

# Safety Data Sheet

acc. to OSHA HCS

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Printing date 10/24/2022


Reviewed on 10/24/2022

## 1 Identification

- **Product identifier**
- **Trade name:** Tretinoin sol.3.33%
- **Article number:** 103514
- **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 Inc  
2400 Pilot Knob Road  
St. Paul, MN 55120  
www.fagron.us  
QA@fagron.us
- **Information department:**  
Tel.: 800-423-6967  
Fax: 800-339-1596
- **Emergency telephone number:**  
Emergency Telephone:  
US: 1-800-535-5053  
International: 1-352-323-3500

## 2 Hazard(s) identification

- **Classification of the substance or mixture**

Flammable Liquids 2	H225 Highly flammable liquid and vapor.
Acute Toxicity - Inhalation 3	H331 Toxic if inhaled.
Eye Damage 1	H318 Causes serious eye damage.
Sensitization - Skin 1	H317 May cause an allergic skin reaction.
Carcinogenicity 1A	H350 May cause cancer.
Toxic to Reproduction 1B	H360 May damage fertility or the unborn child.
- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**  
  
GHS02 GHS05 GHS06 GHS07 GHS08
- **Signal word** Danger
- **Hazard-determining components of labeling:**  
ethanol  
denatonium benzoate  
Tretinoin  
Bergamot extract
- **Hazard statements**  
Highly flammable liquid and vapor.  
Toxic if inhaled.  
Causes serious eye damage.

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Trade name: **Tretinoin sol.3.33%**

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- May cause an allergic skin reaction.
- May cause cancer.
- May damage fertility or the unborn child.

· **Precautionary statements**

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
- Ground/bond container and receiving equipment.
- Use explosion-proof electrical/ventilating/lighting/equipment.
- Use only non-sparking tools.
- Take precautionary measures against static discharge.
- Avoid breathing dust/fume/gas/mist/vapors/spray
- Use only outdoors or in a well-ventilated area.
- Contaminated work clothing must not be allowed out of the workplace.
- Wear protective gloves/protective clothing/eye protection/face protection.
- If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- 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.
- IF exposed or concerned: Get medical advice/attention.
- Specific treatment (see on this label).
- If skin irritation or rash occurs: Get medical advice/attention.
- Wash contaminated clothing before reuse.
- In case of fire: Use CO<sub>2</sub>, powder or water spray to extinguish.
- Store in a well-ventilated place. Keep container tightly closed.
- Store in a well-ventilated place. Keep cool.
- Store locked up.
- Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**
- **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

CAS: 64-17-5	ethanol	50–≤100%
CAS: 3734-33-6	denatonium benzoate	≥3–≤5%
CAS: 8007-75-8	Bergamot extract	≥0.1–<1%

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CAS: 302-79-4 Tretinoin

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0.1–≤1%

## 4 First-aid measures

- **Description of first aid measures**
- **General information:**  
Immediately remove any clothing soiled by the product.  
Remove breathing apparatus 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.
- **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:**  
CO<sub>2</sub>, extinguishing 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 neutralizing 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.

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· **Protective Action Criteria for Chemicals**

· **PAC-1:**

CAS: 64-17-5	ethanol	1,800 ppm
CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	200 ppm

· **PAC-2:**

CAS: 64-17-5	ethanol	3300* ppm
CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	2700* ppm

· **PAC-3:**

CAS: 64-17-5	ethanol	15000* ppm
CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	4000* ppm

## 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 protection against explosions and fires:**

Keep ignition sources away - Do not smoke.  
Protect against electrostatic charges.  
Keep respiratory protective device available.

· **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 receptacle tightly sealed.  
Store in cool, dry conditions in well sealed receptacles.

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

## 8 Exposure controls/personal protection

· **Additional information about design of technical systems:** No further data; see item 7.

· **Control parameters**

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

The following constituent is the only constituent of the product which has a PEL, TLV or other recommended exposure limit.

At this time, the other constituents have no known exposure limits.

<b>CAS: 64-17-5 ethanol</b>	
PEL	Long-term value: 1900 mg/m <sup>3</sup> , 1000 ppm
REL	Long-term value: 1900 mg/m <sup>3</sup> , 1000 ppm
TLV	Short-term value: 1000 ppm
	A3

· **Additional information:** The lists that were valid during the creation were used as basis.

