

Product Name: Trilipix Capsules
Issued: Dec-27-2016



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: 0074-3162-90; 0074-3161-90

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
+1-847-932-7900
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

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
Risk Phrases: R22 - Harmful if swallowed
R41 - Risk of serious damage to eyes

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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

Precautionary Statements
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	Weight-%	EINECS/ELINCS Number	EEC Classification	EU - GHS Substance Classification	REACH Reg. No
Choline Fenofibrate 856676-23-8	50-60	NA	Xi, R41 Xn, R22, R48/22	STOT RE 2 (H373) Eye Dam. 1 (H318)	No data available
Hydroxypropyl Methylcellulose 9004-65-3	10-30	NA		Not Hazardous*	No data available
Eudragit L 100-55 25212-88-8	1-8.9	NA	R53	Acute Tox. 2 (H330) Aquatic Chronic 4 (H413)	No data available
Talc, Nonasbestos Containing 14807-96-6	1-9.9	Present		Not Hazardous*	No data available
Kollidon 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	Present		Not Hazardous*	No data available

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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 Aggravated by Exposure No medical conditions aggravated by occupational exposure are known. 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

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

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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	500 mcg/m ³ TWA	None
Hydroxypropyl Methylcellulose 9004-65-3	Not applicable	None
Eudragit L 100-55 25212-88-8	Not applicable	None
Talc, Nonasbestos Containing 14807-96-6	Not applicable	None
Kollidon 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	2 mg/m ³ TWA			30 mg/m ³ (STEL)	

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14807-96-6				2.4 mg/m ³ (STEL) 10 mg/m ³ (TWA) 0.8 mg/m ³ (TWA)	
Kollidon 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

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

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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 (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
Choline Fenofibrate 856676-23-8	ALD >	1000	mg/kg	Rats
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Eudragit L 100-55 25212-88-8	LD50 >	2000	mg/kg	Rats
Kollidon 9003-39-8	LD50 = Liquid Liquid LD50 >	100000 1040 40000	mg/kg	Rats Liquid Rabbits Liquid Mice
Hydroxypropyl Cellulose 9004-64-2	LD50 =	5000-10,200	mg/kg	Mice Rats
Triethyl Citrate	LD50 =	3500	mg/kg	Cats Liquid Rats

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77-93-0		5900		
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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
Eudragit L 100-55 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 Liquid Skeletal Muscle	Rats	30 75	mg/kg	Oral Diet	for 4 weeks once weekly or twice over 3 days

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 Liquid 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:

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

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Data for component (s) given below:

Chemical Name	Weight-%	LC 50 (mg/l)	Species	Duration
Choline Fenofibrate 856676-23-8	50-60	> 100	Fathead Minnow	96 Hours
Eudragit L 100-55 25212-88-8	1-8.9	>100	Brachydanio rerio	96 Hours

Chemical Name	Weight-%	48h EC50 (daphnia - mg/l) (48HLCD)	Species	Duration
Choline Fenofibrate 856676-23-8	50-60	> 100	Daphnia magna	48 Hours
Eudragit L 100-55 25212-88-8	1-8.9	>100	Daphnia magna	48 Hours

Chemical Name	Weight-%	72h IC50 (algae - mg/l) (72HICA)	Species	Duration
Choline Fenofibrate 856676-23-8	50-60	> 100 > 100	Selenastrum Capricornutum Liquid Activated sludge	72 Hours
Eudragit L 100-55 25212-88-8	1-8.9	>100 >1000	Unicellular Green Algae Liquid Activated sludge	72 Hours Liquid 0.5 hours

12.2. Persistence and degradability

Active ingredient Not readily biodegradable Liquid Data for component (s) given below:

Chemical Name	Weight-%	% Degradation	Duration
Choline Fenofibrate 856676-23-8	50-60	31	28 days
Eudragit L 100-55 25212-88-8	1-8.9	< 10%	28 days

12.3. Bioaccumulative potential

Data for components given below.

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

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
Choline Fenofibrate 856676-23-8	-	-	-	Not listed	-
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed	X
Eudragit L 100-55 25212-88-8	-	X	X	Not listed	X
Talc, Nonasbestos Containing 14807-96-6	Present	X	X	Not listed	X
Kollidon 9003-39-8	-	X	X	Not listed	X
Hydroxypropyl Cellulose 9004-64-2	-	X	X	Not listed	X
Triethyl Citrate 77-93-0	Present	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	Present	
Eudragit L 100-55 25212-88-8	Present	-	X	X	Present	
Talc, Nonasbestos Containing 14807-96-6	Present	-	X	X	Present	
Kollidon 9003-39-8	Present	-	X	X	Present	
Hydroxypropyl Cellulose 9004-64-2	Present	-	X	X	Present	
Triethyl Citrate 77-93-0	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

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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	Weight-%	NTP:	IARC:	ACGIH:
Choline Fenofibrate	50-60	Not listed	Not listed	Not listed
Hydroxypropyl Methylcellulose	10-30	Not listed	Not listed	Not listed
Eudragit L 100-55	1-8.9	Not listed	Not listed	Not listed
Talc, Nonasbestos Containing	1-9.9	Not listed	Not listed	A4 - Not Classifiable as a Human Carcinogen (containing no asbestos fibers)
Kollidon	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	Weight-%	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
Eudragit L 100-55	1-8.9	No	Not applicable	Not applicable
Talc, Nonasbestos Containing	1-9.9	No	Not applicable	Not applicable
Kollidon	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

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

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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

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

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Supersedes the SDS dated: Oct-17-2011

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