Roche Dermatologics
a division of Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Emergency: (800) 827-6243
Chemtrec: (800)-424-9300
Information: (800) 526-6367

MATERIAL SAFETY DATA SHEET

SECTION 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Material Name .....: ACCUTANE(R) 25% Suspension
Inventory Code .....: 76330
TSCA Status .....: FDA Exemption - Not on Inventory.
Therapeutic Category: Keratolytic

SECTION 2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name	CAS Number	Concentration %
Vegetable Oil	68334-00-9	71
Isotretinoin	4759-48-2	25
Yellow wax (purified beeswax)	8012-89-3	4

SECTION 3. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW
Physical State .....: Liquid.
Color .....: Yellow-orange

Can cause birth defects.

POTENTIAL HEALTH EFFECTS
Relevant Routes of
Exposure .....: Skin Contact, Eye Contact, Ingestion.
Target Organs .....: Respiratory System, Gastrointestinal System, Central Nervous System, Hematopoietic/ Blood System, Female Reproductive System, Hepatic System, Dermal System, Ocular System, Skeletal System.

SECTION 3. HAZARDS IDENTIFICATION (Continued. . .)

Acute Effects
General .....: This material has not been tested as a whole; therefore, information described below is based on one or more of its ingredients. 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 such as 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 such as muscle weakness or pain and skeletal abnormalities. May cause drying and/or irritation of the mucous membrane.
Eye .....: May cause excessive drying of the eyes. May cause conjunctivitis.

Chronic Effects
General .....: May cause enlargement of the liver. May cause elevation of liver enzyme and triglyceride levels. May cause bronchitis. May cause muscle weakness and pain.

Carcinogenicity ....: Not listed by NTP, IARC, or OSHA.

Reproductive
Toxicity .....: Isotretinoin
Can cause birth defects.

Conditions
Aggravated .....: Liver conditions and/or impaired liver function. Diabetes. Heart Conditions. Depression. Pseudotumor Cerebri.

Additional Health
Hazard Information .: Individuals taking Vitamin A as a nutritional supplement should avoid exposure to this material.

SECTION 4. FIRST AID MEASURES

Inhalation .....: Remove to fresh air. If discomfort occurs or persists, get medical attention.

Skin Contact .....: Remove contaminated clothing and shoes. Wash skin with soap and plenty of water. If irritation occurs or persists, get medical attention. Wash clothing and shoes before reuse.

Eye Contact .....: Immediately flush eyes with plenty of water. If irritation occurs or persists, get medical attention.

Ingestion .....: If large quantities of this material are swallowed, get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

SECTION 5. FIRE FIGHTING MEASURES

Flash Point .....: Not Applicable
Extinguishing Media : Water, Carbon Dioxide, Dry Chemical, Foam.
Unusual Fire and Explosion Hazards ..: Toxic emissions may be given off in a fire. See Decomposition Products in Section 10. Stability and Reactivity.
Fire Fighting Instructions .....: Wear NIOSH/MSHA approved positive pressure, self contained breathing apparatus and full protective turn out gear. Use caution in approaching fire. Use water to keep fire exposed containers cool.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Spill Clean Up Procedures .....: Review Section 3-Hazards Identification, and Section 8-Exposure Controls/Personal Protection before proceeding with the clean up. Shut off the source of the spill or leak if it is safe to do so. 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.
Treatment and Disposal .....: Decontaminate equipment. Dispose of protective clothing with the spilled material. Dispose of in accordance with recommendations in Section 13 Disposal Considerations.
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.

SECTION 7. HANDLING AND STORAGE

Storage Temperature (min/max) .....: 15-30 C
Shelf Life .....: 12 months
Special Sensitivity : Light.

SECTION 7. HANDLING AND STORAGE (Continued. . .)

Handling & Storage
Precautions .....: Do not get in eyes, on skin or on clothing.
Do not breathe vapor or mist.
Use with adequate ventilation.
When handling, use proper personal protective equipment specified in section 8.
Wash thoroughly after handling.
Keep container tightly closed when not in use.
Store in light resistant containers.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS
Ventilation .....: General room ventilation is adequate unless the process generates mist or vapor.

PERSONAL PROTECTION
Respirator Type(s) .: None Recommended.
Conditions for Use .: Under normal conditions of use, respiratory protection is not expected to be necessary. OSHA considers effective engineering controls to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls. Whenever respiratory protection is used, a complete respirator program should be developed in accordance with OSHA Subpart I (29CFR1910.134) requirements.
Glove Materials ....: Any plastic or rubber glove.
Conditions for Use .: Gloves are required if there is a potential for skin contact.
Skin Protection ....: Use protective clothing (lab coats, disposable coveralls, etc.) in both production and laboratory areas. Consult the protective clothing manufacturer, supplier and/or industrial hygienist.
Eye Protection .....: Safety Glasses Required, Safety Goggles Recommended.

OTHER CONTROL MEASURES
Administrative Controls .....: Post the work area and limit access to authorized personnel only.
Additional Protective Measures : Work clothing should be removed in a changeroom on site and laundered professionally. Launder contaminated clothing separately. Employees should shower and change into street clothes before leaving the facility. Provide safety showers and eyewash stations in the work area.

SECTION 8. EXPOSURE CONTROLS / PERSONAL PROTECTION (Continued. . .)

