SAFETY DATA SHEET

According to Globally Harmonized System of Classification and Labelling of Chemicals (GHS),
Third Revised Edition UNITED NATIONS
New York and Geneva, 2019

Fenofibrate Tablet (54 mg/160 mg)

1. IDENTIFICATION

GHS Product identifier: Fenofibrate tablet

Product code:#
Chemical Description: 2-[4-(4-chlorobenzoyl) phenoxy]-2-methylpropanoic acid, 1-methylethyl ester

Other means of identification:
Recommended use of the chemical: Pharmaceutical use -- Reduction of LDL-C, Total-C, Triglycerides and Apo B in adult patients with primary hypercholesterolemia or mixed dyslipidemia (Fredrickson Types IIa and IIb)

Restrictions on use: The product should be used only for the above mentioned uses and may not be used for any other purpose than stated above.

Manufactured by:

Mankind Pharma Ltd.,
Unit III, Opp. Dental College, Rampur Ghat,
Teh. -Paonta Sahib (HP-173025), India.
CIN No.: U74899DL1991PLC044843

Emergency phone number: +91 1704227600

2. HAZARDS IDENTIFICATION

Classification
Globally Harmonized System, UN (GHS)

Classification	Category	Exposure Route	Labels (as per, UN-GHS)	Signal Word	Warning
Acute Toxicity	5	Oral		**Hazard Statements:**	**H302 : Harmful if swallowed** **H332 : Harmful if inhaled** **H373 : Causes damage to organs through prolonged or repeated exposure [Warning Specific target organ toxicity, repeated exposure)** **H413 : May cause long lasting harmful effects to aquatic life [Hazardous to the aquatic environment, long-term hazard]** **Only hazard codes of ingredients with percentage values shown..**
Skin Irritation	3	Dermal			
Aquatic toxicity	Chronic 4	-			
STOT (RE)	2	Oral			

Signal Word	Warning
Precautionary Statements:	P260: Do not breathe dust P273: Avoid release to the environment. P314: Get medical advice if you feel unwell. P501: Dispose of contents/container to local/national/international regulation.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical nature: Mixture containing Fenofibrate

Hazardous ingredients	CAS	Content
Fenofibrate	49562-28-9	37.84%
Sodium dodecyl sulphate	151-21-3	*

4. FIRST-AID MEASURES

Occupational exposure to fenofibrate may occur through inhalation and dermal contact with this compound at workplaces where fenofibrate is produced or used. No limits for exposure have been established.

Inhalation

In case of irritation of the respiratory system or mucous membranes, seek medical attention. Move to fresh air. Seek medical attention if you feel unwell or if exposure prolonged.

Skin contact

Remove contaminated clothing. Wash affected skin with soap and plenty of water. If skin irritation or dermatitis commences or persists, seek medical attention. Cover skin burns with dry sterile dressings after decontamination.

Eye contact

Immediately flush contaminated eyes with gently flowing water. Irrigate each eye continuously with 0.9% saline (NS) during transport.

Ingestion

Monitor vital signs and observe clinical status. If indicated, elimination of unabsorbed drug should be achieved by emesis.Fenofibrate is highly bound to plasma proteins, hemodialysis should not be considered.

Advice for the doctor

Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed), Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if needed. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary edema and treat if necessary.

On ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool.

Monitor for shock and treat if necessary. Anticipate seizures and treat if necessary. Do not use emetics.

5. FIRE-FIGHTING MEASURES

Fire extinguishing agents

Water spray, Foam, Carbon dioxide (CO_2), Dry powder.

Fire/explosion hazard

No data available

Specific hazards arising from the chemical

No data available

Personal protection

Self-contained breathing apparatus.

Special exposure hazards

Do not release chemically contaminated water into drains, soil or surface water. Dispose of contaminated water and soil according to local regulations.

6. ACCIDENTAL RELEASE MEASURES

Personal protection

Goggles, gloves, protective clothing, respiratory protection.
Remove ignition sources and provide sufficient ventilation.

Environmental precautions
Prevent contamination of soil, drains and surface waters.
Spillage procedure
Take up mechanically and collect in suitable container (adequately labelled) for disposal.

7. HANDLING AND STORAGE

Handling
Occupational hygiene
Avoid ingestion, inhalation, skin and eye contact. Handle in accordance with good industrial hygiene practice and any legal requirements.
Storage
Handling- Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure.
Fire precautions
Avoid dust formation and ignition sources. Ensure good local exhaust ventilation.
Keep away from heat/sparks/open flames/hot surfaces – No smoking.

