** Cyclosporine capsule premix  
**Issued:** Jun-13-2013

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

H302 - Harmful if swallowed, H350 - May cause cancer if swallowed, H360FD - May damage fertility. May damage the unborn child, H225 - Highly flammable liquid and vapor

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

**Issued:** Jun-13-2013

**Supersedes the SDS dated:** Feb-18-2000

**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.*