# Safety Data Sheet

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According to REACH Regulations (EC) 1907/2006 and (EU) 2020/878

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

### 1.1 Product identifier

| | | |
|---|---|---|
| Product code | : | GP3498 |
| Product name | : | Fingolimod hydrochloride |
| CAS number | : | 162359-56-0 |
| Physical form | : | solid, substance |
| REACH | : | A registration number is not available for this substance as the substance or its uses are exempted from registration, the annual tonnage does not require a registration or the registration is envisaged for a later registration deadline. |

### 1.2 Relevant identified uses of the substance or mixture and uses advised against

PC21: Laboratory chemicals.

### 1.3 Details of the supplier of the safety data sheet

| | | | | | |
|---|---|---|---|---|---|
| Company name | : | Glentham Life Sciences Ltd | Telephone | : | +44 (0) 1225 667 798 |
| | | Unit 5 Leafield Way | Fax | : | +44 (0) 2033 978 909 |
| | | Corsham SN13 9SW | Email | : | info@glentham.com |
| | | United Kingdom | Web | : | www.glentham.com |

### 1.4 Emergency telephone number

Emergency telephone number : NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 – 17.00 GMT)

## 2. Hazards identification

### 2.1 Classification of the substance or mixture

**Classification under CLP according to (EC) 1272/2008**

| | |
|---|---|
| H302 | Acute Tox. 4 |
| H332 | Acute Tox. 4 |

### 2.2 Label elements

**Label elements under CLP according to (EC) 1272/2008**

**Pictograms**



GHS07

**Signal words** Warning

**Hazard statements**

| | |
|---|---|
| H302 | Harmful if swallowed |
| H332 | Harmful if inhaled |

**Precautionary statements**

| | |
|---|---|
| P261 | Avoid breathing dust/fume/gas/mist/vapors/spray. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| P301+P312 | IF SWALLOWED: call a POISON CENTER/doctor/... IF you feel unwell. |
| P304+P341 | IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. |
| P264 | Do not breathe fume. |

### 2.3 Other hazards

**PBT**

This substance is not identified as a PBT substance.

## 3.0 Composition/information on ingredients

### 3.1 Substances

| Name | Identifier | % | Classification |
|---|---|---|---|
| Fingolimod hydrochloride | CAS: 162359-56-0<br>EC:<br>REACH: Not applicable | | H302, Acute Tox. 4<br>H332, Acute Tox. 4 |

## 4. First aid measures

### 4.1 Description of first aid measures

| | |
|---|---|
| **Skin contact** | Consult a doctor. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Remove all contaminated clothes and footwear immediately unless stuck to skin. |
| **Eye contact** | Consult a doctor. Bathe the eye with running water for 15 minutes. |
| **Ingestion** | Consult a doctor. Do not induce vomiting. If conscious, give half a litre of water to drink immediately. Wash out mouth with water. |
| **Inhalation** | Remove casualty from exposure ensuring one's own safety whilst doing so. Consult a doctor. |

### 4.2 Most important symptoms and effects, both acute and delayed

| | |
|---|---|
| **Skin contact** | There may be irritation and redness at the site of contact. |
| **Eye contact** | The eyes may water profusely. There may be pain and redness. |
| **Ingestion** | Nausea and stomach pain may occur. There may be soreness and redness of the mouth and throat. There may be vomiting. |
| **Inhalation** | Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be vomiting. |
| **Delayed / immediate effects** | Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur. |

### 4.3 Indication of any immediate medical attention and special treatment needed

**Immediate / special treatment**

Do not induce vomiting.

## 5. Fire-fighting measures

### 5.1 Extinguishing media

Suitable extinguishing media for the surrounding fire should be used.

### 5.2 Special hazards arising from the substance or mixture

**Exposure hazards**

In combustion emits toxic fumes.

### 5.3 Advice for fire-fighters

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

## 6. Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

**Personal precautions**

If outside do not approach from downwind. If outside keep bystanders upwind and away from danger point. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Refer to section 8 of SDS for personal protection details.

### 6.2 Environmental precautions

Do not discharge into drains or rivers.

### 6.3 Methods and material for containment and cleaning up

**Clean-up procedures**

Transfer to a closable, labelled salvage container for disposal by an appropriate method.

### 6.4 Reference to other sections

Refer to section 8 of SDS.

## 7. Handling and storage

### 7.1 Precautions for safe handling

**Handling requirements**

Avoid direct contact with the substance. Avoid the formation or spread of dust in the air. Do not handle in a confined space. Ensure there is sufficient ventilation of the area.

### 7.2 Conditions for safe storage, including any incompatibilities

**Storage conditions**

Avoid contact with water or humidity. Keep container tightly closed. Store in cool, well ventilated area.

### 7.3 Specific end use(s)

No data available.

## 8. Exposure controls/personal protection

### 8.1 Control parameters

**Workplace exposure limits**

No workplace exposure limit control parameters set

### 8.2 Exposure controls

| | |
|---|---|
| **Engineering measures** | Ensure there is sufficient ventilation of the area. |
| **Respiratory protection** | Respiratory protective device with particle filter. Self- contained breathing apparatus must be available in case of emergency. |
| **Hand protection** | Protective gloves. |
| **Eye protection** | Ensure eye bath is to hand. Safety glasses. |
| **Skin protection** | Protective clothing. |

## 9. Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | |
|---|---|
| Physical state | Solid |
| Colour | White |
| Odour | No data available. |
| Melting point/Freezing point | 107-108 °C |
| Boiling point/initial boiling point/boiling range | No data available. |
| Flammability | No data available. |
| Lower/Upper explosion limit | No data available. |
| Flash Point | No data available. |
| Auto-ignition temperature | No data available. |
| Decomposition temperature | No data available. |
| pH | No data available. |
| Kinematic viscosity | No data available. |
| Solubility | No data available. |
| Partition coefficient n-octanol/water | No data available. |
| Vapour pressure | No data available. |
| Density/relative density | No data available. |
| Relative vapour pressure | No data available. |
| Particle characteristics | No data available. |

### 9.2 Other information

No data available.