EXPOSURE LIMITS
Vegetable Oil
OSHA PEL: 5.00 mg/m3 Time Weighted Average, Respirable Fraction.
OSHA PEL: 15.0 mg/m3 Time Weighted Average.
ACGIH TLV: 10.0 mg/m3 Time Weighted Average.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State .....: Liquid.
Color .....: Yellow-orange
Pure/Mixture .....: Mixture.
H2O Solubility .....: Insoluble.
Evaporation Rate
(Butyl Acetate=1) ..: >1

SECTION 10. STABILITY AND REACTIVITY

Stability .....: Normally stable even under fire exposure conditions and not water reactive
Decomposition
Products .....: Carbon monoxide and carbon dioxide
Polymerization .....: No
Conditions of
Polymerization .....: Will not occur.

SECTION 11. TOXICOLOGICAL INFORMATION

ACCUTANE(R) 25% Suspension
Acute Oral, Single Dose, Rat: >4000 mg/kg
Summary: Acute oral LD50 (rat) is greater than 4000 mg/kg body weight which classifies this formulation as slightly toxic orally under the study conditions utilized.

Isotretinoin
Irritation Eye, Rabbit
Summary: This material was practically non-irritating to the eyes of rabbits under the study conditions utilized.

Irritation Skin, Rabbit
Summary: A primary skin irritation score of 0.0 indicates that this material was non-irritating to the skin of rabbits under the study conditions utilized.

SECTION 11. TOXICOLOGICAL INFORMATION (Continued. . .)

Carcinogenicity Oral, Rat
Summary: An increased incidence of pheochromocytoma was observed in rats given this material in the diet at doses of 2, 8, and 32 mg/kg/day for greater than 18 months; however, this finding may be unique to this animal species which is prone to the development of pheochromocytoma. Therefore, the relevance to the human population is not clear.

Reproductive Oral, Rat
Summary: No adverse effects on gonadal function, fertility, conception rate, gestation or parturition were observed in rats at doses as high as 32 mg/kg/day, under the study conditions utilized.

Reproductive Dog
Summary: In dogs, testicular atrophy was noted after treatment with this material for approximately 30 weeks at dosages up to 60 mg/kg/day, under the study conditions utilized. In general, there was microscopic evidence for appreciable depression of spermatogenesis, but some sperm were observed in all testes examined and in no instance were completely atrophic tubules seen.

Teratogenicity Oral, Monkey
Summary: Evidence of teratogenicity was observed in monkeys when a dose of 2.5 mg/kg/day was administered during gestation days 10 through 25 and then a dose of 5 mg/kg/day was administered during gestation days 26 and 27, under the study conditions utilized.

Teratogenicity Oral, Rat
Summary: Evidence of teratogenicity was observed in rats when a dose of 150 mg/kg/day was administered orally on gestation days 7 through 15, under the study conditions utilized.

Teratogenicity Oral, Rabbit
Summary: Evidence of teratogenicity was observed in rabbits when a dose of 10 mg/kg/day was administered orally on gestation days 7 through 18, under the study conditions utilized.

Mutagenicity
Summary: No evidence of mutagenicity was observed in the mouse micronucleus assay, in the unscheduled DNA synthesis assay, and in the following assays with or without metabolic activation: the HGPRT assay, the chromosomal aberration assay, and the "treat and plate" yeast assay. The results of the Ames assay in one laboratory were completely negative while in the second laboratory a weakly positive response was seen with S. typhimurium TA100, therefore, of questionable significance.

SECTION 12. ECOLOGICAL INFORMATION

Isotretinoin
Concentration lethal to 50% of the organisms, Trout: 0.520 mg/L
Summary: The LC50 of this material (rainbow trout, 96 h) is 0.52 mg/l, whereas, the NOEC is 0.045 mg/l. Therefore, this material is classified as highly toxic for fish under the study conditions utilized.

SECTION 12. ECOLOGICAL INFORMATION (Continued. . .)

Aerobic Biodegradation (H20)
Summary: This material shows a potential of bioaccumulation; inherent biodegradability 59% after 28 days, under the study conditions utilized.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal
Recommendations ....: This material is suitable for incineration. DO NOT dispose of even small amounts in the sewage system. These recommendations are based on the product as shipped. Use, processing, alteration or contamination may affect these disposal recommendations. State, local or site restrictions affecting the available proper disposal options may vary.
RCRA Waste # .....: Not regulated under RCRA
Empty Containers ...: Empty containers must be triple rinsed prior to disposal, recycling, or reuse.

SECTION 14. TRANSPORTATION INFORMATION

Enforcement Agency .: US Dept. of Transportation
Country/Community ..: USA
Proper Ship. Name ..: Non-regulated

Enforcement Agency .: International Air Transport Association
Country/Community ..: International
Proper Ship. Name ..: Non-regulated

Enforcement Agency .: IMO
Country/Community ..: International
Proper Ship. Name ..: Marine pollutant

SECTION 15. REGULATORY INFORMATION

Law/Regulation .....: Safe Drinking Water and Toxic Enforcement Act of 1986 Proposition 65
Common Name .....: Prop 65
Enforcement Agency .: California Environmental Protection Agency
Governing Authority : California, USA
Criteria Met .....: Formulation contains Isotretinoin which is known to the state to causereproductive toxicity.

Law/Regulation .....: Hazardous Chemical Reporting: Community Right-To-Know 40CFR370
Common Name .....: SARA Title III Section 312 - Hazardous Chemical Inventory
Enforcement Agency .: Environmental Protection Agency (EPA)
Governing Authority : USA
Criteria Met .....: Acute

SECTION 16. OTHER INFORMATION

Additional Information .....: NFPA RATING: These ratings are based on NFPA Code 704 and are intended for use by emergency personnel to determine the immediate hazards of a material.

....Health	0
....Fire	0
....Reactivity	0

APPROVAL INFORMATION

Preparer .....: Hesham M. Soliman
Approver .....: Corporate Environmental & Safety Affairs
Approval Date .....: 12/08/94
Reason For Issue ...: New