

**Product Name:** Tricor Tablets  
**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:** Tricor Tablets  
**Synonyms:** Fenofibrate Tablets; ControLip; Lipidil EZ 48 mg tablets; Lipidil EZ 148 mg tablets; ControLip capsules; Lipidil EZ Tablets; Lipidil Tablets  
**List Number:** 6122; 6123; 4013; 4009; N080; 4010; T076; W037; W039

#### **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**

**Serious eye damage/eye irritation** Category 2  
**Specific target organ systemic toxicity (repeated exposure)** Category 2

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

**Indication of danger:** Xi - Irritant  
Xn - Harmful  
**Risk Phrases:** R36 - Irritating to eyes  
R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

#### **2.2 Label elements**

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## Section 2. Hazards identification



**Signal Word:**

Warning

**Hazard Statements:**

H319 - Causes serious eye irritation

H373 - May cause damage to organs through prolonged or repeated exposure

P264 - Wash face, hands and any exposed skin thoroughly after handling

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

P337 + P313 - If eye irritation persists: Get medical advice/attention

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P314 - Get medical advice/attention 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.
Fenofibrate 49562-28-9	10-24	256-376-3	Xn, R48/22 R53	Aquatic Chronic 4 (H413) STOT RE2 (H373)	No data available
Sucrose 57-50-1	10-30	200-334-9		Not Hazardous*	No data available
Lactose 63-42-3	10-30	200-559-2		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	10-30	232-674-9		Not Hazardous*	No data available
Polyvinyl Pyrrolidone 9003-39-8	10-30	NA		Not Hazardous*	No data available
Hydroxypropyl Methylcellulose 9004-65-3	1-10	NA		Not Hazardous*	No data available
Polyvinyl alcohol 9002-89-5	1-10	NA		Not Hazardous*	No data available
Sodium Lauryl Sulfate 151-21-3	1-2	205-788-1	Xi; R37/38/41 Xn; R20/22	STOT SE 3 (H335) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Acute Tox. 4 (H302) Acute Tox. 4 (H332)	No data available

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### Section 3. Composition/information on ingredients

Titanium Dioxide 13463-67-7	1-5	236-675-5		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:** Available information support the following: constipation, headaches, rash, cramps, abdominal pain, diarrhea.

**Medical Conditions Aggravated by Exposure:** None known from occupational exposure.

#### 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

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**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

Avoid contact with skin, eyes and clothing. 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
Fenofibrate 49562-28-9	0.5 mg/m <sup>3</sup> TWA	None
Sucrose 57-50-1	Not Applicable	None
Lactose 63-42-3	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Polyvinyl Pyrrolidone 9003-39-8	Not Applicable	None
Hydroxypropyl Methylcellulose 9004-65-3	Not Applicable	None
Polyvinyl alcohol 9002-89-5	Not Applicable	None
Sodium Lauryl Sulfate 151-21-3	Not Applicable	None

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Titanium Dioxide 13463-67-7	Not Applicable	None
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Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Sucrose 57-50-1	10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)	
Lactose 63-42-3	10 mg/m <sup>3</sup> total dust, 3 mg/m <sup>3</sup> respirable dust				
Cellulose Microcrystalline 9004-34-6	10 mg/m <sup>3</sup> total dust	TWA: 10 mg/m <sup>3</sup>		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	
Polyvinyl Pyrrolidone 9003-39-8	10 mg/m <sup>3</sup> for nuisance dust; 3 mg/m <sup>3</sup> respirable particulate				
Hydroxypropyl Methylcellulose 9004-65-3	10 mg/m <sup>3</sup> total dust; 3 mg/m <sup>3</sup> respirable dust				
Sodium Lauryl Sulfate 151-21-3	10 mg/m <sup>3</sup> as nuisance dust; 3 mg/m <sup>3</sup> for respirable fraction				
Titanium Dioxide 13463-67-7	10 mg/m <sup>3</sup> TWA	TWA: 10 mg/m <sup>3</sup>		10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)	

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Sucrose 57-50-1		10 mg/m <sup>3</sup> (TWA)		20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA)
Cellulose Microcrystalline 9004-34-6		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	20 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 20 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (TWA)
Titanium Dioxide 13463-67-7		10 mg/m <sup>3</sup> (TWA)	3 mg/m <sup>3</sup> (TWA)	30 mg/m <sup>3</sup> (STEL) 12 mg/m <sup>3</sup> (STEL) 10 mg/m <sup>3</sup> (TWA) 4 mg/m <sup>3</sup> (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:

Not determined.

### Environmental Exposure Controls:

Not determined

## Section 9. Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

**Product Name:** Tricor Tablets  
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**Appearance:** Oval 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

## **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

Not determined.

