

1. Identification

Product identifier	Clofibrate	
Other means of identification		
Catalog number	1139000	
Chemical name	Propanoic acid, 2-(4-chlorophenoxy)-2-methyl-, ethyl ester	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
OSHA hazard(s)	Not classified.	

Label elements



Signal word	Warning	
Hazard statement	Harmful if swallowed.	
Precautionary statement		
Prevention	Wash thoroughly after handling.	
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.	
Storage	Not available.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	Not classified.	

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Clofibrate		637-07-0	100

4. First-aid measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.

Ingestion	Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.
Most important symptoms/effects, acute and delayed	Gastrointestinal disturbances.
Indication of immediate medical attention and special treatment needed	Treatment of overdose should be symptomatic and supportive and may include the following: Gastric lavage may be indicated if performed soon after ingestion. Administer charcoal as an aqueous slurry. Observe for potential CNS depression, musculoskeletal, cardiovascular, and liver or kidney damage. [Meditext 2010]
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of vapors. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	No exposure standards allocated.
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for aerosol-generating procedures.

Individual protection measures, such as personal protective equipment

Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Colorless to pale yellow oil or liquid.
Physical state	Liquid.
Form	Liquid.
Odor	Slight characteristic odor.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	< 77 °F (< 25 °C)
Initial boiling point and boiling range	298.4 - 302 °F (148 - 150 °C)
Flash point	235.40 °F (113.00 °C) Closed Cup
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	0.0003386 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Practically insoluble.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Phenol derivative, fibric acid derivative.
Molecular formula	C ₁₂ H ₁₅ ClO ₃
Molecular weight	242.72 g/mol
Solubility (other)	Soluble in alcohol, in acetone, in chloroform, in benzene, and in ether.
Specific gravity	1.138 - 1.144

10. Stability and reactivity

Reactivity	No reactivity hazards known.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents. Strong bases.
Hazardous decomposition products	Cl ⁻ . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
Inhalation	Due to lack of data the classification is not possible.

Skin contact	Due to lack of data the classification is not possible.
Eye contact	Due to lack of data the classification is not possible.
Symptoms related to the physical, chemical, and toxicological characteristics	Nausea. Vomiting. Diarrhea. Increased appetite. Weight gain. Stomach pain. Gas. Heartburn. Mouth sores. Dizziness. Drowsiness. Headache.
Delayed and immediate effects of exposure	Gallbladder toxicity. Pancreatic toxicity. Cardiovascular toxicity.
Medical conditions aggravated by exposure	Liver impairment. Kidney impairment. Primary biliary cirrhosis. Peptic ulcer. History of myocardial infarction.
Acute toxicity	Harmful if swallowed.

Product	Species	Test Results
Clofibrate (CAS 637-07-0)		
<i>Oral</i>		
LD50	Mouse	1280 mg/kg
	Rat	940 mg/kg

Skin corrosion/irritation	Due to lack of data the classification is not possible.
Serious eye damage/eye irritation	Due to lack of data the classification is not possible.
Respiratory sensitization	Due to lack of data the classification is not possible.
Skin sensitization	Due to lack of data the classification is not possible.
Germ cell mutagenicity	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.

Mutagenicity

Chinese hamster V79 assay
Result: Negative.
E. coli assay
Result: Negative.
Mouse lymphoma assay
Result: Negative.
S. typhimurium Ames assay
Result: Negative.

Carcinogenicity	Based on available data, the classification criteria are not met. This material is not considered to be a carcinogen by IARC, NTP, or OSHA. IARC: Group 3; this material is not classifiable as to its carcinogenicity in humans.
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0 - 500 mg/kg/day Carcinogenicity study
Result: No carcinogenic effects.
Species: Mouse
1500 - 9000 ppm Carcinogenicity study
Result: Hepatocellular carcinomas were observed.
Species: Rat

Reproductive toxicity	Based on available data, the classification criteria are not met.
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Reproductivity

14 mg/kg/day Reproductivity study
Result: No adverse reproductive effects.
Species: Rat
15 mg/kg/day Reproductivity study
Result: No developmental findings.
Species: Rabbit
150 mg/kg/day Reproductivity study
Result: Aborted litters were observed.
Species: Rabbit
300 mg/kg/day Reproductivity study
Result: No effects on fertility.
Species: Rat

Specific target organ toxicity - single exposure	Due to lack of data the classification is not possible.
Specific target organ toxicity - repeated exposure	Due to lack of data the classification is not possible.
Aspiration hazard	Due to lack of data the classification is not possible.

12. Ecological information

Ecotoxicity

Product		Species	Test Results
Clofibrate (CAS 637-07-0)			
Crustacea	EC50	Daphnia magna	28.2 mg/l, 48 hours
Fish	LC50	Fish	7.7 mg/l, 96 hours

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential Not available.

Mobility in soil Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Not available.

Hazardous waste code Not available.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Clofibrate)
Transport hazard class(es)	9
Subsidiary class(es)	Not available.
Packing group	III

IATA

UN number	UN3082
UN proper shipping name	Environmentally hazardous substance, liquid, n.o.s. (Clofibrate)
Transport hazard class(es)	9
Subsidiary class(es)	-
Packaging group	III

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

DOT; IATA



15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

WARNING: This product contains a chemical known to the State of California to cause cancer.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date 05-14-2010

Revision date 04-15-2014

Version # 02

Further information Not available.

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Revision Information This document has undergone significant changes and should be reviewed in its entirety.