

**Product Name:** Depakene syrup  
**Issued:** Jul-02-2015

**abbvie**  
**SAFETY DATA SHEET**

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

**1.1 Product Identifier**

**Product Name:** Depakene syrup  
**Synonyms:** Depakene Oral Solution; Depakene Jarabe; Valcote JBE; Depakine JBE; Valproic Acid Oral Solution  
**List Number:** 5682

**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  
+1-847-932-7900  
**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

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

**Risk Phrases:** R61 - May cause harm to the unborn child

**2.2 Label elements**



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**Signal Word:** Danger

**Hazard Statements:** H360 - May damage fertility or the unborn child

**Precautionary Statements**  
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.
Sucrose 57-50-1	40-60	Present		Not Hazardous*	No data available
Water 7732-18-5	20-40	Present		Not Hazardous*	No data available
Sorbitol 50-70-4	5-20	Present		Not Hazardous*	No data available
Glycerol 56-81-5	5-20	Present		Not Hazardous*	No data available
Valproic Acid 99-66-1	1-10	Present	Xn, R22; Xi, R36/38; R61	Acute Tox Oral 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repro Cat1A (H360)	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

**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.

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**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. 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**

**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**

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**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>
Sucrose 57-50-1	Not Applicable	None
Water 7732-18-5	Not Applicable	None
Sorbitol 50-70-4	Not Applicable	None
Glycerol 56-81-5	Not Applicable	None
Valproic Acid 99-66-1	160 mcg/m <sup>3</sup>	None

<b>Chemical Name</b>	<b>ACGIH TLV</b>	<b>France</b>	<b>German MAK</b>	<b>Ireland</b>	<b>Italy</b>
Sucrose 57-50-1	10 mg/m <sup>3</sup> TWA	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)	
Glycerol 56-81-5	10 mg/m <sup>3</sup> (total mist)	TWA: 10 mg/m <sup>3</sup>	100 mg/m <sup>3</sup> Peak	10 mg/m <sup>3</sup> (TWA)	

<b>Chemical Name</b>	<b>The Netherlands</b>	<b>Spain</b>	<b>Switzerland</b>	<b>UK OEL/MEL</b>
Sucrose 57-50-1		10 mg/m <sup>3</sup> (TWA)		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)
Glycerol 56-81-5		10 mg/m <sup>3</sup> (TWA)	50 mg/m <sup>3</sup> (TWA) 100 mg/m <sup>3</sup> (STEL)	30 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)

### **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

<b>Appearance:</b>	Red Liquid
<b>Odor:</b>	Cherry odor
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	7-8
<b>Boiling Pt. @ 760 mm Hg (°C):</b>	Not determined.
<b>Melting/Freezing Point (°C):</b>	Not determined
<b>Flash Point (°C):</b>	Not determined.
<b>Evaporation Rate at 20°C:</b>	Not determined.
<b>Flammability (Solid):</b>	Not determined.
<b>Lower Explosive Limit:</b>	Not determined.
<b>Upper Explosive Limit:</b>	Not determined.
<b>Vapor Pressure (mm Hg):</b>	Not determined.
<b>Vapor Density (Air = 1):</b>	Not determined.
<b>Density, g / mL:</b>	1.28-1.31
<b>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Freely soluble in: water.
<b>Partition coefficient: n-octanol/water</b>	Not determined.
<b>Autoignition Temp. (°C):</b>	Not determined.
<b>Decomposition temperature (°C):</b>	Not determined.
<b>Viscosity (centipoise):</b>	Not determined.
<b>Explosion Severity:</b>	Not determined.
<b>Oxidizer Properties:</b>	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 (NO<sub>x</sub>)

## **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
Sucrose 57-50-1	LD50 >	29,700	mg/kg	Rats
Sorbitol 50-70-4	LD50 =	15900-17800	mg/kg	Mice
Glycerol 56-81-5	LD50 >	4090	mg/kg	Animals
Valproic Acid 99-66-1	LD50 =	670-2307	mg/kg	Rats Mice

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

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	10,000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Glycerol 56-81-5	LC 50 >	0.57	mg/L , 1 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.

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**Target Organ Effects:** Not determined.

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

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Glycerol 56-81-5	No Data.	Negative	No Data.	No Data.

**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.

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**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** Not applicable

according to Annex II of  
MARPOL 73/78 and the IBC

**Code:**

## 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
Sucrose 57-50-1	Present	X	X	Not listed.	X
Water 7732-18-5	Present	X	X	Not listed.	X
Sorbitol 50-70-4	Present	X	X	Not listed.	X
Glycerol 56-81-5	Present	X	X	Not listed.	X
Valproic Acid 99-66-1	Present	-	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sucrose 57-50-1	-	Present	-	X	Present	
Water 7732-18-5	-	2-(4)-1220	-	X	Present	
Sorbitol 50-70-4	Present	-	-	X	Present	
Glycerol 56-81-5	Present	-	-	X	Present	
Valproic Acid 99-66-1	Present	Present	-	X	Present	HSR006827



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### 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:
Sucrose	40-60	Not Listed	Not Listed	Not Listed
Water	20-40	Not Listed	Not Listed	Not Listed
Sorbitol	5-20	Not Listed	Not Listed	Not Listed
Glycerol	5-20	Not Listed	Not Listed	Not Listed
Valproic Acid	1-10	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):
Sucrose	40-60	No	Not Applicable	Not applicable
Water	20-40	No	Not Applicable	Not applicable
Sorbitol	5-20	No	Not Applicable	Not applicable
Glycerol	5-20	No	Not Applicable	Not applicable
Valproic Acid	1-10	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:** Listed. Reproductive toxicity

Component	Percent	Proposition 65 Listed Materials
Valproic Acid 99-66-1 ( 1-10 )	1-10	developmental toxicity, initial date 7/1/87

**WHMIS Hazard Class:** Not determined.

### NFPA Rating:

Health: 0

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

**Product Name:** Depakene syrup  
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**Risk Phrases:**

R61 - May cause harm to the unborn child

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

H360 - May damage fertility or the unborn child if inhaled

**Document Authored By:** Occupational and Environmental Toxicology

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**Supersedes the SDS dated:** Sep-03-2011

**Disclaimer:**

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