

1 Identification

- **Product identifier**
- **Trade name:** Tretinoin sol.3.33%
- **Article number:** 103514
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture**
Additive for cosmetic or pharmaceutical preparations
Pharmaceutical intermediate
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Fagron Services B.V.
Molenwerk 13, UITGEEEST, 1911DB
Netherlands
Phone: +31251361400

Supplier
Azelis Australia
Suite 217
117 Old Pittwater Road
Brookvale
NSW 2100
Australia
Phone: +61 0299392188
Fax: +61 0299392799
e-mail: info@azelis.com.au

- **Further information obtainable from:** info@fagron.com.au
- **Emergency telephone number:**
In case of emergency, please call your local poisons:
Emergency Australia: 13 11 26
Emergency NZ: 0800 764 766 (0800 POISON)

1800 127 406 (24 h, Australia) | +64 4 917 9888 (24 h, Worldwide) CareChem 24x7 : EUROPE:
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(English only)

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Acute Tox. 3 H331 Toxic if inhaled.
Eye Dam. 1 H318 Causes serious eye damage.
Repr. 1B H360 May damage fertility or the unborn child.

- **Label elements**
- **GHS label elements**
The product is classified and labelled according to the Globally Harmonised System (GHS).

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· **Hazard pictograms**



GHS02 GHS05 GHS06 GHS08

· **Signal word** Danger

· **Hazard-determining components of labelling:**

denatonium benzoate
Tretinoin

· **Hazard statements**

Highly flammable liquid and vapour.
Toxic if inhaled.
Causes serious eye damage.
May damage fertility or the unborn child.

· **Precautionary statements**

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Immediately call a POISON CENTER/doctor.
Specific treatment (see on this label).
Store locked up.
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.

3 Composition and Information on Ingredients

· **Chemical characterisation: Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 64-17-5	ethanol Flam. Liq. 2, H225; Eye Irritation 2A, H319	50–≤100%
CAS: 3734-33-6	denatonium benzoate Acute Tox. 2, H330; Eye Dam. 1, H318; Acute Tox. 4, H302	≥3–≤5%
CAS: 8007-75-8	Bergamot extract Skin Irrit. 2, H315; Eye Irritation 2A, H319; Skin Sens. 1, H317; Flam. Liq. 4, H227	≥0.1–<1%
CAS: 302-79-4	Tretinoin Repr. 1B, H360; Skin Irrit. 2, H315	≥0.3–≤1%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

4 First Aid Measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.
Remove breathing equipment only after contaminated clothing have been completely removed.
In case of irregular breathing or respiratory arrest provide artificial respiration.

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- **After inhalation:**
Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:**
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **Information for doctor:**
- **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 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **Special hazards arising from the substance or mixture**
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**
Mouth respiratory protective device.
Wear self-contained respiratory protective device.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Wear protective equipment. Keep unprotected persons away.
- **Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Use neutralising agent.
Dispose contaminated material as waste according to item 13.
Ensure adequate ventilation.
- **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

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Open and handle receptacle with care.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Keep respiratory protective device available.

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- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store in a cool location.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.
- **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 64-17-5 ethanol

WES | Long-term value: 1880 mg/m³, 1000 ppm

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **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.
Store protective clothing separately.
Avoid contact with the eyes.
Avoid contact with the eyes and skin.
- **Respiratory protection:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- **Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- **Material of gloves**
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. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- **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.

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· Eye protection:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and Chemical Properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Fluid
Colour:	According to product specification
· Odour:	Characteristic
· Odour threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/freezing point:	-114.5°C
Initial boiling point and boiling range:	78°C
· Flash point:	13°C
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	425°C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· Explosion limits:	
Lower:	3.5 Vol %
Upper:	15 Vol %
· Vapour pressure at 20°C:	59 hPa
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water at 20°C:	1,000 g/l
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic at 20°C:	1.2 mPas
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	95.8 %
VOC (EC)	95.79 %

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Solids content:	3.0 %
Other information	No further relevant information available.

