

**Product Name:** Calcijex Placebo, 1 mL Reduced Aluminum  
**Issued:** Feb-22-2005



## MATERIAL SAFETY DATA SHEET

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

**Manufacturer Name and Address:** Abbott Laboratories  
Pharmaceutical Products Division  
200 Abbott Park Road  
Abbott Park, Illinois 60064-3537

**Customer Service Telephone:** 1 - 800 - 441 - 4987 (PPD Technical Information)

**Emergency Telephone:** 1 (800) 424-9300 CHEMTREC (USA)  
1 (703) 527 3887 CHEMTREC (INTERNATIONAL)

**Product Name:** Calcijex Placebo, 1 mL Reduced Aluminum

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients	Percent	OSHA PEL	ACGIH TLV	AIHA WEEL	Abbott EEL	Skin Notation
Water 7732-18-5	97.4	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Sodium Phosphate, Dibasic 7558-79-4	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Polysorbate 20 9005-64-5	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Monobasic Sodium Phosphate 7558-80-7	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Sodium Chloride 7647-14-5	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Edetate Disodium 139-33-3	Proprietary	Not Listed	Not Listed	Not Applicable	Not Applicable	None
Sodium Ascorbate 134-03-2	Proprietary	15 mg/m <sup>3</sup> total dust, 5 mg/m <sup>3</sup> respirable dust	10 mg/m <sup>3</sup> total dust	Not Applicable	Not Applicable	None

**Notes:**

OSHA PEL: US Occupational Safety and Health Administration- Permissible Exposure Limit.  
ACGIH TLV: American Conference of Governmental Industrial Hygienists - Threshold Limit Value.  
AIHA WEEL: American Industrial Hygiene Association - Workplace Environmental Exposure Level.  
Abbott EEL: Abbott Laboratories Employee Exposure Limit.  
TWA: 8-hour Time Weighted Average.  
STEL: 15-minute Short Term Exposure Limit.  
C: Ceiling Limit.

### 3. HAZARDS IDENTIFICATION

#### Emergency Overview:

Clear, colorless to yellow solution.  
Odor: Not determined.  
Not toxic by ingestion, inhalation or dermal contact.

#### Routes of Exposure:

**Oral:** No  
**Dermal:** No

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**Inhalation:** No

**Hazard Information:**

**Ingestion Rating:** Not determined.  
**Skin Absorption Rating:** Not determined.  
**Inhalation Rating:** Not determined.  
**Corrosiveness Rating:** Not determined.  
**Skin Contact Rating:** Not determined.  
**Skin Sensitization Rating:** Not determined.  
**Eye Contact Rating:** Not determined.  
**Target Organs:** Not determined.

**Carcinogenicity Rating:**

Ingredients	Percent	OSHA:	NTP:	IARC:	ACGIH:
Water	97.4	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Phosphate, Dibasic	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Polysorbate 20	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Monobasic Sodium Phosphate	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Chloride	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Edetate Disodium	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Ascorbate	Proprietary	Not Listed	Not Listed	Not Listed	Not Listed

**NFPA Rating:** Not determined.

**Signs and Symptoms:** None known from occupational exposure.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

#### 4. FIRST AID MEASURES

**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.

#### 5. FIRE FIGHTING MEASURES

**FLAMMABILITY:**

**Autoignition Temp. (°C):** Not determined.

**FIRE-FIGHTING INFORMATION:**

**Product Name:** Calcijex Placebo, 1 mL Reduced Aluminum  
**Suitable Extinguishing Media:** Use appropriate medium for the underlying cause of the fire.  
**Special Exposure Hazards:** Avoid inhalation of combustion products.

## 6. ACCIDENTAL RELEASE MEASURES

**Methods of Cleaning and Collecting:** Absorb with suitable material. Flush with water.  
**Personal Precautions:** Use personal protective equipment identified in Section 8.  
**Environmental Precautions:** Not determined.

## 7. HANDLING AND STORAGE

**Handling:** No special handling required.  
**Storage:** Store according to label instructions.  
**Special Precautions:** Not applicable.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Engineering Controls:** No special provisions are required under normal product use conditions.  
**Respiratory Protection:** Respiratory protection is not needed during normal product use. Use approved NIOSH respiratory protection if TLV exceeded or overexposure is likely.  
**Eyes:** Wear eye protection appropriate to handling activities.  
**Gloves:** Water-resistant gloves  
**Other PPE Data:** Not determined.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Clear, colorless to yellow solution.  
**Odor:** Odor: Not determined.  
**Boiling Pt. @ 760 mm Hg (°C):** Not determined. Water, approximately  
**Melting/Freezing Point:** Not determined. Water, approximately  
**Vapor Pressure (mm Hg)** Not determined.  
**Bulk Density at 20°C:** Not determined.  
**Solubility:** Not determined.  
**Specific Gravity:** Not determined.  
**pH:** 5.9 - 7.0  
**Viscosity (centipoise):** Not determined.

