

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Depakote ER Tablets  
**Synonyms:** Divalproex Sodium Extended-Release; Depakote ER 500 mg; Depakote ER 250 mg; Epival CR Tablets; Epival Divalproex Sodium CR Tablets; Epival ER; Valcote ER; Depakote ER tabletas  
**List Number:** 7126; 3826; M756

#### **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**

**Acute oral toxicity** Category 4  
**Skin corrosion/irritation** Category 2  
**Serious eye damage/eye irritation** Category 2  
**Reproductive toxicity** 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

Product Name:  
Issued:

Depakote ER Tablets  
Jun-06-2013

## Section 2. Hazards identification

### 2.2 Label elements



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.
Sodium Hydrogen Divalproate 76584-70-8	35-60	NA	Xn, R22; Xi, R36/38; R61	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Acute Tox. 4 (H302) Repr. 1A (H360)	No data available
Hydroxypropyl Methylcellulose 9004-65-3	20-50	NA		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	1-10	Present		Not Hazardous*	No data available
Lactose 63-42-3	0-10	Present		Not Hazardous*	No data available
Silica, Amorphous 112926-00-8	1-5	NA		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.

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

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**

**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:** None expected from incidental contact. 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, vomiting, nausea, diarrhea, lack of energy, muscle weakness, dizziness, gastrointestinal upset, abdominal pain, leucopenia, anorexia, anemia, thrombocytopenia, abnormal liver function, sedation, hair loss, rash, psychiatric changes. 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, gastrointestinal system, pancreas, nervous system, liver. Hypersensitivity to the material and/or similar materials. Current use of treatments such as: phenobarbital therapy.

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

**Notes To Physician:** Monitor pancreatic function.

## **Section 5. Firefighting measures**

### **5.1 Extinguishing Media**

**Suitable Extinguishing Media:** Use extinguishing agent suitable for type of surrounding fire

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

**Unsuitable Extinguishing Media:** Not determined

### 5.2 Special hazards arising from the substance or mixture

**Special Exposure Hazards:** None known.

### 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)

**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>
Sodium Hydrogen Divalproate 76584-70-8	750 mcg/m <sup>3</sup> as Valproic Acid	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

Lactose 63-42-3	Not Applicable	None
Silica, Amorphous 112926-00-8	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m <sup>3</sup> total dust; 3 mg/m <sup>3</sup> respirable dust				
Cellulose Microcrystalline 9004-34-6	10 mg/m <sup>3</sup> total dust	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	
Lactose 63-42-3	10 mg/m <sup>3</sup> total dust, 3 mg/m <sup>3</sup> respirable dust				
Silica, Amorphous 112926-00-8	10 mg/m <sup>3</sup>				
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
Cellulose Microcrystalline 9004-34-6		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	20 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)
Silica, Amorphous 112926-00-8			4 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>Engineering Controls:</b>	No special provisions are required under normal product use conditions. When handling bulk formulation, use in a well-ventilated area.
<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>	Ovaloid tablet
<b>Odor:</b>	Odorless.

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

**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

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:**

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

**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
Sodium Hydrogen Divalproate 76584-70-8	LD50 =	2060	mg/kg	Mice
	LD50 =	2710 .	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Lactose 63-42-3	LD50 >	10000	mg/kg	Rats

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

Chemical Name	Acute Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LD50 >	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Cellulose Microcrystalline 9004-34-6	LC 50 >	5800	mg/m <sup>3</sup> , 4 hour	Rats

**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:** 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 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
Sodium Hydrogen Divalproate 76584-70-8	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.

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Sodium Hydrogen Divalproate 76584-70-8	Lungs Liver	Rats	80 - 170	Not Specified	mg/kg	2 years
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

**Mutagenicity:** Active Ingredient : Negative in mutagenicity assays.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Cellulose Microcrystalline 9004-34-6				

**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



**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

**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
Sodium Hydrogen Divalproate 76584-70-8	-	-	-	Not listed.	-
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Lactose 63-42-3	Present	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X
Titanium Dioxide 13463-67-7	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sodium Hydrogen Divalproate 76584-70-8	Present	Present	-	-	-	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Lactose 63-42-3	-	Present	X	X	Present	
Silica, Amorphous 112926-00-8	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

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

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:
Sodium Hydrogen Divalproate	35-60	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	20-50	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	1-10	Not Listed	Not Listed	Not Listed
Lactose	0-10	Not Listed	Not Listed	Not Listed
Silica, Amorphous	1-5	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):
Sodium Hydrogen Divalproate	35-60	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	20-50	No	Not Applicable	Not applicable
Cellulose Microcrystalline	1-10	No	Not Applicable	Not applicable
Lactose	0-10	No	Not Applicable	Not applicable
Silica, Amorphous	1-5	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
Sodium Hydrogen Divalproate	35-60	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.

**Product Name:** Depakote ER Tablets  
**Issued:** Jun-06-2013

## 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

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

**Issued:** Jun-06-2013

**Supersedes the SDS dated:** Apr-30-2009

**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.*