

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 : GP2028
 Product name : Isotretinoin, USP grade
 CAS number : 4759-48-2
 EINECS : 225-296-0
 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 : NHS Direct 111 (UK, 24 hours), 112 (EU, 24 Hours), +44 (0) 1225 667 798 (09.00 – 17.00 GMT) number

2. Hazards identification

2.1 Classification of the substance or mixture

Classification under CLP according to (EC) 1272/2008

H315	Skin Irr. 2
H319	Eye Irr. 2A
H335	STOT SE 3
H336	STOT SE 3
H360	Repr. 1B

2.2 Label elements

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

Pictograms



GHS07 GHS08

Signal words

Danger

Hazard statements

H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H360	May damage fertility or the unborn child

Precautionary statements

P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
P308+P313	IF exposed or concerned: Get medical advice/attention.
P264	Do not breathe fume.
P261	Avoid breathing dust.

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
Isotretinoin, USP grade	CAS: 4759-48-2 EC: 225-296-0 REACH: Not applicable	98.0%	H315, Skin Irr. 2 H319, Eye Irr. 2A H335, STOT SE 3 H336, STOT SE 3 H360, Repr. 1B

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. Wash immediately with plenty of soap and water.
Eye contact	Consult a doctor. Bathe the eye with running water for 15 minutes.
Ingestion	Consult a doctor. 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. There may be mild irritation at the site of contact.
Eye contact	The eyes may water profusely. There may be irritation and redness.
Ingestion	There may be irritation of the throat. There may be soreness and redness of the mouth and throat.
Inhalation	Exposure may cause coughing or wheezing. There may be irritation of the throat with a feeling of tightness in the chest.
Delayed / immediate effects	Delayed effects can be expected after long-term exposure. Immediate effects can be expected after short-term exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment

Eye bathing equipment should be available on the premises.

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. Evacuate the area immediately. 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

Alert the neighbourhood to the presence of fumes or gas. Do not discharge into drains or rivers.

6.3 Methods and material for containment and cleaning up

Clean-up procedures

Clean-up should be dealt with only by qualified personnel familiar with the specific substance. 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	174-175 °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

Flames. Hot surfaces. 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

Skin corrosion/irritation (Category 2)

c) Serious eye damage/irritation

Serious eye damage/eye irritation (Category 2A)

d) Respiratory or skin sensitisation

No data available.

e) Germ cell mutagenicity

No data available.

f) Carcinogenicity

No data available.

g) Reproductive toxicity

Reproductive toxicity (Category 1B)

h) STOT-single exposure

Specific target organ toxicity, single exposure; Respiratory tract irritation (Category 3)

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. There may be mild irritation at the site of contact.
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Eye contact	The eyes may water profusely. There may be irritation and redness.
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Ingestion	There may be irritation of the throat. There may be soreness and redness of the mouth and throat.
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Inhalation	Exposure may cause coughing or wheezing. There may be irritation of the throat with a feeling of tightness in the chest.
Delayed / immediate effects	Delayed effects can be expected after long-term exposure. Immediate effects can be expected after short-term exposure.
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

H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H336	May cause drowsiness or dizziness
H360	May damage fertility or the unborn child

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.