

**Product Name:** Vicodin Meltrex Tablets  
**Issued:** Jun-14-2013

## **SAFETY DATA SHEET**

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

#### **1.1 Product Identifier**

**Product Name:** Vicodin Meltrex Tablets  
**Synonyms:** Hydrocodone bitartrate and acetaminophen tablets, USP  
**List Number:** 3327

#### **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**

<b>Acute oral toxicity</b>	Category 4
<b>Skin corrosion/irritation</b>	Category 2
<b>Respiratory sensitization</b>	Category 1
<b>Skin sensitization</b>	Category 1
<b>Specific target organ systemic toxicity (single exposure)</b>	Category 3
<b>Chronic aquatic toxicity</b>	Chronic toxicity 3

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

**Indication of danger:** Xi - Irritant  
Xn - Harmful

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## Section 2. Hazards identification

**Risk Phrases:**

- R22 - Harmful if swallowed
- R37 - Irritating to respiratory system
- R38 - Irritating to skin
- R42 - May cause sensitization by inhalation
- R43 - May cause sensitization by skin contact
- R52 - Harmful to aquatic organisms
- R53 - May cause long-term adverse effects in the aquatic environment

### 2.2 Label elements



**Signal Word:** Danger

**Hazard Statements:**

- H302 - Harmful if swallowed
- H315 - Causes skin irritation
- H317 - May cause an allergic skin reaction
- H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
- H335 - May cause respiratory irritation
- H412 - Harmful to aquatic life with long lasting effects

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell

P272 - Contaminated work clothing should not be allowed out of the workplace

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing

P312 - Call a POISON CENTER or doctor/physician if you feel unwell

P273 - Avoid release to the environment

### 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.
Acetaminophen 103-90-2	50-80	Present	Xn, R22 R52-53	Acute Tox. 4 (H302) Aquatic Chronic 3 (H412)	No data available
Hydroxypropyl Cellulose 9004-64-2	0-20	NA		Not Hazardous*	No data available

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### Section 3. Composition/information on ingredients

Methyl Methacrylate 80-62-6	10-20	Present	F; R11 R43 Xi; R36/37/38	Flam. Liq. 2 (H225) Skin Irrit. 2 (H315) Skin Sens. 1 (H317) STOT SE 3 (H335)	No data available
Pluronic P123 (Poloxamer) 9003-11-6	0-10	NA		Not Hazardous*	No data available
Hydrocodone Bitartrate 34195-34-1	0-10	NA	Xn, R22; R42, R43, R67	STOT SE 3 (H336) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Acute Tox. 4 (H302)	No data available
Colloidal Silicon Dioxide 7631-86-9	0-10	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:** Clinical data suggests the following: lightheadedness, dizziness, sedation, nausea, vomiting, cognitive dysfunction, incoordination, respiratory distress, rash, anorexia, abnormal liver function, abnormal kidney function, altered white blood cells and thrombocytes.

**Medical Conditions Aggravated by Exposure:** Data suggest any pre-existing ailments in the following organs: central nervous system, respiratory system, skin, urinary bladder, gastrointestinal system, kidneys. Hypersensitivity to the material and/or similar materials.

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

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**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**