## **Section 11. Toxicological information**

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## 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
Fenofibrate 49562-28-9	LD50 =	1600 > 5000	mg/kg	Rats Mice Dogs Hamsters
Sucrose 57-50-1	LD50 >	29,700	mg/kg	Rats
Lactose 63-42-3	LD50 >	10000	mg/kg	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	mg/kg	Rats
Polyvinyl Pyrrolidone 9003-39-8	LD50 >	40,000	mg/kg	Rats Mice
Hydroxypropyl Methylcellulose 9004-65-3	LD50 >	2250	mg/kg	Rats
Sodium Lauryl Sulfate 151-21-3	LD50 =	1000-2700	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 <sup>3</sup> , 4 hour	Rats
Sodium Lauryl Sulfate 151-21-3	LC 50 >	3900	mg/m <sup>3</sup> , 1 hour	Rats

**Corrosivity:** Minor Component : Corrosive to eyes.

**Dermal Irritation:** Minor ingredient: Reported to produce skin irritation.

**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
Fenofibrate 49562-28-9	Liver	Rats	25	mg/kg	Oral	52 weeks
Sucrose 57-50-1						
Titanium Dioxide 13463-67-7	Lungs	Rats	10,000	mg/L	Inhalation	2 years

**Reproductive Effects:** Not determined.

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**Carcinogenicity:** Active ingredient : In animals produced tumors in the following tissue (s): liver.  
There is no evidence that these findings are relevant to humans  
Data for component(s) given below.

Chemical Name	Site of Tumors	Species	Dosage	Route	Units	Duration
Fenofibrate 49562-28-9	Liver	Mice Rats	60 200	Oral	mg/kg	18 months 2 years
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
Fenofibrate 49562-28-9	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**

Data for component (s) given below.

Chemical Name	Percent	EC 50 (mg/l)	Species	Duration
Sodium Lauryl Sulfate 151-21-3	1-2	1.8	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Sodium Lauryl Sulfate 151-21-3	1-2	53	Unicellular Green Algae	72 Hours

**12.2. Persistence and degradability**

Active ingredient: Not readily biodegradable.

**12.3. Bioaccumulative potential**

Data for components given below.

Chemical Name	Percent	Log Po/w
Fenofibrate 49562-28-9	10-24	4.78

**12.4. Mobility in soil**

Data for component(s) given below:



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Chemical Name	Percent	Log KOC:
Fenofibrate 49562-28-9	10-24	4.36

### 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
Fenofibrate 49562-28-9	256-376-3	-	-	Not listed.	-
Sucrose 57-50-1	200-334-9	X	X	Not listed.	X
Lactose 63-42-3	200-559-2	X	X	Not listed.	X
Cellulose Microcrystalline 9004-34-6	232-674-9	X	X	Not listed.	X

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Polyvinyl Pyrrolidone 9003-39-8	-	X	X	Not listed.	X
Hydroxypropyl Methylcellulose 9004-65-3	-	X	X	Not listed.	X
Polyvinyl alcohol 9002-89-5	-	X	X	Not listed.	X
Sodium Lauryl Sulfate 151-21-3	205-788-1	X	X	Not listed.	X
Titanium Dioxide 13463-67-7	236-675-5	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Fenofibrate 49562-28-9	-	-	-	X	KE-05546	
Sucrose 57-50-1	-	8-(4)-345	X	X	KE-17258	
Lactose 63-42-3	-	8-(4)-389	X	X	KE-17416	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	KE-05339	
Polyvinyl Pyrrolidone 9003-39-8	Present	-	X	X	KE-13324	
Hydroxypropyl Methylcellulose 9004-65-3	Present	-	X	X	KE-05368	
Polyvinyl alcohol 9002-89-5	Present	-	X	X	KE-29060	
Sodium Lauryl Sulfate 151-21-3	Present	-	X	X	KE-21884	HSR003122
Titanium Dioxide 13463-67-7	Present	-	X	X	KE-33900	

**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:
Fenofibrate	10-24	Not Listed	Not Listed	Not Listed
Sucrose	10-30	Not Listed	Not Listed	Not Listed
Lactose	10-30	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	10-30	Not Listed	Not Listed	Not Listed
Polyvinyl Pyrrolidone	10-30	Not Listed	Not Listed	Not Listed
Hydroxypropyl Methylcellulose	1-10	Not Listed	Not Listed	Not Listed
Polyvinyl alcohol	1-10	Not Listed	Not Listed	Not Listed
Sodium Lauryl Sulfate	1-2	Not Listed	Not Listed	Not Listed
Titanium Dioxide	1-5	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):
Fenofibrate	10-24	No	Not Applicable	Not applicable
Sucrose	10-30	No	Not Applicable	Not applicable
Lactose	10-30	No	Not Applicable	Not applicable
Cellulose Microcrystalline	10-30	No	Not Applicable	Not applicable
Polyvinyl Pyrrolidone	10-30	No	Not Applicable	Not applicable
Hydroxypropyl Methylcellulose	1-10	No	Not Applicable	Not applicable
Polyvinyl alcohol	1-10	No	Not Applicable	Not applicable

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Chemical Name	Percent	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Sodium Lauryl Sulfate	1-2	No	Not Applicable	Not applicable
Titanium Dioxide	1-5	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

**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:** R36 - Irritating to eyes, 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**

H335 - May cause respiratory irritation, H315 - Causes skin irritation, H318 - Causes serious eye damage, H302 - Harmful if swallowed, H332 - Harmful if inhaled

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

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**Supersedes the SDS dated:** Nov-10-2011

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