

Product Name:
Issued:

Vicoprofen
Jul-29-2014



SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Vicoprofen

Synonyms: Hydrocodone Bitartrate and Ibuprofen Tablets; Vicoprofen Tablets, 7.5 mg/200 mg; Vicoprofen Tablets

Trade name: Vicoprofen

List Number: 0723; 2277

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
+1-847-932-7900

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
Serious eye damage/eye irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ systemic toxicity (single exposure)	Category 3

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

Indication of danger: Xn - Harmful
Xi - Irritant

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Section 2. Hazards identification

Risk Phrases:

R22 - Harmful if swallowed
R36/37 - Irritating to eyes and respiratory system
R42 - May cause sensitization by inhalation
R43 - May cause sensitization by skin contact

2.2 Label elements



Signal Word:

Danger

Hazard Statements:

H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation

P280 - Wear protective gloves/protective clothing/eye protection/face protection
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
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell

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.
Ibuprofen 15687-27-1	40-60	Present	Xn, R22; Xi, R36/37	STOT SE 3 (H335) Eye Irrit. 2 (H319) Acute Tox. 4 (H302)	No data available
Cellulose Microcrystalline 9004-34-6	5-20	Present		Not Hazardous*	No data available
Starch 9005-25-8	5-20	Present		Not Hazardous*	No data available

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Section 3. Composition/information on ingredients

Croscarmellose sodium 74811-65-7	5-20	NA		Not Hazardous*	No data available
Hydroxypropyl Methylcellulose 9004-65-3	1-10	NA		Not Hazardous*	No data available
Hydrocodone Bitartrate 34195-34-1	1-10	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
Silica, Amorphous 112926-00-8	1-10	NA		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, 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, 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

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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

Exposure limits:

Product Name: Vicoprofen
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Chemical Name	Employee Exposure Limit	Skin Notation
Ibuprofen 15687-27-1	660 mcg/m ³	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Starch 9005-25-8	Not Applicable	None
Croscarmellose sodium 74811-65-7	Not Applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Hydrocodone Bitartrate 34195-34-1	5 mcg/m ³ TWA	None
Silica, Amorphous 112926-00-8	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 4 mg/m ³ (TWA)	
Starch 9005-25-8	10 mg/m ³ total dust for Starch			4 mg/m ³ (TWA)	
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Silica, Amorphous 112926-00-8	10 mg/m ³				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	12 mg/m ³ (STEL) 4 mg/m ³ (TWA)
Starch 9005-25-8		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	12 mg/m ³ (STEL) 4 mg/m ³ (TWA)
Silica, Amorphous 112926-00-8			4 mg/m ³ (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

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance: White Convex tablet

Product Name:	Vicoprofen
Issued:	Jul-29-2014
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

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 (NO_x)

Section 11. Toxicological information

11.1. Information on toxicological effects

Product Name: Vicoprofen
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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
Ibuprofen 15687-27-1	LD50 =	636 495-1690	mg/kg mg/kg	Rats Guinea Pigs Mice Rabbits Hamsters
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Hydrocodone Bitartrate 34195-34-1	LD50 =	375	mg/kg	Rats

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

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

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	Rats Mice	

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: The active ingredient is an eye irritant.

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

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Active Ingredient : May cause respiratory tract irritation
 Minor Ingredient : May cause drowsiness or dizziness

Reproductive Effects: Not determined.

Carcinogenicity: Not determined.

Mutagenicity: Data for component (s) given below.

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Ibuprofen 15687-27-1	No Data.	Negative	No Data.	No Data.

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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
Ibuprofen 15687-27-1	40-60	173	Bluegill	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Ibuprofen 15687-27-1	40-60	9.06	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Ibuprofen 15687-27-1	40-60	7.1	Unicellular Green Algae	96 Hours

12.2. Persistence and degradability

Not determined.

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Ibuprofen 15687-27-1	40-60	<4

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.

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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
Ibuprofen 15687-27-1	Present	X	X	Not listed.	X
Cellulose Microcrystalline 9004-34-6	Present	X	X	Not listed.	X
Starch 9005-25-8	Present	X	X	Not listed.	X
Croscarmellose sodium 74811-65-7	-	-	-	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Hydrocodone Bitartrate 34195-34-1	-	-	-	Not listed.	-
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Ibuprofen 15687-27-1	Present	-	-	X	Present	HSR007001
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	Present	
Starch 9005-25-8	Present	-	X	X	Present	
Croscarmellose sodium 74811-65-7	-	-	X	X	-	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	Present	

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Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Hydrocodone Bitartrate 34195-34-1	-	-	-	-	-	
Silica, Amorphous 112926-00-8	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:
Ibuprofen	40-60	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	5-20	Not Listed	Not Listed	Not Listed
Starch	5-20	Not Listed	Not Listed	Not Listed
Croscarmellose sodium	5-20	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	1-10	Not Listed	Not Listed	Not Listed
Hydrocodone Bitartrate	1-10	Not Listed	Not Listed	Not Listed
Silica, Amorphous	1-10	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):
Ibuprofen	40-60	No	Not Applicable	Not applicable
Cellulose Microcrystalline	5-20	No	Not Applicable	Not applicable
Starch	5-20	No	Not Applicable	Not applicable
Croscarmellose sodium	5-20	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	1-10	No	Not Applicable	Not applicable
Hydrocodone Bitartrate	1-10	No	Not Applicable	Not applicable
Silica, Amorphous	1-10	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: 1

Fire: 1

Reactivity: 0

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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, R36/37 - Irritating to eyes and respiratory system, R42 - May cause sensitization by inhalation, R43 - May cause sensitization by skin contact

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

H335 - May cause respiratory irritation, H319 - Causes serious eye irritation, H302 - Harmful if swallowed, 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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