

**Product Name:**  
**Issued:**

**Depakene Capsules**  
**Jun-06-2013**



## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Depakene Capsules  
**Synonyms:** Depakene Capsulas; Depakene Capsules, 250 mg; Valproic Acid Capsules; Depakene 250 mg;  
**List Number:** 5681; D795

#### **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:** Abbott Laboratories  
100 Abbott Park Road  
Abbott Park, IL 60064  
USA  
+1-847-937-6100  
**E-mail Address:** Abbott.SDS@abbott.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**

<b>General Note</b>	Abbott Laboratories
<b>Acute oral toxicity</b>	Category 4
<b>Skin corrosion/irritation</b>	Category 2
<b>Serious eye damage/eye irritation</b>	Category 2
<b>Reproductive toxicity</b>	Category 1A

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

**Indication of danger:** Xn - Harmful  
Xi - Irritant  
**Risk Phrases:** R22 - Harmful if swallowed  
R36/38 - Irritating to eyes and skin  
R61 - May cause harm to the unborn child

#### **2.2 Label elements**

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## Section 2. Hazards identification



Signal Word:

Danger

Hazard Statements:

H302 - Harmful if swallowed  
H315 - Causes skin irritation  
H319 - Causes serious eye irritation  
H360 - May damage fertility or the unborn child

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
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

### 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.
Valproic Acid 99-66-1	40-60	Present	Xn, R22; Xi, R36/38; R61	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Repr. 1A (H360)	No data available
Corn Oil 8001-30-7	40-60	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

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**Eye Contact:** Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function 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. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function as necessary.

**Inhalation:** Remove from source of exposure. If signs of irritation or toxicity occur seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function as necessary.

**Ingestion:** Remove from source of exposure. If irritation persists or signs of toxicity occur, seek medical attention. Naloxone has been reported to reverse the CNS depressant effects of valproic acid. Provide symptomatic/supportive care, monitoring liver function 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. Direct contact with the eyes could result in the following: eye irritation. Direct contact with the skin could result in the following: skin irritation. Clinical data suggests the following: headaches, nausea, lack of energy, dizziness, gastrointestinal upset, muscle weakness, leucopenia, anemia, thrombocytopenia, vomiting, abdominal pain, anorexia, abnormal liver function. Clinical overdose may result in the following: coma.

**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, skin, pancreas, liver. Hypersensitivity to the material and/or similar materials. liver, nervous system, male reproductive system, female reproductive system, gastrointestinal system, or hematopoietic 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**

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**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)**

**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>
Valproic Acid 99-66-1	750 mcg/m <sup>3</sup>	None
Corn Oil 8001-30-7	Not Applicable	None

### **8.2. Exposure controls**

**Engineering Controls:** No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.

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**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:** Light Yellow Liquid in a Capsule  
**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**

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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:** Not determined.  
**Inhalation:** Not determined.

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

Chemical Name	Acute Test	Value	Units	Species
Valproic Acid 99-66-1	LD50 =	670-2307	mg/kg	Rats Mice
Corn Oil 8001-30-7	LD50 >	100,000	mg/kg	Rats

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

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

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

Chemical Name	Test Type	Value	Units	Species	Comments
Corn Oil 8001-30-7	LD 50 (ip) >	50,000	mg/kg	Mice	None.

**Corrosivity:** Not determined.

**Dermal Irritation:** Active Ingredient : Produced mild to moderate skin irritation in animals.

**Eye Irritation:** Active Ingredient : Produced severe eye irritation in animals. Recovery after 24 hours.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

**Target Organ Effects:** Not determined.

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

Chemical Name	Species	Dosage	Units	Route	Duration
Valproic Acid 99-66-1	Rats Mice Rabbits	> 65	mg/kg	Oral	During Gestation

**Carcinogenicity:** None expected from normal clinical use of this product. Confirmed animal carcinogen with unknown relevance to humans  
Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Valproic Acid 99-66-1	Liver Lungs	Rats	80-170	Oral	mg/kg	2 years

**Mutagenicity:** Active Ingredient : Negative for genotoxicity in a battery of in vitro assays.

**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.

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## 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
Valproic Acid 99-66-1	Present	-	X	Not listed.	X
Corn Oil 8001-30-7	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Valproic Acid 99-66-1	Present	Present	-	X	Present	HSR006827
Corn Oil 8001-30-7	-	-	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:**



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Chemical Name	Percent	NTP:	IARC:	ACGIH:
Valproic Acid	40-60	Not Listed	Not Listed	Not Listed
Corn Oil	40-60	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):
Valproic Acid	40-60	No	Not Applicable	Not applicable
Corn Oil	40-60	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:** Listed.  
**WHMIS Hazard Class:** Not determined.

**NFPA Rating:**  
Health: 1  
Fire: 1  
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:** R22 - Harmful if swallowed, R36/38 - Irritating to eyes and skin, R61 - May cause harm to the unborn child

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

H315 - Causes skin irritation, H319 - Causes serious eye irritation, H302 - Harmful if swallowed, H360 - May damage fertility or the unborn child if inhaled

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

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**Supersedes the SDS dated:** Dec-12-2005

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