

**Safety data sheet**  
*according to 1907/2006/EC, Article 31*

Printing date 30.06.2021

Version number 1

Revision: 30.06.2021

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**· **1.1 Product identifier**· **Product name:** Gemfibrozil Assay Standard· **Part number:** Cat 363· **CAS Number:**  
25812-30-0· **EC number:**  
247-280-2· **1.2 Relevant identified uses of the substance or mixture and uses advised against***No further relevant information available.*· **Application of the substance / the mixture** *Reference material for laboratory use only*· **1.3 Details of the supplier of the safety data sheet**· **Manufacturer/Supplier:***British Pharmacopoeia Commission  
MHRA  
10 South Colonnade  
Canary Wharf  
London E14 4PU  
United Kingdom**Tel : +44 (0)20 3080 6561**eMail: bpcrs@mhra.gov.uk*· **Further information obtainable from:** *eMail: bpcrs@mhra.gov.uk*· **1.4 Emergency telephone number:** *+44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)***SECTION 2: Hazards identification**· **2.1 Classification of the substance or mixture**· **Classification according to Regulation (EC) No 1272/2008***Acute Tox. 4      H302 Harmful if swallowed.**Skin Irrit. 2      H315 Causes skin irritation.**Eye Irrit. 2      H319 Causes serious eye irritation.**Aquatic Chronic 3      H412 Harmful to aquatic life with long lasting effects.*· **2.2 Label elements**· **Labelling according to Regulation (EC) No 1272/2008***The substance is classified and labelled according to the CLP regulation.*· **Hazard pictograms****GHS07**· **Signal word** *Warning*· **Hazard statements***H302 Harmful if swallowed.**H315 Causes skin irritation.**H319 Causes serious eye irritation.**H412 Harmful to aquatic life with long lasting effects.*

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**· Precautionary statements**

- P273 *Avoid release to the environment.*  
P280 *Wear protective gloves / eye protection / face protection.*  
P301+P312 *IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.*  
P305+P351+P338 *IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*  
P321 *Specific treatment (see on this label).*  
P501 *Dispose of contents/container in accordance with local/regional/national/international regulations.*

**· 2.3 Other hazards****· Results of PBT and vPvB assessment**

- PBT:** Not applicable.
- vPvB:** Not applicable.

**SECTION 3: Composition/information on ingredients****· 3.1 Substances****· CAS No. Description**

25812-30-0 Gemfibrozil

**· Identification number(s)** None**· EC number:** 247-280-2**· RTECS:** YV7120000**· Additional information:** For the wording of the listed hazard phrases refer to section 16.**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information:**

Symptoms of poisoning may occur even after several hours; therefore medical observation for at least 48 hours after the accident is recommended.

**· After inhalation:** Supply fresh air; consult doctor in case of complaints.**· After skin contact:**

Immediately wash with water and soap and rinse thoroughly.

If skin irritation continues, consult a doctor.

**· After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**· After swallowing:**

Rinse mouth. Do not induce vomiting.

Seek medical treatment.

**· 4.2 Most important symptoms and effects, both acute and delayed** No further relevant information available.**· 4.3 Indication of any immediate medical attention and special treatment needed**

No further relevant information available.

**SECTION 5: Firefighting measures****· 5.1 Extinguishing media****· Suitable extinguishing agents:** Use fire extinguishing methods suitable for surrounding conditions.**· 5.2 Special hazards arising from the substance or mixture**

Formation of toxic gases is possible during heating or in case of fire.

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- **5.3 Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.

**SECTION 6: Accidental release measures**

- **6.1 Personal precautions, protective equipment and emergency procedures** Wear protective clothing.
- **6.2 Environmental precautions:**  
Inform respective authorities in case of seepage into water course or sewage system.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:** Pick up mechanically.
- **6.4 Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

**SECTION 7: Handling and storage**

- **7.1 Precautions for safe handling** Store in cool, dry place in tightly closed receptacles.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Please refer to the manufacturer's certificate for specific storage and transport temperature conditions.  
Store only in the original receptacle unless other advice is given on the CoA.  
Keep container in a well-ventilated place. Keep away from sources of ignition and heat.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Keep container tightly sealed.
- **7.3 Specific end use(s)** No further relevant information available.

**SECTION 8: Exposure controls/personal protection**

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **Additional information:** Lists used were valid at the time of SDS preparation.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**  
Keep away from foodstuffs, beverages and feed.  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.  
Avoid contact with the eyes and skin.
- **Respiratory protection:**  
Not required.  
Use suitable respiratory protective device in case of insufficient ventilation.
- **Hand protection**  
The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

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*Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation*

*The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374*



Protective gloves

- **Material of gloves** Nitrile rubber, NBR

- **Penetration time of glove material**

*The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.*

- **Eyeface protection**



Tightly sealed goggles

## SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**

- **General Information**

- **Physical state**

Solid

- **Colour:**

White

- **Odour:**

Odourless

- **Odour threshold:**

Not determined.

