



Material Safety Data Sheet

ACCUTANE(R) Capsule Suspension (40 mg)

1. Product and Company Identification

Product name	ACCUTANE(R) Capsule Suspension (40 mg)	
Product code	CSE-1010	
Company information	Enquiries: Hoffmann-La Roche Inc. 340 Kingsland Street USA-Nutley, N.J. 07110-1199 United States of America	Local representation:
	Phone 001-973/235 50 00	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	
Roche Nutley Inventory Code	76325	
Characterization	final product	

2. Composition/Information on ingredients

Ingredients	Concentration
Vegetable oil CAS: 68334-00-9	82 - 96 %
Isotretinoin CAS: 4759-48-2	3.2 - 12.7 %

3. Hazards identification

Emergency Overview

Form	liquid
Color	yellow-orange
Hazard Overview	- Can cause birth defects

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Potential Health Effects	<ul style="list-style-type: none">- Exposure: Ingestion, Skin contact, Eye contact- Target Organs: eye, skin, liver, respiratory tract, gastrointestinal system, Central nervous system, Female reproductive system, Skeletal system- Acute Effects: May cause excessive drying of the eyes., May cause conjunctivitis., This material has not been tested as a whole; therefore, the information described below is based on one or more of its ingredients., May cause drying and/or irritation of the mucous membrane., May cause skin reactions such as cracks in lips and around mouth, dry skin, skin peeling, itching and redness of the skin., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause hepatic (liver) system effects., Signs and symptoms may include elevation of liver enzyme levels and jaundice (yellowing of the skin and eyes)., May cause musculoskeletal effects., Signs and symptoms may include muscle weakness or pain and skeletal abnormalities.- Chronic Effects: May cause elevation of liver enzyme and triglyceride levels., May cause enlargement of the liver., May cause bronchitis., May cause muscle weakness and pain.- Carcinogenicity: formulation not listed by NTP, IARC or OSHA
Additional Health Information	<ul style="list-style-type: none">- Reproductive Toxicity: Can cause birth defects.- Conditions Aggravated: Liver conditions and/or impaired liver function, diabetes, heart conditions, depression and pseudotumor cerebri.- Additional Health Hazard Information: Individuals taking Vitamin A as a nutritional supplement should avoid exposure to this material.
4. First-aid measures	
Eye contact	<ul style="list-style-type: none">- in case of contact with eyes rinse thoroughly with plenty of water and get medical advice
Skin contact	<ul style="list-style-type: none">- remove immediately contaminated clothes, wash affected skin with water and soap
Inhalation	<ul style="list-style-type: none">- in case of inhalation remove to fresh air and seek medical aid
Ingestion	<ul style="list-style-type: none">- consult physician
5. Fire-fighting measures	
Suitable extinguishing media	<ul style="list-style-type: none">- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	<p>Not established</p>
Protection of fire-fighters	<ul style="list-style-type: none">- use self-contained breathing apparatus
Special method of fire-fighting	<ul style="list-style-type: none">- cool endangered containers with water spray

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6. Accidental release measures

- | | |
|-------------------------|---|
| Personal precautions | - ensure adequate ventilation |
| Methods for cleaning up | - Absorb small spills with noncombustible absorbent material
- Dike large spills and pump into metal drums or absorb with noncombustible absorbent material.
- Put saturated absorbent material into a suitable labeled open head drum.
- Secure the drum cover and move the container to a safe holding area
- Wash spill area thoroughly with soapy water
- Check area for residual material and repeat clean up if detected |

7. Handling and storage

Handling

- | | |
|--------------------|---------------------------------|
| Technical measures | - Use with adequate ventilation |
|--------------------|---------------------------------|

Storage

- | | |
|--------------------|--|
| Storage conditions | - room temperature
- protected from light |
| Validity | - 12 months, 15 to 30 °C, |

8. Exposure controls/Personal protection

- | | |
|-----------------------------|---|
| Engineering Measures | - see 7. |
| Threshold value (USA) air | - ACGIH-TLV: 10 mg/m ³ *1
- OSHA-PEL: 5 mg/m ³ (respirable fraction) *1
- OSHA-PEL: 15 mg/m ³ *1 |
| Threshold value (Roche) air | - IOEL: 0.05 mg/m ³ (Internal Occupational Exposure Limit, men) *2 |

Personal protective equipment

- | | |
|------------------------|--|
| Respiratory protection | - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary during normal operations |
| Hand protection | - protective gloves |
| Eye protection | - safety glasses |
| Body protection | - protective clothing |

*1 referring to: Vegetable oil

*2 referring to: Isotretinoin

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9. Physical and chemical properties

Color	yellow-orange
Form	liquid
Solubility	insoluble, water

10. Stability and reactivity

Stability	- stable under normal conditions
Conditions to avoid	- light
Materials to avoid	- None known

11. Toxicological information

Acute toxicity	- LD ₅₀ > 4'000 mg/kg (oral, rat, 24 h)	*2
Local effects	- skin: strongly irritant (guinea pig); 1 % solution in acetone	*2
	- mucous membranes: irritant	*2
	- skin: irritant	*2
Mutagenicity	- not mutagenic (various test systems)	*2
Carcinogenicity	- not cancerogenic	*2
Reproduction toxicity	- teratogenic (human and animal)	*2
Note	- dosage: daily 0.5 - 1.0 mg/kg (oral)	*2
	- systemic symptoms: signs of vitamin A hypervitaminosis (dryness of mucous membranes, exanthems, pruritus; high doses: signs of intracranial pressure like headache, vomiting, etc.)	*2
*2 referring to:	Isotretinoin	

12. Ecological information

Inherent biodegradability	- inherently biodegradable 59 %, 28 days (MITI Test II, OECD No. 302 C)	*2
Ecotoxicity	- highly toxic for fish (rainbow trout) LC ₁₀₀ (96 h) 0.61 mg/l LC ₅₀ (96 h) 0.52 mg/l LC ₀ (96 h) 0.45 mg/l NOEC (96 h) 0.05 mg/l (OECD No. 203)	*2
	- barely toxic for microorganisms (activated sludge) LC ₅₀ (3 h) > 100 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)	*2
	- strongly toxic for planktonic crustaceans (Daphnia magna) EC ₅₀ (48 h) 2.06 mg/l (FDA Technical Assistance Document No. 4.08)	*2

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Note - the substance shows a potential of bioaccumulation *2

*2 referring to: Isotretinoin

13. Disposal considerations

Waste from residues - incinerate in qualified installation with flue gas scrubbing
- observe local/national regulations regarding waste disposal

RCRA waste - not regulated under RCRA

14. Transport information

Note - not classified by transport regulations, proper shipping name
non-regulated

15. Regulatory information

US Regulations - Law: safe drinking water and toxic enforcement act of 1986
- Ident_No: Proposition 65
- Common name: Prop 65
- Agency: California Environmental Protection Agency
- Authority: California
- Criteria met: contains a chemical known to the state to cause reproductive toxicity
- Law: hazardous chemical reporting: community right-to know
- Ident_No: 40CFR370
- Common name: SARA title 312
- Agency: Environmental Protection Agency EPA
- Authority: USA
- Criteria met: acute

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

16. Other information

Use - ACCUTANE(R) is a keratolytic drug used in the treatment of nodular acne.

Edition documentation - changes from previous version in sections 8

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.