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	:	GP2795
Product name	:	Ketotifen fumarate
CAS number	:	34580-14-8
EINECS	:	252-100-0
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

2.2 Label elements

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

Pictograms



GHS07

Signal words Warning

Hazard statements

H302	Harmful if swallowed

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.
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
Ketotifen fumarate	CAS: 34580-14-8 EC: 252-100-0 REACH: Not applicable	98%	H302, Acute Tox. 4

4. First aid measures

4.1 Description of first aid measures

Skin contact	Wash immediately with plenty of soap and water.
Eye contact	Bathe the eye with running water for 15 minutes.
Ingestion	Do not induce vomiting. If conscious, give half a litre of water to drink immediately. Transfer to hospital as soon as possible. Wash out mouth with water.
Inhalation	Remove casualty from exposure ensuring one's own safety whilst doing so. Transfer to hospital as soon as possible. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Skin contact	There may be mild irritation at the site of contact.
Eye contact	There may be pain and redness.
Ingestion	Nausea and stomach pain may occur. There may be difficulty swallowing. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Nausea and stomach pain may occur. 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

Do not create dust. If outside do not approach from downwind. 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. 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.
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	192 °C (decomp)
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 mild irritation at the site of contact.
Eye contact	There may be pain and redness.
Ingestion	Nausea and stomach pain may occur. There may be difficulty swallowing. There may be soreness and redness of the mouth and throat. There may be vomiting.
Inhalation	Absorption through the lungs can occur causing symptoms similar to those of ingestion. Nausea and stomach pain may occur. 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

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

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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.