



Material Safety Data Sheet

# ACCUTANE(R) Capsule Suspension (10 mg)

## 1. Product and Company Identification

Product name	ACCUTANE(R) Capsule Suspension (10 mg)	
Product code	CSE-1008	
Use	- ACCUTANE(R) is a keratolytic drug used in the treatment of nodular acne.	
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 E-Mail info.sds@roche.com	
	US Emergency phone: (800)-827-6243 US Chemtrec phone: (800)-424-9300	
Roche Nutley Inventory Code	76324	

## 2. 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"> <li>- Exposure: Ingestion, Skin contact, Eye contact</li> <li>- Target Organs: eye, skin, liver, respiratory tract, gastrointestinal system, Central nervous system, Female reproductive system, Skeletal system</li> <br/> <li>- 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.</li> <br/> <li>- 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.</li> <br/> <li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li> </ul> |
| Additional Health Information | <ul style="list-style-type: none"> <li>- Reproductive Toxicity: Can cause birth defects.</li> <li>- Conditions Aggravated: Liver conditions and/or impaired liver function, diabetes, heart conditions, depression and pseudotumor cerebri.</li> <li>- Additional Health Hazard Information: Individuals taking Vitamin A as a nutritional supplement should avoid exposure to this material.</li> </ul>  |

### 3. Composition/Information on ingredients

Characterization	final product
<b>Ingredients</b>	<b>Concentration</b>
Vegetable oil CAS: 68334-00-9	82 - 96 %
Isotretinoin CAS: 4759-48-2	3.2 - 12.7 %

### 4. First-aid measures

- |              |   |
|--------------|---|
| Eye contact  | - in case of contact with eyes rinse thoroughly with plenty of water and get medical advice |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with water and soap           |
| Inhalation   | - in case of inhalation remove to fresh air and seek medical aid                            |
| Ingestion    | - consult physician   |

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### 5. Fire-fighting measures

Suitable extinguishing media	- water spray jet, dry powder, foam, carbon dioxide
Flash point (liquid)	(Not established)
Protection of fire-fighters	- use self-contained breathing apparatus
Special method of fire-fighting	- cool endangered containers with water spray

### 6. Accidental release measures

Personal precautions	- ensure adequate ventilation
Methods for cleaning up	<ul style="list-style-type: none"><li>- Absorb small spills with noncombustible absorbent material</li><li>- Dike large spills and pump into metal drums or absorb with noncombustible absorbent material.</li><li>- Put saturated absorbent material into a suitable labeled open head drum.</li><li>- Secure the drum cover and move the container to a safe holding area</li><li>- Wash spill area thoroughly with soapy water</li><li>- Check area for residual material and repeat clean up if detected</li></ul>

### 7. Handling and storage

#### Handling

Technical measures	- Use with adequate ventilation
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#### Storage

Storage conditions	<ul style="list-style-type: none"><li>- room temperature</li><li>- protected from light</li></ul>
Validity	- 12 months, 15 to 30 °C

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### 8. Exposure controls/Personal protection

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

### 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

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

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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	
<b>12. Ecological information</b>		
Inherent biodegradability	- inherently biodegradable 59 %, 28 days (MITI Test II, OECD No. 302 C)	*2
Ecotoxicity	- highly toxic for fish (rainbow trout) LC <sub>100</sub> (96 h) 0.61 mg/l LC <sub>50</sub> (96 h) 0.52 mg/l LC <sub>0</sub> (96 h) 0.45 mg/l NOEC (96 h) 0.05 mg/l (OECD No. 203)	*2
	- barely toxic for microorganisms (activated sludge) LC <sub>50</sub> (3 h) > 100 mg/l (Activated Sludge Respir. Inhib. Test, OECD No. 209)	*2
	- strongly toxic for planktonic crustaceans (Daphnia magna) EC <sub>50</sub> (48 h) 2.06 mg/l (FDA Technical Assistance Document No. 4.08)	*2
Note	- the substance shows a potential of bioaccumulation	*2
*2 referring to:	Isotretinoin	
<b>13. Disposal considerations</b>		
Waste from residues	- incinerate in qualified installation with flue gas scrubbing - observe local/national regulations regarding waste disposal - DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.	
RCRA waste	- not regulated under RCRA	
<b>14. Transport information</b>		
Note	- not classified by transport regulations, proper shipping name non-regulated	

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### 15. Regulatory information

US Regulations	<ul style="list-style-type: none"><li>- Law: safe drinking water and toxic enforcement act of 1986</li><li>- Ident_No: Proposition 65</li><li>- Common name: Prop 65</li><li>- Agency: California Environmental Protection Agency</li><li>- Authority: California</li><li>- Criteria met: contains a chemical known to the state to cause reproductive toxicity</li><li>- Law: hazardous chemical reporting: community right-to know</li><li>- Ident_No: 40CFR370</li><li>- Common name: SARA title 312</li><li>- Agency: Environmental Protection Agency EPA</li><li>- Authority: USA</li><li>- Criteria met: acute</li></ul>
TSCA Status	<ul style="list-style-type: none"><li>- FDA Exemption - not on inventory</li></ul>
Reporting Requirements	<ul style="list-style-type: none"><li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li><li>- 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.</li><li>- State and local regulations vary and may impose additional reporting requirements.</li></ul>

### 16. Other information

Edition documentation	<ul style="list-style-type: none"><li>- changes from previous version in sections 13</li></ul>
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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.