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- **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.
- **Breathing equipment:**  
 In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **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

- **Body protection:** Protective work clothing

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Fluid
<b>Color:</b>	According to product specification
- **Odor:** Characteristic
- **Odor threshold:** Not determined.
- **pH-value:** Not determined.
- **Change in condition**

<b>Melting point/Melting range:</b>	-114.5°C (-174.1°F)
<b>Boiling point/Boiling range:</b>	78°C (172.4°F)

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· <b>Flash point:</b>	13°C (55.4°F)
· <b>Flammability (solid, gaseous):</b>	Not applicable.
· <b>Ignition temperature:</b>	425°C (797°F)
· <b>Decomposition temperature:</b>	Not determined.
· <b>Auto igniting:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.
· <b>Explosion limits:</b>	
Lower:	3.5 Vol %
Upper:	15 Vol %
· <b>Vapor pressure at 20°C (68°F):</b>	59 hPa (44.3 mm Hg)
· <b>Density:</b>	Not determined.
· <b>Relative density</b>	Not determined.
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water at 20°C (68°F):</b>	1,000 g/l
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <b>Viscosity:</b>	
Dynamic at 20°C (68°F):	1.2 mPas
Kinematic:	Not determined.
· <b>Solvent content:</b>	
Organic solvents:	95.8 %
VOC content:	95.79 %
	957.9 g/l / 7.99 lb/gal
<b>Solids content:</b>	3.0 %
· <b>Other information</b>	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.

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## 11 Toxicological information

- Information on toxicological effects

- Acute toxicity:

- LD/LC50 values that are relevant for classification:

ATE (Acute Toxicity Estimate)		
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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- Primary irritant effect:

- on the skin: No irritant effect.

- on the eye: Strong irritant with the danger of severe eye injury.

- Sensitization: Sensitization possible through skin contact.

- Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Toxic  
Irritant

- Carcinogenic categories

IARC (International Agency for Research on Cancer)		
CAS: 64-17-5	ethanol	1
CAS: 128-37-0	Butylated hydroxytoluene	3

- NTP (National Toxicology Program)

None of the ingredients is listed.

- OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

## 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.

- Behavior 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 (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

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Must not reach bodies of water or drainage ditch undiluted or unneutralized.

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 of together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packagings:**

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

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

## 14 Transport information

· **UN-Number**

· **DOT, IMDG, IATA**

UN1992

· **UN proper shipping name**

· **DOT**

Flammable liquids, toxic, n.o.s. (Ethanol, denatonium benzoate)

· **IMDG**

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

· **IATA**

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

· **Transport hazard class(es)**

· **DOT**



· **Class**

3 Flammable liquids

· **Label**

3, 6.1

· **IMDG**



· **Class**

3 Flammable liquids

· **Label**

3/6.1

· **IATA**



· **Class**

3 Flammable liquids

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· Label	3 (6.1)
· Packing group	
· DOT, IMDG, IATA	II
· Environmental hazards:	Not applicable.
· 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.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· DOT	
· Quantity limitations	On passenger aircraft/rail: 1 L On cargo aircraft only: 60 L
· IMDG	
· 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
· 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
- Sara

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

All components have the value ACTIVE.

· Hazardous Air Pollutants

None of the ingredients is listed.

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

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Trade name: Tretinoin sol.3.33%

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· **Chemicals known to cause developmental toxicity:**

CAS: 64-17-5	ethanol
CAS: 302-79-4	Tretinoin

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

CAS: 78-93-3	2-Butanone Methyl Ethyl Ketone MEK	I
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· **TLV (Threshold Limit Value)**

CAS: 64-17-5	ethanol	A3
CAS: 128-37-0	Butylated hydroxytoluene	A4

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **National regulations:**

· **Information about limitation of use:**

Workers are not allowed to be exposed to the hazardous carcinogenic materials contained in this preparation. Exceptions can be made by the authorities in certain cases.

· **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.

· **Department issuing SDS:**

Fagron US  
Quality Assurance

· **Contact:** QA@fagron.us

· **Date of preparation / last revision** 10/24/2022 / -

· **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

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Flammable Liquids 2: Flammable liquids – Category 2

Acute Toxicity - Inhalation 3: Acute toxicity – Category 3

Eye Damage 1: Serious eye damage/eye irritation – Category 1

Sensitization - Skin 1: Skin sensitisation – Category 1

Carcinogenicity 1A: Carcinogenicity – Category 1A

Toxic to Reproduction 1B: Reproductive toxicity – Category 1B

USA