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Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

Printing date 29.09.2025 Version number 1.00 Revision: 29.09.2025

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

· Product identifier

· Trade name: Tretinoin, API

· Article number: 9560

· CAS Number:

302-79-4

· EC number:

206-129-0

- · Registration number The substance is exempt from REACH-registration.
- Relevant identified uses of the substance or mixture and uses advised against
- · Application of the substance / the mixture

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

- · Uses advised against No relevant information available.
- Details of the supplier of the safety data sheet
- Manufacturer/Supplier:

CAELO

Caesar & Loretz GmbH

Herderstr. 31

D-40721 Hilden

GERMANY

· Further information obtainable from:

E-mail: info@caelo.de

Tel.: +49210349940 (during regular opening hours)

· Emergency telephone number:

Poison Information Center Bonn Venusberg-Campus 1, 53127 Bonn

Tel: +49 (0) 228-192400

2 Hazards identification

- · 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.

Repr. 1A H360FD May damage fertility. May damage the unborn child. Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

- · Label elements
- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

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· Hazard pictograms



· Signal word Danger

· Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

H360FD May damage fertility. May damage the unborn child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.

P280 Wear protective gloves.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth. P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

· Other hazards

- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.
- · Determination of endocrine-disrupting properties Not applicable.

3 Composition/information on ingredients

- · Substances
- · CAS No. Description

CAS: 302-79-4 tretinoin

- · Identification number(s)
- · EC number: 206-129-0

4 First aid measures

· Description of first aid measures

· General information:

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

· After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

• After skin contact: Immediately wash with water and soap and rinse thoroughly.

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- · After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: Drink plenty of water and provide fresh air. Call for a doctor immediately.
- Most important symptoms and effects, both acute and delayed

No further relevant information available.

· Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Firefighting measures

- · Extinguishing media
- Suitable extinguishing agents:

All regular extinguishing media can be used.

Use fire extinguishing methods suitable to surrounding conditions.

· Special hazards arising from the substance or mixture

Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.

- · Advice for firefighters
- · Protective equipment: In case of fire wear suitable protective clothes and respiratory protection.
- **Additional information**

Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

6 Accidental release measures

· Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

· Environmental precautions:

Do not allow to enter sewers/ surface or ground water.

Inform respective authorities in case of seepage into water course or sewage system.

· Methods and material for containment and cleaning up:

Take up dry. Clean up with water.

Dispose contaminated material as waste according to section 13.

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.

7 Handling and storage

- · Precautions for safe handling Prevent formation of dust.
- · Information about fire and explosion protection: No special measures required.
- · Conditions for safe storage, including any incompatibilities
- Storage:
- · Requirements to be met by storerooms and receptacles:

Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).

- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:

Store in nitrogen.

Protect from exposure to the light.

· Storage class: TRHS 510: 6.1 C Combustible acutely toxic or chronic substances

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· Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace: Not required.
- · Additional information: The lists valid during the making were used as basis.
- · Exposure controls
- · Appropriate engineering controls No further data; see section 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 skin.

Avoid contact with the eyes and skin.

- · Respiratory protection: Dust protection mask.
- · Hand protection Protective gloves
- Material of gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

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.

- · Eye/face protection Tightly sealed goggles
- · Body protection: Protective work clothing

9 Physical and chemical properties

- · Information on basic physical and chemical properties
- · General Information

Physical state
Colour:
Odour:
Odourless
Odour threshold:
Melting point/freezing point:

Solid
Yellow
Odourless
Not determined.
180–182 °C

· Boiling point or initial boiling point and boiling

range Undetermined.

· Flammability Product is not flammable.

Lower and upper explosion limit

Lower: Not determined.
Upper: Not determined.
Flash point: Not applicable.
Decomposition temperature: Not determined.
pH Not applicable.

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· Viscosity:

Kinematic viscosity Not applicable. · Dynamic: Not applicable.

·Solubility

Not determined. · water: · Partition coefficient n-octanol/water (log value) Not determined. Not applicable. · Vapour pressure:

Density and/or relative density

Not determined. · Density: · Relative density Not determined. · Vapour density Not applicable. · Particle characteristics Not determined

· Other information

· Appearance:

· Form: Solid

· Important information on protection of health

and environment, and on safety.

