

Product Name: Marinol Capsules
Issued: Nov-17-2016



SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name: Marinol Capsules
Synonyms: Dronabinol capsules; Marinol Capsules, 2.5 mg; Marinol Capsules, 5 mg; Marinol Capsules, 10 mg
Trade name: Marinol
List Number: 0021; 0022; 0023; 1029; 1030; 1028; 1056; 1060; 1063

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: Manufactured for:
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) Liquid +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

Reproductive toxicity Category 2

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

2.2. Label elements



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Signal Word: Warning

Hazard Statements: H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements P201 - Obtain special instructions before use
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
P405 - Store locked up

2.3. Other hazards

Not determined

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Sesame Oil 8008-74-0	60-80	Present		Not Hazardous*	No data available
Gelatin 9000-70-8	5-20	Present		Not Hazardous*	No data available
Glycerol 56-81-5	5-20	Present		Not Hazardous*	No data available
Dronabinol 1972-08-3	1-9.9	NA		Repro Cat.2 (H361)	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

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4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms Clinical data suggests the following: variable central nervous system effects, palpitation, flushing, cardiac changes, gastrointestinal pain, nausea, vomiting, dizziness, anxiety, confusion, euphoria.

Medical Conditions Aggravated by Exposure Data suggest any pre-existing ailments in the following organs: cardiovascular system, Pregnancy.

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

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.

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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
Sesame Oil 8008-74-0	Not applicable	None
Gelatin 9000-70-8	Not applicable	None
Glycerol 56-81-5	Not applicable	None
Dronabinol 1972-08-3	Not applicable	None
Titanium Dioxide 13463-67-7	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Glycerol 56-81-5	10 mg/m ³ (total mist)	TWA: 10 mg/m ³	200 mg/m ³ TWA 400 mg/m ³ Peak	30 mg/m ³ (STEL) 10 mg/m ³ (TWA)	
Titanium Dioxide 13463-67-7	10 mg/m ³ TWA	TWA: 10 mg/m ³		30 mg/m ³ (STEL) 12 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Glycerol 56-81-5		10 mg/m ³ (TWA)	50 mg/m ³ (TWA) 100 mg/m ³ (STEL)	30 mg/m ³ (STEL) 10 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.

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Environmental Exposure Controls: Not determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Liquid Opaque Soft elastic capsule (SEC)
Odor:	Not determined
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:	Not determined
n-octanol/water	
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

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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: Unlikely
Inhalation: Unlikely

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

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	4090	mg/kg	Animals
Dronabinol 1972-08-3	LD50 = Liquid Liquid LD50 <	666 482 3150	mg/kg	Rats Liquid Mice Liquid Monkeys

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

Chemical Name	Acute Test	Value	Units	Species
Glycerol 56-81-5	LD50 >	10,000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Glycerol 56-81-5	LC 50 >	0.57	mg/L , 1 hour	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Dronabinol 1972-08-3	LD50 (iv) = Liquid Liquid Liquid LD50 (ip) = =	29 42 125 373 168	mg/kg	Rats Liquid Mice Liquid Monkeys Liquid Rats Liquid Mice	

Corrosivity Not determined

Dermal Irritation: Not determined

Eye irritation Not determined

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

Reproductive Effects Active Ingredient : In animals adverse reproductive effects include: fetal abnormalities. fetal toxicity.

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Carcinogenicity Data for component (s) given below:

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Titanium Dioxide 13463-67-7	Lungs	Rats	250,000	Inhalation	mg/L	2 years

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Glycerol 56-81-5	No Data.	Negative	No Data.	No Data.

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

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 and 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.

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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 Not applicable

**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
Sesame Oil 8008-74-0	Present	X	X	Not listed	X
Gelatin 9000-70-8	Present	X	X	Not listed	X
Glycerol 56-81-5	Present	X	X	Not listed	X
Dronabinol 1972-08-3	-	-	-	Not listed	-
Titanium Dioxide 13463-67-7	Present	X	X	Not listed	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Sesame Oil 8008-74-0	-	Present	X	X	Present	
Gelatin 9000-70-8	Present	-	X	X	Present	
Glycerol 56-81-5	Present	-	X	X	Present	
Dronabinol 1972-08-3	-	-	-	-	-	
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

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Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Sesame Oil	60-80	Not listed	Not listed	Not listed
Gelatin	5-20	Not listed	Not listed	Not listed
Glycerol	5-20	Not listed	Not listed	Not listed
Dronabinol	1-9.9	Not listed	Not listed	Not listed
Titanium Dioxide	0.1-1	Not listed	Not listed	A4 - Not Classifiable as a Human Carcinogen

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Sesame Oil	60-80	No	Not applicable	Not applicable
Gelatin	5-20	No	Not applicable	Not applicable
Glycerol	5-20	No	Not applicable	Not applicable
Dronabinol	1-9.9	No	Not applicable	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: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

Component	Weight-%	Proposition 65 Listed Materials
Titanium Dioxide 13463-67-7 (0.1-1)	0.1-1	carcinogen, 9/2/2011 (airborne, unbound particles of respirable size)

WHMIS Hazard Class Not determined

NFPA Rating:

Health: 1

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

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

H361 - Suspected of damaging fertility or the unborn child if inhaled

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