

Product Name: Trilipix Capsules
Issued: Jan-02-2013

SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Trilipix Capsules
Synonyms: Trilipix Capsules 45 mg; Trilipix Capsules 135 mg; Trilipix (Fenofibric Acid) Capsules, Delayed Release
Trade name: Trilipix
List Number: 9189: 9642

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
Serious eye damage/eye irritation Category 1
Specific target organ systemic toxicity (repeated exposure) Category 2
Chronic aquatic toxicity Chronic toxicity 4

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

Indication of danger: T - Toxic
Xn - Harmful
Xi - Irritant

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Section 2. Hazards identification

Risk Phrases: R22 - Harmful if swallowed
R41 - Risk of serious damage to eyes
R53 - May cause long-term adverse effects in the aquatic environment
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

2.2 Label elements



Signal Word: Danger

Hazard Statements: H302 - Harmful if swallowed
H318 - Causes serious eye damage
H373 - May cause damage to organs through prolonged or repeated exposure
H413 - May cause long lasting harmful effects to aquatic life

P264 - Wash face, hands and any exposed skin thoroughly after handling
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P260 - Do not breathe dust/fume/gas/mist/vapors/spray

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.
Choline Fenofibrate 856676-23-8	50-60	NA	Xi, R41 Xn, R22, R48/22	Eye Dam. 1 (H318) Acute Tox. 4 (H302) STOT Re. 2 (H373)	No data available
Hydroxypropyl Methylcellulose 9004-65-3	10-30	NA		Not Hazardous*	No data available
Methacrylic acid co-polymer 25212-88-8	1-8.9	NA	T+, R26; R53	Acute Tox. 2 (H330) Aquatic Chronic 4 (H413)	No data available

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Section 3. Composition/information on ingredients

Talc, Nonasbestos Containing 14807-96-6	1-9.9	238-877-9		Not Hazardous*	No data available
Povidone 9003-39-8	1-9.9	NA		Not Hazardous*	No data available
Hydroxypropyl Cellulose 9004-64-2	1-9.9	NA		Not Hazardous*	No data available
Triethyl Citrate 77-93-0	1-9.9	201-070-7		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. Analogy suggests the following: headaches, diarrhea, gastrointestinal upset, muscle weakness, altered liver enzymes. vomiting.

Medical Conditions No medical conditions aggravated by occupational exposure are known.

Aggravated by Exposure: Data suggest any pre-existing ailments in the following organs: liver, gastrointestinal system, muscle. 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

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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:

Chemical Name	Employee Exposure Limit	Skin Notation
Choline Fenofibrate 856676-23-8	0.5 mg/m ³ TWA	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Methacrylic acid co-polymer 25212-88-8	Not Applicable	None

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Talc, Nonasbestos Containing 14807-96-6	Not Applicable	None
Povidone 9003-39-8	Not Applicable	None
Hydroxypropyl Cellulose 9004-64-2	Not Applicable	None
Triethyl Citrate 77-93-0	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m ³ total dust; 3 mg/m ³ respirable dust				
Talc, Nonasbestos Containing 14807-96-6	2 mg/m ³ , respirable dust			10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	
Povidone 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				
Hydroxypropyl Cellulose 9004-64-2	10 mg/m ³ as nuisance dust, for Cellulose				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Talc, Nonasbestos Containing 14807-96-6	0.25 mg/m ³ (TWA)	2 mg/m ³ (TWA)	2 mg/m ³ (TWA)	3 mg/m ³ (STEL) 1 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.
Environmental Exposure Controls:	Not determined

Section 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance:	Capsule
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.

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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

Routes of Exposure:

Oral: Clinical Route
Dermal: Unlikely
Inhalation: Unlikely

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

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Chemical Name	Acute Test	Value	Units	Species
Choline Fenofibrate 856676-23-8	ALD >	1000	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Methacrylic acid co-polymer 25212-88-8	LD50 >	2000	mg/kg	Rats
Povidone 9003-39-8	LD50 =	100000 1040	mg/kg	Rats Rabbits
	LD50 >	40000		Mice
Hydroxypropyl Cellulose 9004-64-2	LD50 =	5000-10,200	mg/kg	Mice Rats
Triethyl Citrate 77-93-0	LD50 =	3500 5900	mg/kg	Cats Rats

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

Chemical Name	Acute Test	Value	Units	Species
Triethyl Citrate 77-93-0	LD50 >	5000	mg/kg	Rabbits

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

Chemical Name	Test	Value	Units	Species
Methacrylic acid co-polymer 25212-88-8	LC 50 =	1.03	mg/L, 4 hour	Rats

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

Chemical Name	Test Type	Value	Units	Species	Comments
Triethyl Citrate 77-93-0	LD50 (ip) =	4000	mg/kg	Rats	None.