**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**

**Product Name:** Vicodin Meltrex Tablets  
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**Exposure limits:**

Chemical Name	Employee Exposure Limit	Skin Notation
Acetaminophen 103-90-2	1000 mcg/m <sup>3</sup>	None
Hydroxypropyl Cellulose 9004-64-2	Not Applicable	None
Methyl Methacrylate 80-62-6	Not Applicable	None
Pluronic P123 (Poloxamer) 9003-11-6	Not Applicable	None
Hydrocodone Bitartrate 34195-34-1	5 mcg/m <sup>3</sup> TWA	None
Colloidal Silicon Dioxide 7631-86-9	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Acetaminophen 103-90-2				10 mg/m <sup>3</sup> (TWA)	
Hydroxypropyl Cellulose 9004-64-2	10 mg/m <sup>3</sup> as nuisance dust, for Cellulose				
Methyl Methacrylate 80-62-6	50 ppm TWA 100 ppm STEL	STEL: 410 mg/m <sup>3</sup> TWA: 205 mg/m <sup>3</sup>	210 mg/m <sup>3</sup> TWA	100 ppm (STEL) 50 ppm (TWA)	
Colloidal Silicon Dioxide 7631-86-9	10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate		4 mg/m <sup>3</sup> TWA	6 mg/m <sup>3</sup> (TWA) 2.4 mg/m <sup>3</sup> (TWA) 6 mg/m <sup>3</sup> (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Acetaminophen 103-90-2				30 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)
Methyl Methacrylate 80-62-6	410 mg/m <sup>3</sup> (STEL) 205 mg/m <sup>3</sup> (TWA)	100 ppm (STEL) 50 ppm (TWA)	210 mg/m <sup>3</sup> (TWA) 420 mg/m <sup>3</sup> (STEL)	100 ppm (STEL) 416 mg/m <sup>3</sup> (STEL) 100 ppm (STEL) 50 ppm (TWA) 208 mg/m <sup>3</sup> (TWA)
Colloidal Silicon Dioxide 7631-86-9			0.3 mg/m <sup>3</sup> (TWA)	18 mg/m <sup>3</sup> (STEL) 7.2 mg/m <sup>3</sup> (STEL) 18 mg/m <sup>3</sup> (STEL) 6 mg/m <sup>3</sup> (TWA) 2.4 mg/m <sup>3</sup> (TWA)

**8.2. Exposure controls**

**Engineering Controls:**

No special provisions are required under normal product use conditions. Use inside a process enclosure when handling the bulk formulation.

**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

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## **Section 9. Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

<b>Appearance:</b>	Tablet
<b>Odor:</b>	Odor not determined.
<b>Odor Threshold:</b>	Not determined
<b>pH:</b>	Not determined.
<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>Specific Gravity:</b>	Not determined.
<b>Solubility(ies):</b>	Not determined.
<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**

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**

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Carbon oxides, Nitrogen oxides (NOx)

## Section 11. Toxicological information

### 11.1. Information on toxicological effects

#### Routes of Exposure:

**Oral:** Clinical Route  
**Dermal:** Yes  
**Inhalation:** Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Acetaminophen 103-90-2	LD50 =	338	mg/kg	Mice
		1944	mg/kg	Rats
Hydroxypropyl Cellulose 9004-64-2	LD50 =	5000-10,200	mg/kg	Mice Rats
Methyl Methacrylate 80-62-6	LD50 =	3625	mg/kg	Mice
		8700		Rats Animals
Pluronic P123 (Poloxamer) 9003-11-6	LD50 >	5000	mg/kg	Rats
Hydrocodone Bitartrate 34195-34-1	LD50 =	375	mg/kg	Rats
Colloidal Silicon Dioxide 7631-86-9	LD50 =	3160	mg/kg	Rats

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

Chemical Name	Acute Test	Value	Units	Species
Pluronic P123 (Poloxamer) 9003-11-6	LD50 >	2000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Methyl Methacrylate 80-62-6	LC 50 =	18,500	mg/m <sup>3</sup> (variable exposure times)	Mice Rat (Male) Rats
		78,000		
Colloidal Silicon Dioxide 7631-86-9	LC 50 >	200	mg/L, 1 hour	Rats

**Other Toxicology Data:** Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Hydrocodone Bitartrate 34195-34-1	LD50 (sc) =	150	mg/kg	Rats	None.
		86	mg/kg	Mice	

**Corrosivity:** Not determined.

**Dermal Irritation:** Not determined.

**Eye Irritation:** Not determined.

**Sensitization:** Not determined.

**Toxicokinetics/Metabolism:** Not determined.

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**Target Organ Effects:** Major Ingredient : In clinical use target organ effects include: central nervous system, respiratory system, skin, gastrointestinal tract, kidneys, liver, blood.  
Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Acetaminophen 103-90-2	Lymphatic system Liver Kidney Thyroid Testes Ovaries Uterus	Rats Mice	600	mg/kg	Oral Diet	Repeat dose study (ies).
Colloidal Silicon Dioxide 7631-86-9	Respiratory System	Rats	126	mg/L	Inhalation	2 years

**Reproductive Effects:** Not determined.

Chemical Name	Species	Dosage	Units	Route	Duration
Hydrocodone Bitartrate 34195-34-1					

**Carcinogenicity:** Not determined.

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

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Acetaminophen 103-90-2	No Data.	Negative	No Data.	Positive
Methyl Methacrylate 80-62-6	No Data.	Positive	Positive	Positive

**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

Data for component (s) given below.

