

Product Name: Lipanthyl
Issued: Mar-29-2013

SAFETY DATA SHEET

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

1.1 Product Identifier

Product Name: Lipanthyl
Synonyms: Fenofibrate tablets; Lipanthyl 160 mg; Lipanthyl 200 mg
List Number: 202750; 203765

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.
Povidone 9003-39-8	30-40	NA		Not Hazardous*	No data available
Fenofibrate 49562-28-9	14-24	256-376-3	Xn, R48/22 R53	Aquatic Chronic 4 (H413)	No data available
Lactose 63-42-3	15-25	200-559-2		Not Hazardous*	No data available
Cellulose Microcrystalline 9004-34-6	10-20	232-674-9		Not Hazardous*	No data available
Fumaric acid 110-17-8	5-10	203-743-0	Xi; R36	Eye Irrit. 2 (H319)	No data available
Silica, Amorphous 112926-00-8	1-5	NA		Not Hazardous*	No data available
Sodium Lauryl Sulfate 151-21-3	0.1-1	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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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

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
Povidone 9003-39-8	Not Applicable	None
Fenofibrate 49562-28-9	0.5 mg/m ³ TWA	None
Lactose 63-42-3	Not Applicable	None
Cellulose Microcrystalline 9004-34-6	Not Applicable	None
Fumaric acid 110-17-8	Not Applicable	None
Silica, Amorphous 112926-00-8	Not Applicable	None
Sodium Lauryl Sulfate 151-21-3	Not Applicable	None

Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Povidone 9003-39-8	10 mg/m ³ for nuisance dust; 3 mg/m ³ respirable particulate				

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Chemical Name	ACGIH TLV	France	German MAK	Ireland	Italy
Lactose 63-42-3	10 mg/m ³ total dust, 3 mg/m ³ respirable dust				
Cellulose Microcrystalline 9004-34-6	10 mg/m ³ total dust	TWA: 10 mg/m ³		20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 4 mg/m ³ (TWA)	
Silica, Amorphous 112926-00-8	10 mg/m ³				
Sodium Lauryl Sulfate 151-21-3	10 mg/m ³ as nuisance dust; 3 mg/m ³ for respirable fraction				

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL
Cellulose Microcrystalline 9004-34-6		10 mg/m ³ (TWA)	3 mg/m ³ (TWA)	20 mg/m ³ (STEL) 12 mg/m ³ (STEL) 20 mg/m ³ (STEL) 10 mg/m ³ (TWA) 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. 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:	Not needed during typical 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

Appearance:	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.

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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

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
Povidone 9003-39-8	LD50 =	100000	mg/kg	Rats
		1040		Rabbits
	LD50 >	40000		Mice

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Chemical Name	Acute Test	Value	Units	Species
Fenofibrate 49562-28-9	LD50 =	1600 > 5000	mg/kg	Rats Mice Dogs Hamsters
Lactose 63-42-3	LD50 >	10000	mg/kg	Rats
Cellulose Microcrystalline 9004-34-6	LD50 >	5000	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 ³ , 4 hour	Rats
Sodium Lauryl Sulfate 151-21-3	LC 50 >	3900	mg/m ³ , 1 hour	Rats

Corrosivity: Not determined.

Dermal Irritation: Not determined.

Eye Irritation: Minor ingredients are eye irritants.

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

Reproductive Effects: Not determined.

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

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.
Cellulose Microcrystalline 9004-34-6				

Aspiration hazard: Not determined

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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	0.1-1	1.8	Daphnia magna	48 Hours

Chemical Name	Percent	EB 50/ErC 50 (mg/l)	Species	Duration
Sodium Lauryl Sulfate 151-21-3	0.1-1	53	Unicellular Green Algae	72 Hours

12.2. Persistence and degradability

Active ingredient: Not readily biodegradable.

12.3. Bioaccumulative potential

Not determined

Chemical Name	Percent	Log Po/w
Fenofibrate 49562-28-9	14-24	4.78

12.4. Mobility in soil

Not determined.

Chemical Name	Percent	Log KOC:
Fenofibrate 49562-28-9	14-24	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

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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
Povidone 9003-39-8	-	X	X	Not listed.	X
Fenofibrate 49562-28-9	256-376-3	-	-	Not listed.	-
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
Fumaric acid 110-17-8	203-743-0	X	X	Not listed.	X
Silica, Amorphous 112926-00-8	-	-	X	Not listed.	X
Sodium Lauryl Sulfate 151-21-3	205-788-1	X	X	Not listed.	X

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Povidone 9003-39-8	Present	-	X	X	KE-13324	
Fenofibrate 49562-28-9	-	-	-	X	KE-05546	
Lactose 63-42-3	-	8-(4)-389	X	X	KE-17416	
Cellulose Microcrystalline 9004-34-6	Present	-	X	X	KE-05339	
Fumaric acid 110-17-8	Present	-	X	X	KE-13658	HSR003272
Silica, Amorphous 112926-00-8	Present	-	X	X	KE-32733	
Sodium Lauryl Sulfate 151-21-3	Present	-	X	X	KE-21884	HSR003122

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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:
Povidone	30-40	Not Listed	Not Listed	Not Listed
Fenofibrate	14-24	Not Listed	Not Listed	Not Listed
Lactose	15-25	Not Listed	Not Listed	Not Listed
Cellulose Microcrystalline	10-20	Not Listed	Not Listed	Not Listed
Fumaric acid	5-10	Not Listed	Not Listed	Not Listed
Silica, Amorphous	1-5	Not Listed	Not Listed	Not Listed
Sodium Lauryl Sulfate	0.1-1	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):
Povidone	30-40	No	Not Applicable	Not applicable
Fenofibrate	14-24	No	Not Applicable	Not applicable
Lactose	15-25	No	Not Applicable	Not applicable
Cellulose Microcrystalline	10-20	No	Not Applicable	Not applicable
Fumaric acid	5-10	No	2270 kg	Not applicable
Silica, Amorphous	1-5	No	Not Applicable	Not applicable
Sodium Lauryl Sulfate	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.

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

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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

H319 - Causes serious eye irritation, H373 - May cause damage to organs through prolonged or repeated exposure

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

Issued: Mar-29-2013

Supersedes the SDS dated: Aug-08-2011

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