

1. Identification

Product identifier**SORIATANE CAPSULES****Other means of identification****Synonyms**SORIATANE (ACITRETIN) CAPSULES * ACITRETIN CAPSULES 45% * FORMULATION CODE:
R0333-R1 * ACITRETIN, FORMULATED PRODUCT**Recommended use**

Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions

No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information**Manufacturer**

Stiefel Laboratories, Inc. (a GSK company)

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GlaxoSmithKline US

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EMERGENCY PHONE NUMBERS -

TRANSPORT EMERGENCIES:

US / International toll call +1 703 527 3887

available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ALPHA-CELLULOSE AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CRYSTALLINE CELLULOSE	9004-34-6	55.7
ACITRETIN	(2E,4E,6E,8E)-9-(4-METHOXY-2,3,6-TRIMETHYLPHENYL)-3,7-DIMETHYL-2,4,6,8-NONATETRAENOIC ACID STIEFEL API	55079-83-9	10 - < 20
SODIUM ASCORBATE	ASCORBIC ACID, SODIUM DERIVATIVE L-ASCORBIC ACID SODIUM SALT L-ASCORBIC ACID, MONOSODIUM SALT ASCORBIC ACID SODIUM SALT ASCORBICIN ASCORBIN CEBITATE CENOLATE ISKIA-C MONOSODIUM ASCORBATE NATRASCORB NATRI-C SODASCORBATE SODIUM L-ASCORBATE VITAMIN C SODIUM OHS84279 RTECS CI7671000	134-03-2	3 - < 5
Other components below reportable levels			20 - < 30

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	The possible symptoms of overexposure include: dry mouth; drying of the nasal passages; nosebleed; skin changes; itching; headache; joint pain; muscle pain; changes in serum lipids; blurred vision; hair loss; nausea; vomiting; changes in liver enzymes; peripheral neuropathy; changes in behaviour.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.

Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	Prevent product from entering drains. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.
Environmental precautions	Avoid release to the environment. Inform appropriate managerial or supervisory personnel of all environmental releases. Prevent further leakage or spillage if safe to do so. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Avoid prolonged exposure. Avoid release to the environment. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Type	Value	Note
ACITRETIN (CAS 55079-83-9)	8 HR TWA	8 mcg/m ³	REPRODUCTIVE HAZARD
	OHC	4	REPRODUCTIVE HAZARD
US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)			
Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m ³	Respirable fraction.
		15 mg/m ³	Total dust.
US. ACGIH Threshold Limit Values			
Components	Type	Value	
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m ³	
US. NIOSH: Pocket Guide to Chemical Hazards			
Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	5 mg/m ³	Respirable.
		10 mg/m ³	Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Exposure guidelines	
Appropriate engineering controls	General ventilation normally adequate.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Not normally needed. If contact is likely, safety glasses with side shields are recommended.
Skin protection	
Hand protection	Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.
Other	Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.
Respiratory protection	No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Capsule.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not explosive.
Oxidizing properties	Not oxidizing.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents. Fluorine.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Ingestion	Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics	The possible symptoms of overexposure include: dry mouth; drying of the nasal passages; nosebleed; skin changes; itching; headache; joint pain; muscle pain; changes in serum lipids; blurred vision; hair loss; nausea; vomiting; changes in liver enzymes; peripheral neuropathy; changes in behaviour.
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Information on toxicological effects

Acute toxicity	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
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Components	Species	Test Results
ACITRETIN (CAS 55079-83-9)		
Acute		
Oral		
LD50	Rat	> 4000 mg/kg
Chronic		
Oral		
LOEL	Rat	3 mg/kg/day 4-week study
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)		
Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation	Health injuries are not known or expected under normal use.
Serious eye damage/eye irritation	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
Respiratory or skin sensitization	
Respiratory sensitization	No studies have been conducted.
Skin sensitization	None known. This product is not expected to cause skin sensitization.
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
Carcinogenicity	Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.
IARC Monographs. Overall Evaluation of Carcinogenicity	
Not available.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	
Not listed.	

US. National Toxicology Program (NTP) Report on Carcinogens

Not available.

Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.
Specific target organ toxicity - single exposure	Not assigned.
Specific target organ toxicity - repeated exposure	Not available.
Aspiration hazard	Not likely, due to the form of the product.
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
ACITRETIN (CAS 55079-83-9)			
Aquatic			
<i>Acute</i>			
Algae	EC50	Green algae (<i>Scenedesmus subspicatus</i>)	> 1.2 mg/l, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>)	0.078 mg/l, 48 hours
Fish	EC50	Rainbow trout (Juvenile <i>Oncorhynchus mykiss</i>)	> 100 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability No data is available on the degradability of this product.

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ACITRETIN 0 Other degradation test system

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

ACITRETIN 6.4
6.4 (Calculated).

Mobility in soil Not available.

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

UN number UN3077

UN proper shipping name Environmentally hazardous substance, solid, nos (ACITRETIN)

Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Special precautions for user Not available.

IATA

UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, nos (ACITRETIN)
Transport hazard class(es) 9
Subsidiary class(es) -
Packaging group III
Environmental hazards No.
Labels required Not available.
ERG Code Not available.
Special precautions for user Not available.

IMDG

UN number UN3077
UN proper shipping name Environmentally hazardous substance, solid, nos (ACITRETIN)
Transport hazard class(es)
Class 9
Subsidiary risk -
Packing group III
Environmental hazards
Marine pollutant No.
EmS Not available.
Special precautions for user Not available.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

DOT; IATA; IMDG



15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No**SARA 313 (TRI reporting)**
Not regulated.**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

US. New Jersey Worker and Community Right-to-Know Act

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

US. Pennsylvania Worker and Community Right-to-Know Law

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	10-29-2015
Revision date	10-29-2015
Version #	06
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 0 Physical hazard: 0

NFPA ratings

Health: 2
Flammability: 0
Instability: 0

References

GSK Hazard Determination

Disclaimer

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Revision information

Product and Company Identification: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Ecological Information: Ecotoxicity
Transport Information: Material Transportation Information
Material Attributes & Uses; Experimental Data: Product Uses