Storage facilities
Store in a cool, dry area with adequate ventilation. Keep tightly closed. Store at 25 °C

Segregation
Store locked up.
Storage conditions
Keep containers closed.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Exposure limit values
Components with occupational exposure limits

CAS No	Name	TWA	STEL	Source
. 49562-28-9	2-[4-(4-chlorobenzoyl) phenoxy]-2-methylpropanoic acid, 1-methylethyl ester	Not known	-	-
9004-34-6	Cellulose	10 mg/m^3 (skin)	-	ACGIH
557-04-0	Magnesium stearate	10 mg/m^3 (eye, skin, & URT irr)	-	ACGIH
151-21-3	Sodium dodecyl sulphate	0.3 mg/m^3		Pfizer OEL

Occupational exposure controls
Appropriate engineering controls
Maintain air concentrations below occupational exposure standards. Prevent dust formation.
General Personal Protection
Goggles, gloves, protective clothing.
Respiratory protection
Breathing apparatus with filter required if occupational exposure limits may be exceeded.
Hand protection
Protective gloves.
Eye protection
Goggles.
Skin and body protection
Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Solid
Form: Tablets
Colour: yellow
Odour: N.A.
pH: not tested
Melting point: not tested
Boiling point: not applicable
Flash point: not applicable
Flammability (solid): not tested
Vapour pressure: not tested
Auto-ignition temperature: not applicable
Decomposition temperature: not tested
Density: not tested
Solubility in water: Practically insoluble in water;

Solubility in solvents: : slightly soluble in methanol, ethanol; soluble in acetone, ether, benzene, chloroform.

n-Octanol/Water Partition Coefficient: 5.2
Viscosity: Not tested
Oxidizing properties: not tested
Explosivity: Stable under ordinary conditions

10. STABILITY AND REACTIVITY

Conditions to avoid
Avoid moisture
Materials to avoid
Acid, Acid chlorides, acid anhydrides, oxidizing agents
Hazardous decomposition products
None under normal storage conditions

11. TOXICOLOGICAL INFORMATION

Acute toxicity
Fenofibrate active ingredient was tested for acute toxicity.

Fenofibrate

LD50 (oral, rat): >2000 mg/kg
LD50 (oral, mouse):>1600 mg/kg

Sodium dodecyl sulphate
LD50 (oral, rat): 1288 mg/kg
LD50 (dermal): > 400 mg/kg and < 2 000 mg/kg

Based on toxicity data of Fenofibrate and its excipients, Fenofibrate tablet can be classified as category 5.

Primary Irritation

(Fenofibrate)
- Skin: Data is not available
- Eye: Data is not available

(Sodium dodecyl sulphate)
- Skin: Causes skin irritation - GHS classification category 2

- Eye: Causes serious eye irritation - GHS classification category 1

(Magnesium stearate)
Skin - category 2
Eye Irritation - category 2

GHS Classification of the mixture for skin irritation is category 3.

The mixture has been evaluated for eye irritation and based on available data, does not meet classification criteria.

Respiratory or Skin sensitization

- Respiratory: Not tested

GHS Classification is not possible.

CMR consideration:

Germ cell mutagenicity:

- Data unavailable

GHS Classification is not possible.

Carcinogenicity

Fischer 344 male rats were dosed with 300 mg/kg/day of fenofibrate for 14 days and the urine and plasma were analyzed on days 2 and 14. Results suggest possible mechanism of nongenotoxic carcinogenisis.

GHS Classification is not possible due to inconclusive data.

Reproductive toxicity

- Data lacking

Due to lack of data the GHS classification is not possible.

Specific target organ toxicity single exposure:

Fenofibrate (active ingredient), data not available (Not classifiable).
SLS may cause respiratory irritation – Category 3.
Since SLS concentration < 20% hence **GHS classification is not applicable**.

Specific target organ toxicity repeated exposure:
Fenofibrate (active ingredient),
Based on available data, **GHS classification for STOT (RE) is category 2.**
Since fenofibrate is present at ≥ 10% in the mixture, it falls under GHS category 2.

Aspiration hazard:
Due to lack of data GHS Classification is not possible.

Additional information:

12. ECOLOGICAL INFORMATION

Ecotoxicity

Data for Fenofibrate substance is lacking. Based on log K_{ow} 5.2, it has been classified as chronic 4.

Acute aquatic toxicity data

- **LC50 (fish, 96 hr):** not tested
- **EC50 (daphnia, 48 hr):** not
- **ErC50 (algae, 72 hr**):not tested
- **IC50 (bacteria, 5 days):** not tested

SLS and Magnesium stearate classified as chronic 3 and chronic 4 respectively. Based on the GHS classification for environmental hazards, the mixture has been classified as chronic 4.

GHS Classification for Fenofibrate tablet is Aquatic chronic 4 based on above data.

Persistence and degradability

Data not available. GHS Classification is not possible.

Behaviour in treatment plants

Data not available. GHS Classification is not possible.

Additional information

Do not discharge product uncontrolled into the environment.

13. DISPOSAL CONSIDERATIONS

Product disposal

Incinerate in approved facility. Observe specific national regulation.

Contaminated packaging

Contaminated, empty containers must be disposed of as chemical waste.

14. TRANSPORT INFORMATION

The substance is not considered to be a dangerous good according to transport regulations

15. REGULATORY INFORMATION

CLASSIFICATION AND LABELLING

Compliance with following regulations:

- Globally Harmonized System of Classification and Labelling of Chemicals (GHS), UNECE 2019 as amended
- UN Recommendations on the Transport of Dangerous Goods, UNECE 2009

16. OTHER INFORMATION

Recommended restrictions on use

This product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with any legal regulation. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should not therefore be construed as guaranteeing specific properties.

MSDS Changes -

Prepared on 14/08/2020