

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

- **1.1 Product identifier**
- **Trade name:** Tretinoin sol.3.33%
- **Article number:** 103514
- **1.2 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
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
FAGRON a.s.  
Holická 1098/31m  
779 00 Olomouc  
Česká republika
- **Further information obtainable from:**  
Tel.: +420 585 222 590  
info@fagron.cz
- **1.4 Emergency telephone number:**  
Toxikologické informační středisko,  
Na Bojišti 1,  
128 08 Praha 2  
tel.: +420 224 919 293, +420 224 915 402 (nepřetržitá lékařská služba),  
e-mail:tis.cuni@cesnet.cz

## SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**  
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.  
Aquatic Chronic 3    H412 Harmful to aquatic life with long lasting effects.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS02   GHS05   GHS06   GHS08

- **Signal word** Danger
- **Hazard-determining components of labelling:**  
denatonium benzoate  
Tretinoin

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- **Hazard statements**
  - H225 Highly flammable liquid and vapour.
  - H331 Toxic if inhaled.
  - H318 Causes serious eye damage.
  - H360 May damage fertility or the unborn child.
  - H412 Harmful to aquatic life with long lasting effects.
- **Precautionary statements**
  - P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P310 Immediately call a POISON CENTER/doctor.
  - P321 Specific treatment (see on this label).
  - P405 Store locked up.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- **Additional information:**
  - Contains Bergamot extract. May produce an allergic reaction.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**
- **Description:** Mixture of substances listed below with nonhazardous additions.

### · Dangerous components:

CAS: 64-17-5 EINECS: 200-578-6	ethanol Flam. Liq. 2, H225; Eye Irrit. 2, H319	50–≤100%
CAS: 3734-33-6 EINECS: 223-095-2	denatonium benzoate Acute Tox. 2, H330; Eye Dam. 1, H318; Acute Tox. 4, H302	≥3–≤5%
CAS: 8007-75-8 EINECS: 289-612-9	Bergamot extract Aquatic Chronic 2, H411; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	≥0,25–<1%
CAS: 302-79-4 EINECS: 206-129-0	Tretinoin Repr. 1B, H360; Aquatic Acute 1, H400; Aquatic Chronic 1, H410; Skin Irrit. 2, H315	≥0,3–≤1%
CAS: 128-37-0 EINECS: 204-881-4	Butylated hydroxytoluene Aquatic Acute 1, H400; Aquatic Chronic 1, H410	≥0,25–≤1%

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

## SECTION 4: First aid measures

- **4.1 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.
- **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.

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- **After eye contact:**  
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **4.2 Most important symptoms and effects, both acute and delayed**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed**  
No further relevant information available.

## SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **5.2 Special hazards arising from the substance or mixture**  
No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**  
Mouth respiratory protective device.  
Wear self-contained respiratory protective device.

## SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:**  
Do not allow product to reach sewage system or any water course.  
Inform respective authorities in case of seepage into water course or sewage system.  
Dilute with plenty of water.  
Do not allow to enter sewers/ surface or ground water.
- **6.3 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.
- **6.4 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.

## SECTION 7: Handling and storage

- **7.1 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.
- **7.2 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.

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- **Further information about storage conditions:**  
Keep container tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.
- **7.3 Specific end use(s)** No further relevant information available.

## SECTION 8: Exposure controls/personal protection

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

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

**CAS: 64-17-5 ethanol**

NPK (Czechia)	Short-term value: 3000 mg/m <sup>3</sup> Long-term value: 1000 mg/m <sup>3</sup>
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- **Additional information:** The lists valid during the making were used as basis.
- **8.2 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.
- **Eye protection:**



Tightly sealed goggles

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- **Body protection:** Protective work clothing

## SECTION 9: Physical and chemical properties

· <b>9.1 Information on basic physical and chemical properties</b>	
· <b>General Information</b>	
· <b>Appearance:</b>	
Form:	Fluid
Colour:	According to product specification
· <b>Odour:</b>	Characteristic
· <b>Odour threshold:</b>	Not determined.
· <b>pH-value:</b>	Not determined.
· <b>Change in condition</b>	
Melting point/freezing point:	-114,5°C
Initial boiling point and boiling range:	78°C
· <b>Flash point:</b>	13°C
· <b>Flammability (solid, gas):</b>	Not applicable.
· <b>Ignition temperature:</b>	425°C
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto-ignition temperature:</b>	Product is not selfigniting.
· <b>Explosive properties:</b>	Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
· <b>Explosion limits:</b>	
Lower:	3,5 Vol %
Upper:	15 Vol %
· <b>Vapour pressure at 20°C:</b>	59 hPa
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapour density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with water at 20°C:</b>	1,000 g/l
· <b>Partition coefficient: n-octanol/water:</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic at 20°C:	1,2 mPas
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	95,8 %
VOC (EC)	95,79 %
Solids content:	3,0 %
· <b>9.2 Other information</b>	No further relevant information available.

