

BRITISH PHARMACOPOEIA CHEMICAL REFERENCE SUBSTANCE

MATERIAL SAFETY DATA SHEET

Last revised: 17th June 2008.

The substance to which this Safety Data Sheet relates is supplied exclusively as a British Pharmacopoeia Chemical Reference Substance (BPCRS) for chemical test and assay purposes. It is not intended to be used for any other purpose and **is not for human consumption**.

The BPCRS is supplied in accordance with the Terms of Trade and Supply as set out in the catalogue. The information set out in this sheet is applicable solely to the substance when used as a BPCRS and is not intended to apply to any other use or preparation of the substance (e.g. at different concentrations, in drug dosage form or in bulk quantities).

The information which follows has been assembled from sources considered reliable, in particular from material provided in the ordinary way by the manufacturer or supplier. It has not been independently verified by the British Pharmacopoeia. The accuracy of the information cannot therefore be guaranteed, nor does it constitute any expression of opinion by the British Pharmacopoeia concerning the substance. This information is not to be regarded as a representation or statement concerning the quality or safety of the substance except that of use as a BPCRS by professional persons having technical skill and at their own discretion and risk.

All persons using BPCRS materials must determine the risks associated with the substance depending on the actual conditions of use and should take appropriate measures.

Information given in sections 2, 3, 4, 5, 6, 9, 10, 11, 12 and 13 relates to the bulk substance and is not necessarily relevant to the BPCRS regarding the small quantities contained in vials. Information in sections 1, 7, 8 and 14 applies only to the BPCRS.

1. IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY

2,2-DIMETHYL-5-(2,4-XYLYLOXY)VALERIC ACID BPCRS

Caution! This product is a synthesis by-product and/or a degradation product. Its properties have not been fully investigated. *Information given in this MSDS refers to the parent compound; gemfibrozil.*

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2. HAZARDS IDENTIFICATION

Harmful if swallowed. Limited evidence of a carcinogenic effect. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Possible risk of impaired fertility.

Symbol: Xn

Risk phrases: R22, R40, R51/53, R62

3. COMPOSITION/INFORMATION ON INGREDIENTS

C₁₅H₂₂O₃

CAS: Not known

Synonym: 5-(2,4-dimethylphenoxy)-2,2-dimethylpentanoic acid

4. FIRST AID MEASURES

Inhalation: Remove to fresh air. If breathing becomes difficult, call a physician.

Skin contact: Flush with copious amounts of water and soap for at least 15 minutes. Remove contaminated clothing and shoes.

Eyes contact: Assure adequate flushing by separating the eyelids with fingers. Flush with copious amounts of water for at least 15 minutes.

Ingestion: Wash out mouth with water and administer fresh water provided person is conscious.

In any case seek medical advice and call the nearest poison centre.

5. FIRE FIGHTING MEASURES

Extinguishing media: Water spray. Carbon dioxide, dry chemical powder or appropriate foam.

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

Wear suitable protective clothing and respiratory protection to prevent contact with skin and eyes. Sweep up, place in a bag and hold for waste disposal. Avoid raising dust. Ventilate and wash affected area with water/detergent.

7. HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin and clothing.

Storage: Keep unopened in the original container at about 2-10 °C. Keep tightly closed.

8. EXPOSURE CONTROL/PERSONAL PROTECTION

Respiratory protection: Protecting mask.

Hand protection: Compatible chemical-resistant gloves (rubber).

Eye protection: Wear protective chemical safety goggles.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: white or almost white, waxy, crystalline powder.

Solubility: practically insoluble in water, very soluble in methylene chloride, freely soluble in anhydrous ethanol and in methanol.

10. STABILITY AND REACTIVITY

Hazardous combustion or decomposition products: CO_x. Hazardous polymerization will not occur.

11. TOXICOLOGICAL INFORMATION

RTECS No: YV7120000 (gemfibrozil)

LD50 (oral-rat): 1414 mg/kg.

May cause skin and/or eye irritation. May cross the placenta and be excreted in breast milk.

See actual entry in RTECS for complete information.

12. ECOLOGICAL INFORMATION

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

LC50 (fish-96h): 22 mg/l

EC50 (daphnies-48h): 21 mg/l

IC50 (algae-72h): 6.2 mg/l

Not readily biodegradable (30 % after 28 days).

Log Pow: 4.17, may redistribute into fat and persist. If not metabolised, may bioaccumulate.

13. DISPOSAL CONSIDERATIONS

Incinerate in an approved facility.
Observe all federal state and local environmental regulations.

14. TRANSPORT INFORMATION

Class 9, UN 3077, PG III

15. REGULATORY INFORMATION

EINECS Number: 247-280-2 (gemfibrozil)
Symbol: Xn
R22, R40, R51/53, R62, S36/37, S61

16. OTHER INFORMATION

R22 Harmful if swallowed.
R64 May cause harm to breastfed babies.
R40 Limited evidence of a carcinogenic effect.
R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
R62 Possible risk of impaired fertility.
S36/37: Wear suitable protective clothing and gloves