

Product Name:

Depakote Sprinkle Capsules

Issued:

Jun-01-2015



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Depakote Sprinkle Capsules

Synonyms: Divalproex Sodium Coated Particles In Capsules; Depakote Sprinkle; Depakote Sprinkle Capsules, 125 mg; Valcote Sprinkle; Epival Sprinkle; Epival Sprinkle Capsulas; Valcote 125 SPR Capsulas; Depakote 125 mg Capsula; Valproic Acid Sprinkle Capsules 125 mg

List Number: 6114; 12044

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

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 Sprinkle Capsules
Jun-01-2015

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

Precautionary Statements
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	50-70	NA	Xn, R22; Xi, R36/38; R61	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)	No data available
Magnesium Stearate 557-04-0	10-20	Present		Not Hazardous*	No data available
Ethyl Cellulose 9004-57-3	10-20	NA		Not Hazardous*	No data available
Silica, Amorphous 112926-00-8	1-10	NA		Not Hazardous*	No data available
Triethyl Citrate 77-93-0	1-5	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

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

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.

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. Clinical data suggests the following: gastrointestinal upset, headaches, nausea, sedation, dizziness, hair loss, thrombocytopenia, psychiatric changes. anemia, leucopenia, skin irritation, muscle weakness, abnormal kidney function. Clinical overdose may result in the following: coma.

Medical Conditions Aggravated by Exposure: None known from occupational exposure. Data suggest any pre-existing ailments in the following organs: 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: Naloxone has been reported to reverse the CNS depressant effects. Monitor liver function.

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

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

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:

Chemical Name	Employee Exposure Limit	Skin Notation
Sodium Hydrogen Divalproate 76584-70-8	160 mcg/m ³ as Valproic Acid	None
Magnesium Stearate 557-04-0	Not Applicable	None
Ethyl Cellulose 9004-57-3	Not Applicable	None
Silica, Amorphous 112926-00-8	Not Applicable	None
Triethyl Citrate 77-93-0	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Magnesium Stearate 557-04-0	10 mg/m ³ total dust			10 mg/m ³ (TWA)	
Ethyl Cellulose 9004-57-3	10 mg/m ³ as nuisance particulate, for Cellulose				
Silica, Amorphous 112926-00-8	10 mg/m ³				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Magnesium Stearate 557-04-0		10 mg/m ³ (TWA)		
Silica, Amorphous 112926-00-8			4 mg/m ³ (TWA)	

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

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.

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: Powder-filled capsule

Odor: Odorless.

Odor Threshold: Not determined

pH: Not determined.

Boiling Pt. @ 760 mm Hg (°C): Not determined.

Melting/Freezing Point (°C): Not determined

Flash Point (°C): N/A

Flash Point Method: N/A

Evaporation Rate at 20°C: Not determined.

Flammability (Solid): Not determined.

Lower Explosive Limit: N/A

Upper Explosive Limit: N/A

Vapor Pressure (mm Hg): Not determined.

Vapor Density (Air = 1): Not determined.

Specific Gravity: Not determined.

Solubility(ies): Not determined.

Partition coefficient: Not determined.

n-octanol/water

Autoignition Temp. (°C): N/A

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

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

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:

Oral: Clinical Route
Dermal: Unlikely
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Sodium Hydrogen Divalproate 76584-70-8	LD50 = LD50 =	2060 2710 .	mg/kg mg/kg	Mice Rats
Triethyl Citrate 77-93-0	LD50 =	3500 5900	mg/kg	Cats Rats

Acute Toxicity - Dermal: Not determined.

Chemical Name	Acute Test	Value	Units	Species
Triethyl Citrate 77-93-0	LD50 >	5000	mg/kg	Rabbits

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

Chemical Name		Test	Value	Units	Species	
Magnesium Stearate 557-04-0		LC 50 >	2000	mg/m³ , 1 hour	Rats	
Chemical Name		Test Type	Value	Units	Species	Comments
Triethyl Citrate 77-93-0		LD50 (ip) =	4000	mg/kg	Rats	None.

Corrosivity: Not determined.

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

Dermal Irritation: No effect anticipated from intact clinical product. Active Ingredient : Produced moderate skin irritation in rabbits.

Eye Irritation: No effect anticipated from intact clinical product. Active Ingredient : Produced severe eye irritation in animals. Transient eye irritation in animals testing.

Sensitization: Not determined.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: None expected from normal clinical use of this product. Active Ingredient : In animal testing, target organs include: gastrointestinal tract, hematopoietic system, liver, nervous system, male reproductive system, female reproductive system, eyes.

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.

Chemical Name	Species	Dosage	Units	Route	Duration
Sodium Hydrogen Divalproate 76584-70-8	Rats Mice Rabbits	> 65	mg/kg	Oral	During Gestation

Carcinogenicity: Not determined.

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

Mutagenicity: None expected from normal clinical use of this product. Active Ingredient : Negative in mutagenicity assays.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Magnesium Stearate 557-04-0	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

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

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 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
Sodium Hydrogen Divalproate 76584-70-8	-	-	-	Not listed.	-
Magnesium Stearate 557-04-0	Present	X	X	Not listed.	X
Ethyl Cellulose 9004-57-3	-	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X

Product Name: Depakote Sprinkle Capsules
Issued: Jun-01-2015

Triethyl Citrate 77-93-0	Present	X	X	Not listed.	X
-----------------------------	---------	---	---	-------------	---

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sodium Hydrogen Divalproate 76584-70-8	Present	Present	-	-	-	
Magnesium Stearate 557-04-0	Present	-	X	X	Present	
Ethyl Cellulose 9004-57-3	Present	-	X	X	Present	
Silica, Amorphous 112926-00-8	Present	-	X	X	Present	
Triethyl Citrate 77-93-0	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/NDL - 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:
Sodium Hydrogen Divalproate	50-70	Not Listed	Not Listed	Not Listed
Magnesium Stearate	10-20	Not Listed	Not Listed	Not Listed
Ethyl Cellulose	10-20	Not Listed	Not Listed	Not Listed
Silica, Amorphous	1-10	Not Listed	Not Listed	Not Listed
Triethyl Citrate	1-5	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	50-70	No	Not Applicable	Not applicable
Magnesium Stearate	10-20	No	Not Applicable	Not applicable
Ethyl Cellulose	10-20	No	Not Applicable	Not applicable
Silica, Amorphous	1-10	No	Not Applicable	Not applicable
Triethyl Citrate	1-5	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.

Component	Percent	Proposition 65 Listed Materials
Sodium Hydrogen Divalproate 76584-70-8 (50-70)	50-70	Listed

WHMIS Trade Secret: Exempt.

WHMIS Hazard Class: Exempt

Health: 1

Fire: 1

Product Name:
Issued:

Depakote Sprinkle Capsules
Jun-01-2015

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)

Issued: Jun-01-2015

Supersedes the SDS dated: Jan-03-2006

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.