10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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 toxicological effects**
- **Acute toxicity**

LD/LC50 values relevant for classification:		
ATE (Acute Toxicity Estimates)		
Oral	LD50	≥18865 mg/kg (rat)
Inhalative	LC50/4 h	≥5.04 mg/l (rat)

CAS: 64-17-5 ethanol		
Oral	LD50	7060 mg/kg (rat)
Inhalative	LC50/4 h	20000 mg/l (rat)

CAS: 3734-33-6 denatonium benzoate		
Oral	LD50	749 mg/kg (rat)
Dermal	LD50	>2000 mg/kg (rat)
Inhalative	LC50/4 h	0.2 mg/l (rat)

CAS: 302-79-4 Tretinoin		
Oral	LD50	1960 mg/kg (rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation** No irritant effect.
- **Serious eye damage/irritation** Strong irritant with the danger of severe eye injury.
- **Respiratory or skin sensitisation** No sensitising effects known.
- **Additional toxicological information:**

The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:

Toxic
Irritant

- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
Repr. 1B

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12 Ecological Information

- **Toxicity**

- **Aquatic toxicity:**

CAS: 302-79-4 Tretinoin

EC50 | 0.1–0.3 mg/kg /(48h) (daphnia)

- **Persistence and degradability** No further relevant information available.

- **Behaviour in environmental systems:**

- **Bioaccumulative potential** No further relevant information available.

- **Mobility in soil** No further relevant information available.

- **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.

Must not reach sewage water or drainage ditch undiluted or unneutralised.

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

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **Other adverse effects** No further relevant information available.

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 official regulations.

- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

14 Transport information

- **UN-Number**

- **ADG, IMDG, IATA**

UN1992

- **UN proper shipping name**

- **ADG**

1992 FLAMMABLE LIQUID, TOXIC, N.O.S.
(ETHANOL (ETHYL ALCOHOL), denatonium benzoate)

- **IMDG**

FLAMMABLE LIQUID, TOXIC, N.O.S.
(ETHANOL (ETHYL ALCOHOL), denatonium benzoate)

- **IATA**







Flammable liquid, toxic, n.o.s. (ETHANOL, denatonium benzoate)

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<ul style="list-style-type: none"> · Transport hazard class(es) · ADG 	 
<ul style="list-style-type: none"> · Class · Label 	3 Flammable liquids. 3+6.1
<ul style="list-style-type: none"> · IMDG 	 
<ul style="list-style-type: none"> · Class · Label 	3 Flammable liquids. 3/6.1
<ul style="list-style-type: none"> · IATA 	 
<ul style="list-style-type: none"> · Class · Label 	3 Flammable liquids. 3 (6.1)
<ul style="list-style-type: none"> · Packing group · ADG, IMDG, IATA 	II
<ul style="list-style-type: none"> · Environmental hazards: 	Not applicable.
<ul style="list-style-type: none"> · Special precautions for user · Hazard identification number (Kemler code): · EMS Number: · Stowage Category · Stowage Code 	Warning: Flammable liquids. 336 F-E,S-D B SW2 Clear of living quarters.
<ul style="list-style-type: none"> · Transport in bulk according to Annex II of Marpol and the IBC Code 	Not applicable.
<ul style="list-style-type: none"> · Transport/Additional information: 	
<ul style="list-style-type: none"> · ADG · Limited quantities (LQ) · Excepted quantities (EQ) 	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
<ul style="list-style-type: none"> · Transport category · Tunnel restriction code 	2 D/E
<ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) 	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500

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.	ml
· UN "Model Regulation":	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (ETHANOL (ETHYL ALCOHOL), DENATONIUM BENZOATE), 3 (6.1), II

15 Regulatory information

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

· Australian Inventory of Industrial Chemicals	
CAS: 64-17-5	ethanol
CAS: 3734-33-6	denatonium benzoate
CAS: 8007-75-8	Bergamot extract
CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK
CAS: 128-37-0	Butylated hydroxytoluene

· Standard for the Uniform Scheduling of Medicines and Poisons		
CAS: 64-17-5	ethanol	Not scheduled
CAS: 8007-75-8	Bergamot extract	S5
CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	S5
CAS: 302-79-4	Tretinoin	S4+APPENDIX D

· Australia: Priority Existing Chemicals	
None of the ingredients is listed.	

- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category**
H2 ACUTE TOXIC
P5c FLAMMABLE LIQUIDS
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 50 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
Therapeutic goods are listed on the Australian Register of Therapeutic Goods(ARTG)
- **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
H225 Highly flammable liquid and vapour.
H227 Combustible liquid.
H302 Harmful if swallowed.
H315 Causes skin irritation.

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H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.
H330 Fatal if inhaled.
H360 May damage fertility or the unborn child.

· **Department issuing SDS:** Product Safety Department

· **Contact:**

· **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
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
VOC: Volatile Organic Compounds (USA, EU)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Flam. Liq. 4: Flammable liquids – Category 4
Acute Tox. 4: Acute toxicity – Category 4
Acute Tox. 2: Acute toxicity – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Skin Sens. 1: Skin sensitisation – Category 1
Repr. 1B: Reproductive toxicity – Category 1B

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