

**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Calcijex, Calcitriol Injection  
**Synonyms:** Calcitriol Injection; Calcitriol Injection Ampule 1 mcg/mL; Calcijex 1 mcg/mL; Calcijex 2 mcg/mL; Calcijex Reduced Aluminum  
**List Number:** 1200; 1210; 8110

#### **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.

**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013

## 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.
Water 7732-18-5	98-100	Present		Not Hazardous*	No data available
Sodium Ascorbate 134-03-2	0.1-1	Present		Not Hazardous*	No data available
Calcitriol 32222-06-3	< 0.001	Present	T; R27,28;R61	Acute Tox. 1 (H310)	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

<b>Eye Contact:</b>	Remove from source of exposure. Flush eyes with copious amounts of water. Seek immediate medical attention. Provide symptomatic/supportive care as necessary. Monitor electrolytes. Monitor cardiovascular function. Monitor renal function.
<b>Skin Contact:</b>	Remove from source of exposure. Flush with copious amounts of water. Seek immediate medical attention. Provide symptomatic/supportive care. Monitor cardiovascular function. Monitor electrolytes. Monitor renal function.
<b>Inhalation:</b>	Remove from source of exposure. Seek immediate medical attention. Provide symptomatic/supportive care as necessary. Monitor serum electrolytes especially calcium, renal and cardiovascular function.
<b>Ingestion:</b>	Remove from source of exposure. Seek immediate medical attention. Provide symptomatic/supportive care as necessary. Monitor cardiovascular function. Monitor respiratory function. Monitor electrolytes. Monitor renal function.
<b>Protection of First-aiders:</b>	Use personal protective equipment

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

<b>Signs and Symptoms:</b>	None known from occupational exposure. Clinical data suggests the following: hypercalcemia, weakness, headaches, nausea, vomiting, dry mouth, constipation, muscle pain, metallic taste, bone and joint pain. Reported to cause the following: polyuria, polydipsia, anorexia, weight loss, conjunctivitis, pancreatitis, photophobia, runny nose, pruritus, hyperthermia, altered libido, altered liver enzymes, hypercholesterolemia, hypercalcemia, increased blood pressure, fast heart rate, hyperphosphatemia.
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**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013

**Medical Conditions**  
**Aggravated by Exposure:** None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: heart, bone, kidney, liver, muscle. Pregnancy.

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

**Notes To Physician:** If ingested and gastric lavage or emesis is not successful, administer mineral oil to promote fecal elimination.

### **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.

#### **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)**

**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013  
**Recommended use:** Pharmaceuticals

## Section 8. Exposure controls/personal protection

### 8.1. Control parameters

#### Exposure limits:

Chemical Name	Employee Exposure Limit	Skin Notation
Water 7732-18-5	Not Applicable	None
Sodium Ascorbate 134-03-2	Not Applicable	None
Calcitriol 32222-06-3	0.0004 mcg/m <sup>3</sup>	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Sodium Ascorbate 134-03-2	10 mg/m <sup>3</sup> total dust				

### 8.2. Exposure controls

**Engineering Controls:** No special provisions 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:** 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:** Clear Colorless Mixture Blend Yellow Liquid  
**Odor:** Not determined.  
**Odor Threshold:** Not determined  
**pH:** 6.8 - 7.6  
**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.

**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013

**Upper Explosive Limit:** Not determined.  
**Vapor Pressure (mm Hg):** Not determined.  
**Vapor Density (Air = 1):** Not determined.  
**Specific Gravity:** 1.016  
**Solubility(ies):** Freely soluble in: water.  
**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**

Not determined

### **10.6 Hazardous decomposition products**

Not determined.

## **Section 11. Toxicological information**

### **11.1. Information on toxicological effects**

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

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

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

**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013

Chemical Name	Acute Test	Value	Units	Species
Sodium Ascorbate 134-03-2	LD50 =	11,900	mg/kg for Ascorbic Acid	Rats
		3367	mg/kg for Ascorbic Acid	Mice
Calcitriol 32222-06-3	LD50 =	1.35 - 2 >5	mg/kg	Mice Rats

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

Chemical Name	Acute Test	Value	Units	Species
Calcitriol 32222-06-3	LD 50 (sc) =	0.066	mg/kg	Mice
		0.145		Rats

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

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

Chemical Name	Test Type	Value	Units	Species	Comments
Calcitriol 32222-06-3	LD50 (sc) =	52-100	mg/kg	Rats Mice	
	LD50 (iv)=	4.97		Rats	
	LD50 (it) =	11	mg/kg, for a similar material	Rabbits	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Active Ingredient : In animals adverse reproductive effects include: fetal abnormalities, fetal toxicity.  
 Data for component (s) given below.

Chemical Name	Species	Dosage	Units	Route	Duration
Calcitriol 32222-06-3	Rats	5	mcg/kg	Not specified	During Gestation
	Rabbits	0.008			

**Carcinogenicity:** Not determined.

**Mutagenicity:** Active Ingredient : Negative in the Ames assay.

**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.

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**Issued:** Jun-12-2013

#### **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:** 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**

**Product Name:** Calcijex, Calcitriol Injection  
**Issued:** Jun-12-2013

### International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Water 7732-18-5	Present	X	X	Not listed.	X
Sodium Ascorbate 134-03-2	Present	X	X	Not listed.	X
Calcitriol 32222-06-3	Present	-	X	Not listed.	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Water 7732-18-5	-	2-(4)-1220	X	X	Present	
Sodium Ascorbate 134-03-2	-	Present	X	X	Present	
Calcitriol 32222-06-3	-	-	-	X	-	HSR007026

### **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:
Water	98-100	Not Listed	Not Listed	Not Listed
Sodium Ascorbate	0.1-1	Not Listed	Not Listed	Not Listed
Calcitriol	< 0.001	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):
Water	98-100	No	Not Applicable	Not applicable
Sodium Ascorbate	0.1-1	No		Not applicable
Calcitriol	< 0.001	No	Not Applicable	Not applicable

**Immediate Health:** No

**Delayed Health:** No

**Fire:** No

**Sudden Pressure:** No

**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**WHMIS Hazard Class:** Not determined.

### **NFPA Rating:**

Health: 0

Fire: 0

Reactivity: 0



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**Issued:** Jun-12-2013

**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.

<b>Section 16. Other information</b>
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**Issued:** Jun-12-2013

**Supersedes the SDS dated:** Apr-01-2009

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