- **Melting point/freezing point:**

61-63 °C

- **Boiling point or initial boiling point and boiling range**

Not determined.

- **Flammability**

Not determined.

- **Lower and upper explosion limit**

- **Lower:**

Not determined.

- **Upper:**

Not determined.

- **Flash point:**

Not applicable.

- **Auto-ignition temperature:**

Not determined.

- **Decomposition temperature:**

Not determined.

- **pH**

Not applicable.

- **Viscosity:**

- **Kinematic viscosity**

Not applicable.

- **Dynamic:**

Not applicable.

- **Solubility**

Hexane, Chloroform, Ethyl Acetate

- **water:**

Not determined.

- **Partition coefficient n-octanol/water (log value)**

Not determined.

- **Vapour pressure:**

Not applicable.

- **Density and/or relative density**

- **Density:**

Not determined.

- **Relative density**

Not determined.

- **Vapour density**

Not applicable.

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- **9.2 Other information**
- **Appearance:**
- **Form:** Solid
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Not determined
- **Explosive properties:** Not determined.
- **Change in condition**
- **Evaporation rate** Not applicable.

- **Information with regard to physical hazard classes**
- **Explosives** Not applicable
- **Flammable gases** Not applicable
- **Aerosols** Not applicable
- **Oxidising gases** Not applicable
- **Gases under pressure** Not applicable
- **Flammable liquids** Not applicable
- **Flammable solids** Not applicable
- **Self-reactive substances and mixtures** Not applicable
- **Pyrophoric liquids** Not applicable
- **Pyrophoric solids** Not applicable
- **Self-heating substances and mixtures** Not applicable
- **Substances and mixtures, which emit flammable gases in contact with water** Not applicable
- **Oxidising liquids** Not applicable
- **Oxidising solids** Not applicable
- **Organic peroxides** Not applicable
- **Corrosive to metals** Not applicable
- **Desensitised explosives** Not applicable

### SECTION 10: Stability and reactivity

- **10.1 Reactivity**  
Stable under normal conditions.  
No further relevant information available.
- **10.2 Chemical stability** Stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:**  
Formation of toxic gases is possible during heating or in case of fire.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** Heat.
- **10.5 Incompatible materials:** Strong oxidizing agents.
- **10.6 Hazardous decomposition products:**  
Formation of toxic gases is possible during heating or in case of fire.

### SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if swallowed.

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**· LD/LC50 values relevant for classification:**

Oral	LD50	1,414 mg/kg (rat)
	LD 50 (Intraperitoneal)	445 mg/kg (rat)

- **Skin corrosion/irritation** Causes skin irritation.
- **Serious eye damage/irritation** Causes serious eye irritation.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **11.2 Information on other hazards**
- **Endocrine disrupting properties** Substance is not listed.

**SECTION 12: Ecological information**

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability** No further relevant information available.
- **12.3 Bioaccumulative potential** No further relevant information available.
- **12.4 Mobility in soil** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**  
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Remark:** Harmful to fish
- **Additional ecological information:**
- **General notes:**  
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water  
Do not allow product to reach ground water, water course or sewage system.  
Danger to drinking water if even small quantities leak into the ground.  
Harmful to aquatic organisms

**SECTION 13: Disposal considerations**

- **13.1 Waste treatment methods**
- **Recommendation**  
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packaging:**
- **Recommendation:** Dispose of in accordance with national regulations.

**SECTION 14: Transport information**

- **14.1 UN number or ID number**
- **ADR, IMDG, IATA** Not applicable
- **ADR, IMDG, IATA** Not applicable

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|---|-----------------|
| · <b>14.3 Transport hazard class(es)</b>                              |                 |
| · <b>ADR, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | Not applicable  |
| · <b>14.4 Packing group</b>   |                 |
| · <b>ADR, IMDG, IATA</b>  | Not applicable  |
| · <b>14.5 Environmental hazards:</b>                                  | Not applicable. |
| · <b>14.6 Special precautions for user</b>                            | Not applicable. |
| · <b>14.7 Maritime transport in bulk according to IMO instruments</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>                                       | Not applicable  |

**SECTION 15: Regulatory information**

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be held responsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

**Abbreviations and acronyms:**

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

**Sources**

Tables 3.1 and 3.2 from Annex 6 of EC 1272/2008, EC 1907/2006, EH40/2005 as amended 2011, Registry of Toxic Effects of Chemical Substances (RTECS), The Dictionary of Substances and their Effects, 1st Edition, IUCLID.

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