· Ignition temperature: Not determined.

Product does not present an explosion hazard. · Explosive properties:

Void

Void

· Change in condition

 Evaporation rate Not applicable.

Information with regard to physical hazard classes

 Explosives Void Flammable gases Void · Aerosols Void · Oxidising gases Void · Gases under pressure Void · Flammable liquids Void · Flammable solids Void · Self-reactive substances and mixtures Void · Pyrophoric liquids Void · Pyrophoric solids Void · Self-heating substances and mixtures Void · Substances and mixtures, which emit flammable gases in contact with water Void · Oxidising liquids Void · Oxidising solids Void Organic peroxides Void

10 Stability and reactivity

Desensitised explosives

· Corrosive to metals

· Reactivity No further relevant information available.

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- · Chemical stability
- Thermal decomposition / conditions to be avoided:

No decomposition if used according to specifications.

- · Possibility of hazardous reactions No dangerous reactions known.
- · Conditions to avoid No further relevant information available.
- · Incompatible materials: No further relevant information available.
- · Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- · Information on hazard classes as defined in Regulation (EC) No 1272/2008
- · Acute toxicity Harmful if swallowed.
- · LD/LC50 values relevant for classification:

Oral LD50 1,100 mg/kg (mouse)

1.960 mg/kg (rat)

- · Primary irritant effect:
- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity May damage fertility. May damage the unborn child.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.
- Information on other hazards
- · Endocrine disrupting properties

On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12 Ecological information

- · Toxicity
- Aquatic toxicity:

LC50 0.2 mg/L /96h (Fish)

EC50 0.1-0.3 mg/L /48h (Daphnia magna)

- · Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- Endocrine disrupting properties

Based on the available data, the substance does not meet the criteria for the identification of substances with properties affecting the endocrine system according to Article 59(1) of the REACH Regulation and the criteria of the Commission Delegated Regulation (EU) 2017/2100 or in the Commission Regulation (EU) 2018/605.

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The product does not contain substances with endocrine disrupting properties.

- · Other adverse effects
- · 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, even in small quantities.

Danger to drinking water if even extremely small quantities leak into the ground.

Also poisonous for fish and plankton in water bodies.

13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to local regulations.

14 Transport information

· UN number or ID number

· ADR, IMDG, IATA UN3077

· UN proper shipping name

· **ADR** 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S. (tretinoin)

• IMDG ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S. (tretinoin)

· IATA Environmentally hazardous substance, solid, n.o.s.

(tretinoin)

· Transport hazard class(es)

· ADR, IMDG, IATA

· Class 9 Miscellaneous dangerous substances and articles.

· Label 9

· Packing group

· ADR, IMDG, IATA

· Environmental hazards:

Marine pollutant:
 Special marking (ADR):
 Special marking (IATA):
 Symbol (fish and tree)
 Symbol (fish and tree)

Special precautions for user Warning: Miscellaneous dangerous substances and

articles.

· Hazard identification number (Kemler code): 90 · EMS Number: F-A,S-F

· EMS Number: F-A,S-· Maritime transport in bulk according to IMO

instruments Not applicable.

· Transport/Additional information:

· ADR

· Limited quantities (LQ) 5 kg

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· Transport category · Tunnel restriction code	3 (-)	(Contd. of page 7)
· IMDG · Limited quantities (LQ)	5 kg	

UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (TRETINOIN), 9, III

15 Regulatory information

UN "Model Regulation":

- · Safety, health and environmental regulations/legislation specific for the substance or mixture
- LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV) Not listed
- · REGULATION (EC) No 1907/2006 ANNEX XVII

Not listed

Conditions of restriction: 75

DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

Substance is not listed.

- · National regulations:
- Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)

TRHS 510: 6.1 C Combustible acutely toxic or chronic substances

Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.

- · Reasons for alterations This version replaces all old versions.
- · 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)

MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)

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

Repr. 1A: Reproductive toxicity - Category 1A

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard - Category 1