

Product Name: Depakene Coated 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: Depakene Coated Tablets
Synonyms: Sodium Valproate Coated Tablets; Depakote Tablets
List Number: D925; E509

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
R62 - Possible risk of impaired fertility

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
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
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) Acute Tox. 4 (H302) Repr. 1A (H360)	No data available
Talc, Nonasbestos Containing 14807-96-6	5-20	Present		Not Hazardous*	No data available
Silica, Amorphous 112926-00-8	1-10	NA		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	1-10	Present		Not Hazardous*	No data available
Cellacefate 9004-38-0	1-10	NA		Not classified	No data available
Kollidon 9003-39-8	1-10	NA		Not Hazardous*	No data available
Dibutyl Phthalate 84-74-2	1-10	Present	N; R50 Repr.Cat.2; R61 Repr.Cat.3; R62	Aquatic Acute 1 (H400) Repr. 1B (H360Df)	No data available
Titanium Dioxide 13463-67-7	0.1-1	Present		Not Hazardous*	No data available

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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. 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 known from occupational exposure. Clinical data suggests the following: gastrointestinal upset, headaches, sedation, nausea, dizziness, hair loss, skin irritation, psychiatric changes, muscle weakness, thrombocytopenia, leucopenia, anemia, abnormal liver 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. Current use of treatments such as: phenobarbital therapy. Hypersensitivity to the material and/or similar materials.

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

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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:

Chemical Name	Employee Exposure Limit	Skin Notation
Sodium Hydrogen Divalproate 76584-70-8	750 mcg/m ³ as Valproic Acid	None
Talc, Nonasbestos Containing 14807-96-6	Not Applicable	None
Silica, Amorphous 112926-00-8	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Cellulose 9004-38-0	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Dibutyl Phthalate 84-74-2	Not Applicable	None

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Titanium Dioxide 13463-67-7	Not Applicable	None
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Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ , respirable dust			10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	
Silica, Amorphous 112926-00-8	10 mg/m ³				
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Kollidon 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Dibutyl Phthalate 84-74-2	5 mg/m ³ TWA	TWA: 5 mg/m ³	0.58 mg/m ³ TWA	10 mg/m ³ (STEL) 5 mg/m ³ (TWA)	
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (TWA)	2 mg/m ³ (TWA)	3 mg/m ³ (STEL) 1 mg/m ³ (TWA)
Silica, Amorphous 112926-00-8			4 mg/m ³ (TWA)	
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)
Dibutyl Phthalate 84-74-2		5 mg/m ³ (TWA)	0.58 mg/m ³ (TWA) 1.16 mg/m ³ (STEL)	10 mg/m ³ (STEL) 5 mg/m ³ (TWA)
Titanium Dioxide 13463-67-7		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (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.

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

Product Name: Depakene Coated Tablets
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Appearance: Tablet
Odor: Characteristic odor
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

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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
Sodium Hydrogen Divalproate 76584-70-8	LD50 =	2060	mg/kg	Mice
	LD50 =	2710	mg/kg	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
	Kollidon 9003-39-8	LD50 =	100000	mg/kg
LD50 >		40000	Rabbits	
Dibutyl Phthalate 84-74-2	LD50 =	7499	mg/kg	Rats
		3474		Mice

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
	Dibutyl Phthalate 84-74-2	LD50 >	20	ml/kg

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 ³ , 4 hour	Rats
	Dibutyl Phthalate 84-74-2	LC 50 =	4250	mg/m ³
		25,000	Mice	

Chemical Name	Test Type	Value	Units	Species	Comments
Dibutyl Phthalate 84-74-2	LD50 (iv) =	720	mg/kg	Mice	

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

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Reproductive Effects: No effect anticipated from intact clinical product. 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.

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
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	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.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Dibutyl Phthalate 84-74-2	1-10	1.3 0.73	Fathead Minnow Bluegill	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Dibutyl Phthalate 84-74-2	1-10	3.4	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Dibutyl Phthalate 84-74-2	1-10	1.2 3.5	Desmodesmus subspicatus	72 Hours 48 Hours

12.2. Persistence and degradability

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Not determined.

Chemical Name	Percent	% Degradation	Duration
Dibutyl Phthalate 84-74-2	1-10	81	28 days

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

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

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International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Sodium Hydrogen Divalproate 76584-70-8	-	-	-	Not listed.	-
Talc, Nonasbestos Containing 14807-96-6	Present	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Cellacefate 9004-38-0	-	X	X	Not listed.	X
Kollidon 9003-39-8	-	X	X	Not listed.	X
Dibutyl Phthalate 84-74-2	Present	X	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	-	-	-	
Talc, Nonasbestos Containing 14807-96-6	Present	-	X	X	Present	
Silica, Amorphous 112926-00-8	Present	-	X	X	Present	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Cellacefate 9004-38-0	Present	-	X	X	-	
Kollidon 9003-39-8	Present	-	X	X	Present	
Dibutyl Phthalate 84-74-2	Present	-	X	X	Present	HSR002713
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
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
Talc, Nonasbestos Containing	5-20	Not Listed	Not Listed	Not Listed
Silica, Amorphous	1-10	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	1-10	Not Listed	Not Listed	Not Listed
Cellacefate	1-10	Not Listed	Not Listed	Not Listed
Kollidon	1-10	Not Listed	Not Listed	Not Listed
Dibutyl Phthalate	1-10	Not Listed	Not Listed	Not Listed
Titanium Dioxide	0.1-1	Not Listed	Not Listed	Not Listed

SARA 313 Information

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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
Talc, Nonasbestos Containing	5-20	No	Not Applicable	Not applicable
Silica, Amorphous	1-10	No	Not Applicable	Not applicable
Cellulose Microcrystalline	1-10	No	Not Applicable	Not applicable
Cellacefate	1-10	No	Not Applicable	Not applicable
Kollidon	1-10	No	Not Applicable	Not applicable
Dibutyl Phthalate	1-10	1.0 % de minimis concentration	4.54 kg	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	50-70	Listed
Dibutyl Phthalate	1-10	Yes

WHMIS Hazard Class: Not determined.

NFPA Rating:
 Health: 2
 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, R62 - Possible risk of impaired fertility

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, H400 - Very toxic to aquatic life, H360Df - May damage the unborn child. Suspected of damaging fertility

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

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Supersedes the SDS dated: Mar-16-2006

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