

Product Name: Vicodin ES 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 ES Tablets
Synonyms: Vicodin ES; Vicodin Tablets, 7.5 mg/750 mg; Vicodin ES (Hydrocodone Bitartrate and Acetaminophen) Tablets
Trade name: Vicodin
List Number: 1973

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
Chronic aquatic toxicity Chronic toxicity 3

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

Indication of danger: Xn - Harmful
Risk Phrases: R22 - Harmful if swallowed
R52 - Harmful to aquatic organisms
R53 - May cause long-term adverse effects in the aquatic environment

2.2 Label elements

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

Section 2. Hazards identification



Signal Word: Warning

Hazard Statements:

H302 - Harmful if swallowed
H412 - Harmful to aquatic life with long lasting effects

P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P273 - Avoid release to the environment
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.
Acetaminophen 103-90-2	97-99	Present	Xn, R22 R52-53	Acute Tox. 4 (H302) Aquatic Chronic 3 (H412)	No data available
Silica, Amorphous 112926-00-8	0.1-1	NA		Not Hazardous*	No data available
Hydrocodone Bitartrate 34195-34-1	< 1	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
Magnesium Stearate 557-04-0	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

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

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

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

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

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
Acetaminophen 103-90-2	1000 mcg/m ³	None
Silica, Amorphous 112926-00-8	Not Applicable	None
Hydrocodone Bitartrate 34195-34-1	5 mcg/m ³ TWA	None
Magnesium Stearate 557-04-0	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Acetaminophen 103-90-2				10 mg/m ³ (TWA)	
Silica, Amorphous 112926-00-8	10 mg/m ³				
Magnesium Stearate 557-04-0	10 mg/m ³ total dust				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Acetaminophen 103-90-2				30 mg/m ³ (STEL) 10 mg/m ³ (TWA)
Silica, Amorphous 112926-00-8			4 mg/m ³ (TWA)	

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

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

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: White Tablet

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): 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

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

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

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 1944	mg/kg mg/kg	Mice Rats
Hydrocodone Bitartrate 34195-34-1	LD50 =	375	mg/kg	Rats

Acute Toxicity - Dermal: Not determined.

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

Chemical Name	Test	Value	Units	Species
Magnesium Stearate 557-04-0	LC 50 >	2000	mg/m ³ , 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 86	mg/kg mg/kg	Rats Mice	None.

Corrosivity: Not determined.

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

Dermal Irritation: Not determined.

Eye Irritation: Not determined.

Sensitization: Minor Ingredient : May cause allergic respiratory and skin reactions.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Minor Ingredient : May cause drowsiness or dizziness
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).

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

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	97-99	814	Fathead Minnow	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Acetaminophen 103-90-2	97-99	9.2	Daphnia magna	48 Hours

12.2. Persistence and degradability

Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

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

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
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Product Name: Vicodin ES Tablets
Issued: Jun-14-2013

Acetaminophen 103-90-2	Present	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X
Hydrocodone Bitartrate 34195-34-1	-	-	-	Not listed.	-
Magnesium Stearate 557-04-0	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
Silica, Amorphous 112926-00-8	Present	-	X	X	Present	
Hydrocodone Bitartrate 34195-34-1	-	-	-	-	-	
Magnesium Stearate 557-04-0	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/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	97-99	Not Listed	Not Listed	Not Listed
Silica, Amorphous	0.1-1	Not Listed	Not Listed	Not Listed
Hydrocodone Bitartrate	< 1	Not Listed	Not Listed	Not Listed
Magnesium Stearate	0.1-1	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	97-99	No	Not Applicable	Not applicable
Silica, Amorphous	0.1-1	No	Not Applicable	Not applicable
Hydrocodone Bitartrate	< 1	No	Not Applicable	Not applicable
Magnesium Stearate	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: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class: Exempt

NFPA Rating:

Health: 2

Product Name:
Issued:

Vicodin ES Tablets
Jun-14-2013

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, 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

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