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## SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

## SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**

- **Acute toxicity**  
Toxic if inhaled.

- **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)
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### CAS: 128-37-0 Butylated hydroxytoluene

Oral	LD50	5000 mg/kg (rat)
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- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation**  
Causes serious eye damage.
- **Respiratory or skin sensitisation** Based on available data, the classification criteria are not met.
- **Additional toxicological information:**
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **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 or 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.

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## SECTION 12: Ecological information

### · 12.1 Toxicity

#### · Aquatic toxicity:

CAS: 302-79-4 Tretinoin

EC50 0,1–0,3 mg/kg /(48h) (daphnia)

· **12.2 Persistence and degradability** No further relevant information available.

· **12.3 Bioaccumulative potential** No further relevant information available.

· **12.4 Mobility in soil** No further relevant information available.

#### · Ecotoxicological effects:

· **Remark:** Harmful to fish

#### · 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.

Harmful to aquatic organisms

#### · 12.5 Results of PBT and vPvB assessment

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **12.6 Other adverse effects** No further relevant information available.

## SECTION 13: Disposal considerations

### · 13.1 Waste treatment methods

#### · Recommendation

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

#### · European waste catalogue

HP3	Flammable
HP4	Irritant - skin irritation and eye damage
HP10	Toxic for reproduction
HP14	Ecotoxic

#### · Uncleaned packaging:

· **Recommendation:** Disposal must be made according to official regulations.

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

## SECTION 14: Transport information

### · 14.1 UN-Number

#### · ADR, IMDG, IATA

UN1992

### · 14.2 UN proper shipping name

#### · ADR

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

#### · IMDG

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







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· IATA	Flammable liquid, toxic, n.o.s. (ETHANOL, denatonium benzoate)
· 14.3 Transport hazard class(es)	
· ADR	
 	
· Class	3 Flammable liquids.
· Label	3+6.1
· IMDG	
 	
· Class	3 Flammable liquids.
· Label	3/6.1
· IATA	
 	
· Class	3 Flammable liquids.
· Label	3 (6.1)
· 14.4 Packing group	II
· ADR, IMDG, IATA	
· 14.5 Environmental hazards:	Not applicable.
· 14.6 Special precautions for user	Warning: Flammable liquids.
· Hazard identification number (Kemler code):	336
· EMS Number:	F-E,S-D
· Stowage Category	B
· Stowage Code	SW2 Clear of living quarters.
· 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· Transport category	2
· Tunnel restriction code	D/E
· IMDG	
· Limited quantities (LQ)	1L
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30

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·	ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1992 FLAMMABLE LIQUID, TOXIC, N.O.S. (ETHANOL (ETHYL ALCOHOL), DENATONIUM BENZOATE), 3 (6.1), II

## SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- 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
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

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

None of the ingredients is listed.

- **REGULATION (EU) 2019/1148**

- **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients is listed.

- **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients is listed.

- **Regulation (EC) No 273/2004 on drug precursors**

CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	3
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- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**

CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	3
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- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## SECTION 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.  
H302 Harmful if swallowed.  
H315 Causes skin irritation.  
H317 May cause an allergic skin reaction.  
H318 Causes serious eye damage.

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H319 Causes serious eye irritation.  
H330 Fatal if inhaled.  
H360 May damage fertility or the unborn child.  
H400 Very toxic to aquatic life.  
H410 Very toxic to aquatic life with long lasting effects.  
H411 Toxic to aquatic life with long lasting effects.

· **Department issuing SDS:** Fagron Česká republika

· **Contact:** msds@fagron.cz

· **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

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

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 Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

Repr. 1B: Reproductive toxicity – Category 1B

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

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

Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2

Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard – Category 3

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