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## 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** 

+1-847-932-7900

**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** 

General Note AbbVie

Acute oral toxicityCategory 4Skin corrosion/irritationCategory 2Serious eye damage/eyeCategory 2

irritation

**Reproductive toxicity** Category 1A

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

**Indication of danger:** Xn - Harmful

Xi - Irritant

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**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



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

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)	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

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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

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**None known from occupational exposure. Data suggest any pre-existing ailments

**Aggravated by Exposure:** 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

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

**Special Exposure Hazards:** Not determined

**5.3 Advice for firefighters** 

Protective Equipment and

As in any fire, wear self-contained breathing apparatus and full protective gear

**Precautions for Firefighters:** 

## 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	160 mcg/m³ 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

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Cellacefate 9004-38-0	Not Applicable	None
Kollidon 9003-39-8	Not Applicable	None
Dibutyl Phthalate 84-74-2	Not Applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Talc, Nonasbestos Containing 14807-96-6	2 mg/m³ TWA			10 mg/m³ (TWA) 0.8 mg/m³ (TWA)	
Silica, Amorphous 112926-00-8	10 mg/m <sup>3</sup>				
Cellulose Microcrystalline 9004-34-6	10 mg/m³ TWA	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)	5.00 mg/m <sup>3</sup> (TWA)
Kollidon 9003-39-8	10 mg/m³ for nuisance dust; 3 mg/m³ respirable particulate				
Dibutyl Phthalate 84-74-2	5 mg/m³ TWA	TWA: 5 mg/m <sup>3</sup>	0.1 ppm Peak 1.16 mg/m³ Peak	10 mg/m³ (STEL) 5 mg/m³ (TWA)	
Titanium Dioxide 13463-67-7	10 mg/m³ TWA	TWA: 10 mg/m <sup>3</sup>		10 mg/m³ (TWA) 4 mg/m³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m <sup>3</sup> (TWA)	2 mg/m³ (TWA)	2 mg/m³ (TWA)	3 mg/m³ (STEL) 1 mg/m³ (TWA)
Silica, Amorphous 112926-00-8			4 mg/m³ (TWA)	
Cellulose Microcrystalline 9004-34-6		10 mg/m³ (TWA)	3 mg/m³ (TWA)	20 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (TWA)
Dibutyl Phthalate 84-74-2		5 mg/m³ (TWA)	0.05 ppm (TWA) 0.58 mg/m <sup>3</sup> (TWA) 0.1 ppm (STEL) 1.16 mg/m <sup>3</sup> (STEL)	10 mg/m³ (STEL) 5 mg/m³ (TWA)
Titanium Dioxide 13463-67-7		10 mg/m³ (TWA)	3 mg/m³ (TWA)	30 mg/m³ (STEL) 12 mg/m³ (STEL) 10 mg/m³ (TWA) 4 mg/m³ (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 of 12

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## 9.1. Information on basic physical and chemical properties

**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.

n-octanol/water

**Partition coefficient:** 

**Autoignition Temp.** (°C): Not determined. **Decomposition temperature** Not determined.

Not determined.

(°C):

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 decompostion products

Carbon oxides, Nitrogen oxides (NOx)

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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 = LD50 =	2060 2710 .	mg/kg mg/kg	Mice Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Kollidon 9003-39-8	LD50 = LD50 >	100000 1040 40000	mg/kg	Rats Rabbits Mice
Dibutyl Phthalate 84-74-2	LD50 =	7499 3474	mg/kg	Rats 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	Rabbits

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

Chemical Name		Test		Value		Units		Spo	ecies
Cellulose Microcrystalline 9004-34-6		LC 50 >		5800		mg/m³,	4 hour	Rats	S
Dibutyl Phthalate 84-74-2		LC 50 =		4250 25,000		mg/m³		Rats Mic	
Chemical Name	Test	Type	Value		Units		Species		Comments
Dibutyl Phthalate	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	Lungs	Rats	10,000	mg/L	Inhalation	2 years
13463-67-7						

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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	Rats	> 65	mg/kg	Oral	During Gestation
76584-70-8	Mice				
	Rabbits				

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	<b>Site of Tumors</b>	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 <sup>3</sup> , 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.

**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	1-10	1.3	Fathead Minnow	96 Hours
84-74-2		0.73	Bluegill	

Chemical Name	Percent	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Dibutyl Phthalate 84-74-2	1-10	3.4	Daphnia magna	48 Hours

Chemical Name	Percent	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Dibutyl Phthalate	1-10	1.2	Desmodesmus subspicatus	72 Hours
84-74-2		3.5		48 Hours

### 12.2. Persistence and degradability

Not determined.

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

#### 12.3. Bioaccumulative potential

Not determined

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#### 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:

## 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.	-
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

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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**

Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA	SARA EHS TPQ
			EHS RQ (lbs):	(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	No	Not Applicable	Not applicable
Titanium Dioxide	0.1-1	No	Not Applicable	Not applicable

Immediate Health:YesDelayed Health:NoFire:No

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**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
Dibutyl Phthalate 84-74-2 ( 1-10 )	1-10	developmental toxicity, initial date 12/2/05 male reproductive toxicity, initial date 12/2/05 female reproductive toxicity, initial date 12/2/05

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

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**Supersedes the SDS dated:** Sep-05-2011

Product Name: Depakene Coated Tablets Issued: Jun-01-2015

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