## 10. STABILITY AND REACTIVITY

**Chemical Stability:** Stable at normal temperature and pressures.  
**Self-Heating Tendency:** Not determined.  
**Materials to Avoid:** Not determined.

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**Hazardous Decomposition Products:** Not determined.

**Hazardous Polymerization:** Not known to occur.

**Conditions to Avoid:** Not determined.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity - Oral:** LD50 not determined for product. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Sodium Phosphate, Dibasic	Proprietary	LD50 =	17,000	mg/kg	Rats
Polysorbate 20	Proprietary	LD50 =	37,000	mg/kg	Rats
Monobasic Sodium Phosphate	Proprietary	LD50 =	8290	mg/kg	Rats
Sodium Chloride	Proprietary	LD50 >	4000	mg/kg	Rats Mice Rabbits
Edetate Disodium	Proprietary	LD50 =	2000-2300	mg/kg	Mice Rats Rabbits
Sodium Ascorbate	Proprietary	LD50 =	11,900 3367	mg/kg for Ascorbic Acid mg/kg for Ascorbic Acid	Rats Mice

**Acute Toxicity - Dermal:** LD50 not determined for product. Data for component (s) given below.

Ingredients	Percent	Acute Test	Value	Units	Species
Sodium Chloride	Proprietary	LD50 >	10,000	mg/kg	Rabbits

**Acute Toxicity - Inhalation:** LC50 not determined for product. Data for component (s) given below.

Ingredients	Percent	Test	Value	Units	Species
Sodium Chloride	Proprietary	LC 50 >	42	mg/L	Rats

Ingredients	Percent	Test Type	Value	Units	Species	Comments
Sodium Phosphate, Dibasic	Proprietary	LD Lo (ip) =	1000	mg/kg	Rats	I.V. administration
Polysorbate 20	Proprietary	LD50 (iv) =	1420	mg/kg	Mice	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Target Organ Effects:** Not determined.

**Reproductive Effects:** Not determined.

**Carcinogenicity:** Not determined.

**Mutagenicity:** Not determined.

Ingredients	Percent	Ames Test:	Mouse Lymphoma Assay	Micronucleus Assay	Chromosomal Abbr. Assay
Edetate Disodium	Proprietary	Negative	No Data.	No Data.	No Data.

### 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

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## 12. ECOLOGICAL INFORMATION

**Aquatic Toxicity:** Not determined.

**Biodegradation:** Not determined.

**General Notes:** 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.

## 13. DISPOSAL CONSIDERATIONS

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

## 14. TRANSPORT INFORMATION

**DOT:**  
**Status:** Not Regulated.

**ICAO/IATA:**  
**Status:** Not determined.

**IMDG:**  
**Status:** Not determined.

**TDG (Canada):**  
**Status:** Not determined.

## 15. REGULATORY INFORMATION

### SARA 313 Information

Ingredients	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Water	97.4	No	Not Applicable	Not applicable
Sodium Phosphate, Dibasic	Proprietary	No	Not Applicable	Not applicable
Polysorbate 20	Proprietary	No	Not Applicable	Not applicable
Monobasic Sodium Phosphate	Proprietary	No	Not Applicable	Not applicable
Sodium Chloride	Proprietary	No	Not Applicable	Not applicable
Edetate Disodium	Proprietary	No	Not Applicable	Not applicable
Sodium Ascorbate	Proprietary	No	Not Applicable	Not applicable

### SARA 311/312 Hazard Categories:

**Immediate Health:** No  
**Delayed Health:** No

<b>Product Name:</b>	<b>Calcijex Placebo, 1 mL Reduced Aluminum</b>
<b>Fire:</b>	No
<b>Sudden Pressure:</b>	No
<b>Reactivity:</b>	No
<b>TSCA Inventory Status:</b>	Not determined.
<b>CERCLA Status:</b>	Not determined.
<b>RCRA Status:</b>	Not determined.
<b>Proposition 65 Status:</b>	Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

#### **EC HAZARD CLASSIFICATION:**

<b>Category of Danger:</b>	None
<b>Indication of danger:</b>	None
<b>ICH Classification:</b>	Not determined.

#### **CANADIAN REGULATIONS:**

<b>Canadian Inventory:</b>	Not determined.
<b>Canadian NDSL:</b>	Not determined.
<b>WHMIS Hazard Class:</b>	Not determined.

#### **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.

## **16. OTHER INFORMATION**

<b>Document Authored By:</b>	Julie Nowak
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