

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 06-Nov-2024

Revision Number 2

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Code(s) CAT 1205
Product Name Tretinoin
Form Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No) 206-129-0
CAS No. 302-79-4
Pure substance/mixture Substance
Formula $C_{20}H_{28}O_2$
Molecular weight 300.44

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

Recommended use Laboratory use
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

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

For further information, please contact



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E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008	
Europe	112
Austria	No information available
Bulgaria	
Croatia	
Cyprus	
Czech Republic	
Denmark	
France	
Hungary	
Ireland	
Italy	
Lithuania	
Luxembourg	
Netherlands	
Norway	
Portugal	
Romania	
Slovakia	
Slovenia	
Spain	
Sweden	
Switzerland	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to
Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 1A - (H360)

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Effects on or via lactation	Yes - (H362)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)

2.2. Label elements

Contains Tretinoin



Signal word
Danger

Hazard statements

H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children
H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P263 - Avoid contact during pregnancy and while nursing
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P391 - Collect spillage

2.3. Other hazards

No information available.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
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	- Candidate List of Substances of Very High Concern (SVHC) for Authorisation	Disruptor Assessment List of Substances
Tretinoin	-	-

SECTION 3: Composition/information on ingredients

3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Tretinoin 302-79-4	100	-	206-129-0	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Repr. 1A (H360) Lact. (H362) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)			

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg	Dermal LD50 mg/kg	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Tretinoin 302-79-4	2000	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration $\geq 0.1\%$ (Regulation (EC) No. 1907/2006 (REACH), Article 59)

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SECTION 4: First aid measures

4.1. Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air. Get medical attention immediately if symptoms occur.
Eye contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
Skin contact	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
Ingestion	Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. Call a doctor.
Self-protection of the first aider	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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

Symptoms	May cause redness and tearing of the eyes. Burning sensation.
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4.3. Indication of any immediate medical attention and special treatment needed

Note to doctors	Treat symptomatically.
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SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Large Fire	CAUTION: Use of water spray when fighting fire may be inefficient.
Unsuitable extinguishing media	Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the	No information available.
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chemical

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions

Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

Other information

Refer to protective measures listed in Sections 7 and 8.

For emergency responders

Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions

Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so.

Methods for cleaning up

Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections

See section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash it before reuse.

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General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions

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 containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection

Avoid contact with eyes. Wear safety glasses with side shields (or goggles). If splashes are

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likely to occur, wear safety glasses with side-shields.

Hand protection

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

Gloves			
Duration of contact	PPE - Glove material	Glove thickness	Break through time
	Wear protective butyl rubber gloves		

Skin and body protection

Wear suitable protective clothing. Long sleeved clothing.

Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.

Environmental exposure controls

Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid
Appearance	Solid
Colour	yellow
Odour	No information available.
Odour threshold	No information available

Property	Values	Remarks • Method
Melting point / freezing point	168 - 170 °C	None known
Initial boiling point and boiling range	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Flash point	No data available	None known

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Autoignition temperature	No data available	None known
Decomposition temperature		None known
pH	No data available	None known
pH (as aqueous solution)	No data available	No information available
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Vapour pressure	No data available	None known
Relative density	No data available	None known
Bulk density	No data available	
Liquid Density	No data available	
Relative vapour density	No data available	None known
Particle characteristics		
Particle Size	No information available	
Particle Size Distribution	No information available	

9.2. Other information

Molecular weight	300.44
Molecular formula	C ₂₀ H ₂₈ O ₂

9.2.1. Information with regards to physical hazard classes
Not applicable

9.2.2. Other safety characteristics
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

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Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong acids. Strong bases. Strong oxidising agents.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhoea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Redness. May cause redness and tearing of the eyes.

Numerical measures of toxicity

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Acute toxicity

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Tretinoin	= 2 g/kg (Rat)		

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	Classification based on data available for ingredients. Causes skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitisation	No information available.
Germ cell mutagenicity	No information available.
Carcinogenicity	No information available.
Reproductive toxicity	Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. May damage fertility or the unborn child. May cause harm to breast-fed children.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.

11.2. Information on other hazards

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11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.

11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Tretinoin	-	LC50: 0.00147 mg/L (96h, Danio rerio)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

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12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging

Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Tretinoin)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Tretinoin), 9, III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	A97, A158, A179, A197, A215
ERG Code	9L

IMDG

14.1 UN number or ID number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substances, solid, n.o.s. (Tretinoin)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
Description	UN3077, Environmentally hazardous substances, solid, n.o.s. (Tretinoin), 9, III, Marine pollutant
14.5 Marine pollutant	P
Environmental hazards	Yes
14.6 Special precautions for user	
Special Provisions	274, 335, 966, 967, 969
EmS-No.	F-A, S-F No information available

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14.7 Maritime transport in bulk according to IMO instruments No information available

RID

14.1 UN number or ID number UN3077
14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Tretinoin)
14.3 Transport hazard class(es) 9
14.4 Packing group III
Description UN3077, Environmentally hazardous substances, solid, n.o.s. (Tretinoin), 9, III
14.5 Environmental hazards Yes
14.6 Special precautions for user
Special Provisions 274, 335, 375, 601
Classification code M7

ADR

14.1 UN number or ID number UN3077
14.2 UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Tretinoin)
14.3 Transport hazard class(es) 9
14.4 Packing group III
Description UN3077, Environmentally hazardous substances, solid, n.o.s. (Tretinoin), 9, III, (-)
14.5 Environmental hazards Yes
14.6 Special precautions for user
Special Provisions 274, 335, 601, 375
Classification code M7
Tunnel restriction code (-)

SECTION 15: Regulatory information

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

National regulations

Germany

Water hazard class (WGK) non-hazardous to water (nwg)

Netherlands

Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Carcinogens	Netherlands - List of Reproductive Toxins
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Chemical name	Netherlands - List of Carcinogens	Netherlands - List of Carcinogens	Netherlands - List of Reproductive Toxins
Tretinoin	-	-	Development Category 1B

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product contains one or more substance(s) subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorisation per REACH Annex XIV
Tretinoin - 302-79-4	75	

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

TSCA

LGC, to the best of its ability, has confirmed that the chemical substances in this product are listed as "Active" in the EPA (Environmental Protection Agency) "TSCA Inventory Notification (Active-Inactive) Requirements Rule" ("the Final Rule") of Feb 2019, as amended Feb 2021."

DSL/NDL

Contact supplier for inventory compliance status

EINECS/ELINCS

Contact supplier for inventory compliance status

ENCS

Contact supplier for inventory compliance status

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IECSC	Contact supplier for inventory compliance status
KECL	Contact supplier for inventory compliance status
PICCS	Contact supplier for inventory compliance status
AIIC	Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
ENCS - Japan Existing and New Chemical Substances
IECSC - China Inventory of Existing Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AICS - Australian Inventory of Chemical Substances

15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child
H362 - May cause harm to breast-fed children
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation

Classification procedure

Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
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Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Chronic aquatic toxicity	Calculation method
Acute aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine's PubMed database (NLM PUBMED)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications
Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme
Organisation for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

Disclaimer

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.

End of Safety Data Sheet