SAFETY DATA SHEET

GlaxoSmithKline

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

Material **ACLOVATE CREAM**

Synonyms ACLOVATE CREAM 0.05% * NDC NO 59075-401-00 * NDC NO 59075-401-01 * NDC NO 59075-401-06 * NDC NO 59075-401-02 * ALCLOMETASONE DIPROPIONATE, FORMULATED PRODUCT

Company Name

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US General Information:	+1-888-825-5249
Transport Emergency (non EU)	+1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
ALCLOMETASONE DIPROPIONATE	66734-13-2	0.05
NON-HAZARDOUS INGREDIENTS	Unassigned	99.95

3. HAZARDS IDENTIFICATION

Fire and Explosion This product is expected to be non-combustible.

Health Caution - Pharmaceutical agent.
Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.
May cause steroid withdrawal rash.
May produce adverse effects on the development of human offspring.

Environment No information is available about the potential of this product to produce adverse environmental effects.

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 treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Health Surveillance Procedures	The need for pre-placement and periodic health surveillance must be determined by risk assessment. Following assessment, if the risk of exposure is considered significant then exposed individuals should receive health surveillance focused on detecting skin conditions. In the event of overexposure, individuals should receive post exposure health surveillance focused on detecting skin conditions and other allergy symptoms.
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 is recommended for fires involving packaging.
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 No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	ALCLOMETASONE DIPROPIONATE	
GSK Occupational Hazard Category	3	
GSK Occupational Exposure Limit	35 mcg/m3 (8 HR TWA)	REPRODUCTIVE HAZARD, SKIN
INGREDIENT	ARLACEL 165 VS	
GSK Occupational Hazard Category	3	

ENGINEERING CONTROLS

Exposure Controls An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them.

Other Equipment or Procedures Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form Cream.

pH of Aqueous Solutions 4.3 to 4.7

10. STABILITY AND REACTIVITY

Stability This product is expected to be stable.

Conditions to Avoid None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity Not expected to be toxic following ingestion.

Skin Effects Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.

Eye Effects Irritation might occur following direct contact with eyes.

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: adrenal glands; immune system.

Sensitisation Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions. Assessment based upon effects of structurally similar substances.

Carcinogenicity No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Toxicity or birth defects may occur in the developing offspring of animals based on the pharmacological activity of this material. Not expected to produce adverse effects on fertility or development under occupational exposure conditions. Insufficient information available to classify the reproductive hazards of this material in human females. Insufficient information available to classify the reproductive hazards of this material in human males. Insufficient information available to classify this material for hazard to milk production.

Pharmacological Effects This material is a selective glucocorticoid receptor agonist.
It is an agent intended for the treatment of inflammatory skin conditions.
Adverse effects of overexposure might include: suppression of adrenal glands; temporary decrease in white blood cell counts; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); increased susceptibility to infection.

Other Adverse Effects None known for this material in humans.

12. ECOLOGICAL INFORMATION

Summary No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

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 material.

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 Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

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

None.

US OSHA Standard (29 CFR Part 1910.1200)

Classification This product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 18-Aug-2003 **SDS Version Number** 6

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.