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Severely irritating and corrosive to eyes.

Sensitization: Active Ingredient : A similar material is not a skin sensitizer.

Toxicokinetics/Metabolism: Not determined.

Target Organ Effects: Data for component (s) given below.

Chemical Name	Target Organs:	Species	Dosage	Units	Route	Duration
Choline Fenofibrate 856676-23-8	Liver Skeletal Muscle	Rats	30 75	mg/kg	Oral Diet	5 weeks

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

Carcinogenicity: Active ingredient : Similar Material : In animals produced tumors in the following tissue (s): liver. The observed tumors do not appear to be relevant for men
Data for similar material given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Talc, Nonasbestos Containing 14807-96-6	Lungs	Rats	18	Inhalation	mg/m ³ , 6 hours	2 years

Mutagenicity: Data for component (s) given below.

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Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Choline Fenofibrate 856676-23-8	Negative	Negative	Negative	Negative

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
Choline Fenofibrate 856676-23-8	50-60	> 100	Fathead Minnow	96 Hours
Methacrylic acid co-polymer 25212-88-8	1-8.9	>100	Brachydanio rerio	96 Hours

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Choline Fenofibrate 856676-23-8	50-60	> 100	Daphnia magna	48 Hours
Methacrylic acid co-polymer 25212-88-8	1-8.9	>100	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Choline Fenofibrate 856676-23-8	50-60	> 100	Selenastrum Capricornutum	72 Hours
Methacrylic acid co-polymer 25212-88-8	1-8.9	>100	Activated sludge	72 Hours
		>1000	Unicellular Green Algae	0.5 hours

12.2. Persistence and degradability

Active ingredient Not readily biodegradable.

Data for component (s) given below.

Chemical Name	Percent	% Degradation	Duration
Choline Fenofibrate 856676-23-8	50-60	31	28 days
Methacrylic acid co-polymer 25212-88-8	1-8.9	< 10%	28 days

12.3. Bioaccumulative potential

Data for components given below.

Chemical Name	Percent	Log Po/w
Choline Fenofibrate 856676-23-8	50-60	2.91

12.4. Mobility in soil

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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
Choline Fenofibrate 856676-23-8	-	-	-	Not listed.	-
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Methacrylic acid co-polymer 25212-88-8	-	X	X	Not listed.	X
Talc, Nonasbestos Containing 14807-96-6	238-877-9	X	X	Not listed.	X
Povidone 9003-39-8	-	X	X	Not listed.	X

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Hydroxypropyl Cellulose 9004-64-2	-	X	X	Not listed.	X
Triethyl Citrate 77-93-0	201-070-7	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Choline Fenofibrate 856676-23-8	-	-	-	-	-	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	KE-05368	
Methacrylic acid co-polymer 25212-88-8	Present	-	X	X	KE-25251	
Talc, Nonasbestos Containing 14807-96-6	Present	-	X	X	KE-32773	
Povidone 9003-39-8	Present	-	X	X	KE-13324	
Hydroxypropyl Cellulose 9004-64-2	Present	-	X	X	KE-05367	
Triethyl Citrate 77-93-0	Present	-	X	X	KE-20840	

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:
Choline Fenofibrate	50-60	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	10-30	Not Listed	Not Listed	Not Listed
Methacrylic acid co-polymer	1-8.9	Not Listed	Not Listed	Not Listed
Talc, Nonasbestos Containing	1-9.9	Not Listed	Not Listed	Not Listed
Povidone	1-9.9	Not Listed	Not Listed	Not Listed
Hydroxypropyl Cellulose	1-9.9	Not Listed	Not Listed	Not Listed
Triethyl Citrate	1-9.9	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):
Choline Fenofibrate	50-60	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	10-30	No	Not Applicable	Not applicable
Methacrylic acid co-polymer	1-8.9	No	Not Applicable	Not applicable
Talc, Nonasbestos Containing	1-9.9	No	Not Applicable	Not applicable
Povidone	1-9.9	No	Not Applicable	Not applicable
Hydroxypropyl Cellulose	1-9.9	No	Not Applicable	Not applicable
Triethyl Citrate	1-9.9	No	Not Applicable	Not applicable

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

RCRA Status: Not determined.

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

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

Risk Phrases: R22 - Harmful if swallowed, R41 - Risk of serious damage to eyes, R53 - May cause long-term adverse effects in the aquatic environment, R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

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

H330 - Fatal if inhaled, H413 - May cause long lasting harmful effects to aquatic life, H318 - Causes serious eye damage, H302 - Harmful if swallowed, H373 - May cause damage to organs (a,b,c) through prolonged or repeated exposure if inhaled

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