Chemical Name	Percent	LC 50 (mg/l)	Species	Duration
Acetaminophen 103-90-2	50-80	814	Fathead Minnow	96 Hours
Colloidal Silicon Dioxide 7631-86-9	0-10	5000	Brachydanio rerio	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Acetaminophen 103-90-2	50-80	9.2	Daphnia magna	48 Hours
Methyl Methacrylate 80-62-6	10-20	69		
Colloidal Silicon Dioxide 7631-86-9	0-10	7600	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
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Colloidal Silicon Dioxide 7631-86-9	0-10	440	Unicellular Green Algae	72 Hours
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#### **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**

**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**

**Product Name:** Vicodin Meltrex Tablets  
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## 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
Acetaminophen 103-90-2	Present	X	X	Not listed.	X
Hydroxypropyl Cellulose 9004-64-2	-	X	X	Not listed.	X
Methyl Methacrylate 80-62-6	Present	X	X	Not listed.	X
Pluronic P123 (Poloxamer) 9003-11-6	-	X	X	Not listed.	X
Hydrocodone Bitartrate 34195-34-1	-	-	-	Not listed.	-
Colloidal Silicon Dioxide 7631-86-9	Present	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Acetaminophen 103-90-2	Present	Present	X	X	Present	HSR005203
Hydroxypropyl Cellulose 9004-64-2	Present	-	X	X	Present	
Methyl Methacrylate 80-62-6	Present	-	X	X	Present	HSR001195
Pluronic P123 (Poloxamer) 9003-11-6	Present	-	X	X	Present	
Hydrocodone Bitartrate 34195-34-1	-	-	-	-	-	
Colloidal Silicon Dioxide 7631-86-9	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:
Acetaminophen	50-80	Not Listed	Not Listed	Not Listed
Hydroxypropyl Cellulose	0-20	Not Listed	Not Listed	Not Listed
Methyl Methacrylate	10-20	Listed	Not Listed	Not Listed
Pluronic P123 (Poloxamer)	0-10	Not Listed	Not Listed	Not Listed
Hydrocodone Bitartrate	0-10	Not Listed	Not Listed	Not Listed
Colloidal Silicon Dioxide	0-10	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):
Acetaminophen	50-80	No	Not Applicable	Not applicable
Hydroxypropyl Cellulose	0-20	No	Not Applicable	Not applicable
Methyl Methacrylate	10-20	1.0 % de minimis concentration	454 kg	Not applicable
Pluronic P123 (Poloxamer)	0-10	No	Not Applicable	Not applicable
Hydrocodone Bitartrate	0-10	No	Not Applicable	Not applicable
Colloidal Silicon Dioxide	0-10	No	Not Applicable	Not applicable

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**Immediate Health:** Yes  
**Delayed Health:** No  
**Fire:** No  
**Sudden Pressure:** No  
**Reactivity:** No

**RCRA Status:** Not determined.

**Proposition 65 Status:** Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

**WHMIS Hazard Class:** Exempt

**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, R37 - Irritating to respiratory system, R38 - Irritating to skin, R42 - May cause sensitization by inhalation, R43 - May cause sensitization by skin contact, R52 - Harmful to aquatic organisms, R53 - May cause long-term adverse effects in the aquatic environment

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

H302 - Harmful if swallowed, H412 - Harmful to aquatic life with long lasting effects, H336 - May cause drowsiness or dizziness, H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled, H317 - May cause an allergic skin reaction, H225 - Highly flammable liquid and vapor, H315 - Causes skin irritation, H335 - May cause respiratory irritation

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

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