## 10. Stability and reactivity

### 10.1 Reactivity

Stable under recommended transport or storage conditions.

**10.2** **Chemical stability**

Stable under normal conditions.

**10.3** **Possibility of hazardous reactions**

**Hazardous reactions**

Decomposition may occur on exposure to conditions or materials listed below. Hazardous reactions will not occur under normal transport or storage conditions.

**10.4** **Conditions to avoid**

Heat.

**10.5** **Incompatible materials**

**Materials to avoid**

Strong acids. Strong oxidising agents.

## 11. Toxicological information

**11.1** **Information on toxicological effects**

**a)** **Acute toxicity**

No data available.

**b)** **Skin corrosion/irritation**

No data available.

**c)** **Serious eye damage/irritation**

No data available.

**d)** **Respiratory or skin sensitisation**

No data available.

**e)** **Germ cell mutagenicity**

No data available.

**f)** **Carcinogenicity**

No data available.

**g)** **Reproductive toxicity**

No data available.

**h)** **STOT-single exposure**

No data available.

**i)** **STOT-repeated exposure**

No data available.

**j)** **Aspiration hazard**

No data available.

**11.2** **Symptoms / routes of exposure**

| | |
|---|---|
| **Skin contact** | There may be irritation and redness at the site of contact. |
| **Eye contact** | The eyes may water profusely. There may be pain and redness. |
| **Ingestion** | Nausea and stomach pain may occur. There may be soreness and redness of the mouth and throat. There may be vomiting. |
| **Inhalation** | Nausea and stomach pain may occur. There may be irritation of the throat with a feeling of tightness in the chest. There may be vomiting. |
| **Delayed / immediate effects** | Immediate effects can be expected after short-term exposure. Nausea and stomach pain may occur. |
| **Other information** | No data available. |

## 12. Ecological information

**12.1** **Toxicity**

No data available.

**12.2** **Persistence and degradability**

Biodegradable.

**12.3** **Bioaccumulative potential**

No bioaccumulation potential.

**12.4** **Mobility in soil**

Readily absorbed into soil.

**12.5** **Results of PBT and vPvB assessment**

This substance is not identified as a PBT substance.

**12.6** **Endocrine disrupting properties**

This substance is not identified as having endocrine disrupting properties

**12.7** **Other adverse effects**

No data available.

## 13. Disposal considerations

**13.1** **Waste treatment methods**

**Disposal operations**

Transfer to a suitable container and arrange for collection by specialised disposal company.

**NB**

The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

## 14. Transport information

This product does not require a classification for transport.

## 15. Regulatory information

**15.1** **Safety, health and environmental regulations/legislation specific for the substance or mixture**

This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.

**Authorisations/Restrictions**

| | |
|---|---|
| Regulation (EC) 1907/2006, REACH, Annex XIV list of substances subject to authorisation: | No data available. |
| Regulation (EC) 1907/2006, REACH, Annex XVII restrictions on the manufacture, placing on the market and use of certain dangerous substances: | No data available. |
| Regulation (EC) 1005/2009 on substances that deplete the ozone layer: | No data available. |
| Regulation (EC) 850/2004 on persistent organic pollutants, amended by (EU) No 2019/1021: | No data available. |

**15.2** **Chemical safety assessment**

A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

## 16. Other information

**H-Statement Full Texts**

| | |
|---|---|
| H302 | Harmful if swallowed |
| H332 | Harmful if inhaled |

**Abbreviations Full Texts**

| | |
|---|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ALARP | As low as is reasonably practicable |
| CAS | Chemical Abstracts Service |
| CLP | Classification, Labelling and Packaging Regulations |
| COSHH | Control of Substances Hazardous to Health |
| EC Number | European Community Number |

| | |
|---|---|
| EC50 | Effective Concentration 50% |
| EILINCS | European List of Notified Chemical Substances |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| GHS | Globally Harmonised System |
| HSE | Health & Safety Executive UK |
| IATA | International Air Transport Association |
| IM | Intramuscular |
| IMDG | The International Maritime Dangerous Goods Code |
| IP | Intraperitoneal |
| IV | Intravascular |
| LD50 | Lethal Dose 50% |
| LOEC | Lowest Observable Effective Concentration |
| LTEL | Long Term Exposure Limit |
| NOEC | No Observable Effective Concentration |
| OECD | Organisation for Economic Cooperations and Development |
| PBT | Persistent Bioaccumulative Toxic |
| PPE | Personal Protective Equipment |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RID | Regulations Concerning the International Carriage of Dangerous Goods by Rail |
| SC | Subcutaneous |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| VOC | Volatile Organic Compounds |
| vPvB | Very Persistent and Very Bioaccumulative |
| WEL | Workplace Exposure Limits |

**This Safety Data Sheet is prepared in accordance with Commission Regulation (EC) 1907/2006, amended by Commission Regulation (EU) 2020/787.**

Disclaimer: Glentham Life Sciences shall not be held liable for any damage resulting from handling or from contact with the above product. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This document does not guarantee the properties or quality of the product.