SAFETY DATA SHEET

* 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material SORIATANE CAPSULES

Synonym(s) SORIATANE (ACITRETIN) CAPSULES * ACITRETIN CAPSULES 45% * FORMULATION CODE: R0333-R1 * STIEFEL PRODUCT * ACITRETIN, FORMULATED PRODUCT

Recommended Use Medicinal Product

Note 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.

Company Name

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EMERGENCY PHONE NUMBERS -

TRANSPORT EMERGENCIES (by country / geographic region):

Africa / EU / Israel / Middle East (English / European languages):	+44 (0) 1235 239 670
Asia Pacific (except China):	+65 3158 1074
China:	+86 10 5100 3039
Middle East / Africa (Arabic-speaking countries):	+44 (0) 1235 239 671
US:	+1 703 527 3887

available 24 hrs/7 days; multi-language response

MEDICAL EMERGENCIES: +1 612 221 3999, Ext 221
available 24 hrs/7 days; multi-language response

2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards

Assume that this product is capable of sustaining combustion.

Health Caution - Pharmaceutical agent.
Handling this product in its final form presents minimal risk from occupational exposure.
Contains one or more components, categorised as potentially harmful to the development of unborn offspring.
Health effects information is based on hazards of components.
Exposure might occur via ingestion.

Environment Dangerous for the environment. Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
ACITRETIN	55079-83-9	45	259-474-4
Other components below reportable levels		55	

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation Physical form suggests that risk of inhalation exposure is negligible.

Skin contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Eye contact Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

Medical Conditions Caused or Aggravated by Exposure None for occupational exposure.

Health Surveillance Procedures Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

Antidotes No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards Not expected for the product, although the packaging is combustible.

Extinguishing Media Water or foam extinguishers are recommended.
Carbon dioxide or dry powder extinguishers may be ineffective.

Special Firefighting Procedures For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods Collect and place it in a suitable, properly labelled container for recovery or disposal.

Decontamination Procedures No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements Avoid breaking or crushing capsules.

STORAGE No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OCCUPATIONAL EXPOSURE LIMITS

INGREDIENT	ACITRETIN	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	8 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD

Other Equipment or Procedures None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Capsule.

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This product contains active ingredient(s) with the following activity: a retinoid (vitamin A derivative).

Symptoms of Overexposure 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. Additional effects of overexposure may occur.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Inhalation Toxicity Inhalation toxicity is not expected.

Skin Effects Irritation is not expected following direct contact.

Eye Effects Irritation is not expected following direct contact with eyes.

Sensitisation Sensitisation (allergic skin reaction) is not expected.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions.
Contains components which have been classified as: Adverse effects on fertility in humans or animals have been reported at doses equal or greater than recommended for therapeutic use. Developmental toxicity has been reported in humans or animals at doses equal or greater than recommended for therapeutic use.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This material contains an active ingredient that has been tested and which may be harmful if released directly to the environment. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

Algal	No toxicity to algae was observed for the active ingredient in this mixture, but the upper range of the test was limited by the low water solubility of the compound.	
	IC50:	> 1.2 mg/l, 72 Hours, Scenedesmus subspicatus, green algae
Daphnid	This material contains an active pharmaceutical ingredient that is very toxic to daphnids.	
	EC50:	0.078 mg/l, 48 Hours, Daphnia magna
Fish	This material contains an active ingredient that is not toxic to fish.	
	EC50:	> 100 mg/l, 96 Hours, Juvenile Oncorhyncus mykiss, rainbow trout

MOBILITY

Partitioning This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

PERSISTENCE/DEGRADATION

Biodegradation This material contains an active ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines). It may persist in the environment.

Aerobic - Ready

Percent Degradation: 0 Other degradation test system

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information	Per UN Model Regulation 5.2.1.6, may require environmentally hazardous substance mark (fish and tree symbol).
Technical Name	ACITRETIN CAPSULES 45%
Proper Shipping Name	Environmentally hazardous substance, solid, nos (SORIATANE CAPSULES)
UN Number	UN 3077
Class/Division	9
Subsidiary Risk	None
Packing Group	III
Risk Label(s)	Class 9

International Air Transport (IATA Requirements)

Classification and Labelling See SP A97.

International Maritime Transport (IMDG Requirements)

Classification and Labelling See SP909 / 944.

US Domestic Transport (DOT Requirements)

Classification and Labelling See DOT SP146.

European Ground Transport (ADR/RID Requirements)

Classification and Labelling As UN Classification and Labelling above

15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification Exempt when packaged for sale to consumers in a retail establishment.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

SDS Version Number 5

SDS Sections Updated

Sections	Subsections
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	

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.