SAFETY DATA SHEET

1. Identification

Product identifier **EUMOVATE CREAM**

Other means of identification Not available.

Synonym(s) EUMOVATE ECZEMA AND DERMATITIS CREAM (UK) * EUMOVATE CREAM * EUMOVATE CREME 0.05% * EUMOVATE KREM 0.05% * EMOVAT CREAM 0.05% * EMOVATE CREAM 0.05% * EUMOSONE SKIN CREAM 0.05% * RETTAVATE CREAM 0.05% * SPECTRO ECZEMACARE MEDICATED CREAM * FORMULA NUMBER RL0090 * FORMULA NUMBER C318B * CLOBETASONE BUTYRATE, 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

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
GLYCERIN	GLYCEROL GLYCERIN ANHYDROUS GLYCERINE GLYCERITOL GLYCYL ALCOHOL 1,2,3-PROPANETRIOL PROPANETRIOL GLYROL GLYSANIN TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE OSMOGLYN	56-81-5	25

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
GLYCERYL MONOSTEARATE	OCTADECANOIC ACID, MONOESTER WITH 1,2,3-PROPANETRIOL STEARIN, MONO- MONOSTEARIN ALPHA-MONOSTEARIN GLYCERIN MONOSTEARATE GLYCEROL MONOOCTADECANOATE GLYCEROL MONOSTEARATE GLYCEROL, 1-STEARATE GLYCERIN 1-MONOSTEARATE GMS GMS (GLYCERIDE) STEARIC ACID GLYCEROL MONOESTER STEARIC ACID MONOGLYCERIDE STEARIC MONOGLYCERIDE ADMUL ALDO HMS CEFATIN CERASYNT SD EMCOL CA TEGIN SEDETINE LIPO GMS 410 C21H42O4 OHS10441 RTECS RG1925000	31566-31-1	9.6
CLOBETASONE BUTYRATE	CLOBETASONE 17-BUTYRATE CCI 5537 AH 6225 PREGNA-1,4-DIENE-3,11,20-TRIONE, 21-CHLORO-9-FLUORO-16-METHYL-17-(1- (16BETA)- 254 (GW ACN) (16BETA)-21-CHLORO-9-FLUORO-16-METH BUTANOATE	25122-57-0	0.05
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID, MONOHYDRATE CITRIC ACID, MONOHYDRATE CITRIC ACID MONOHYDRATE C6H10O8 OHS84211 RTECS GE7810000	5949-29-1	0.05

Non-hazardous components

Chemical name	Common name and synonyms	CAS number	%
4-CHLORO-M-CRESOL	PHENOL, 4-CHLORO-3-METHYL- 4-CHLORO-3-METHYLPHENOL M-CRESOL, 4-CHLORO- 3-METHYL-4-CHLOROPHENOL 6-CHLORO-M-CRESOL 6-CHLORO-3-HYDROXYTOLUENE 2-CHLORO-5-HYDROXYTOLUENE 4-CHLORO-1-HYDROXY-3-METHYLBENZE P-CHLORO-M-CRESOL CHLOROCRESOL P-CHLOROCRESOL APTAL BAKTOL BAKTOLAN CANDASEPTIC OTTAFACT PCMC RCRA U039 UN 2669 C7H7CLO OHS29890 RTECS GO7100000 875 (GW ACN) 4-CHLOR-3-METHYLPHENOL 4-KLOORI-3-METYYLIFENOLI 4-KLOR-3-METYLFENOL CHLOORKRESOL CHLORKRESOL CHLOROCRÉSOL CLOROCRESOL CLOROCRESOLO KLOORIKRESOLI KLOROKRESOOL PARACHLOROMETA CRESOL	59-50-7	0.1
Other components below reportable levels			65.2

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

4. First-aid measures

Inhalation
In case of accident by inhalation: remove casualty to fresh air and keep at rest. If breathing is difficult, trained personnel should give oxygen. If not breathing, give artificial respiration.

Skin contact
Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.

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).

Most important symptoms/effects, acute and delayed
Irritation of eyes and mucous membranes. The following adverse effects have been noted with therapeutic use of this material: irritation; itching; burning; pain symptoms of hypersensitivity (such as skin rash, hives, itching, and/or difficulty breathing).

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 local poison control information centre.

General information
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 adrenal suppression.

5. Fire-fighting measures

Suitable extinguishing media
Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media
Water.

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
Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

Specific methods Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8 of the MSDS.

Methods and materials for containment and cleaning up 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. Use water spray to reduce vapors or divert vapor cloud drift. Prevent entry into waterways, sewer, basements or confined areas. 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 in original containers for re-use. For waste disposal, see section 13 of the MSDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities Keep away from heat and sources of ignition. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
CLOBETASONE BUTYRATE (CAS 25122-57-0)	8 HR TWA	20 mcg/m3	
	OHC	3	SKIN
		3	REPRODUCTIVE HAZARD
HYDROUS CITRIC ACID (CAS 5949-29-1)	8 HR TWA	5000 mcg/m3	
	OHC	1	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
GLYCERYL MONOSTEARATE (CAS 31566-31-1)	TWA	10 mg/m3	

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. 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.

Individual protection measures, such as personal protective equipment

Eye/face protection If contact is likely, safety glasses with side shields are recommended.

Hand protection The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other Wear suitable protective clothing.

Respiratory protection 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	An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional. New or expectant mothers are at greater risk if exposed to the active ingredient which is readily absorbed through the skin. They should not handle unpackaged product. Risk assessments must take this into consideration. Female employees anticipating pregnancy or with a confirmed pregnancy must be encouraged to notify an occupational health professional or their line manager. This will act as the trigger for individual re-assessment of the employee's work practices.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Cream.
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	> 375.8 °F (> 191 °C) Closed Cup (Estimation based on components).
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)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion	May be harmful if swallowed.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Pharmacological effects might occur following direct contact with skin. Repeated contact may increase sensitivity of skin to bruising.

Eye contact May be irritating to eyes.

Symptoms related to the physical, chemical and toxicological characteristics The following adverse effects have been noted with therapeutic use of this material: itching; burning; pain; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing).

Information on toxicological effects

Acute toxicity May be harmful if swallowed. May be harmful in contact with skin.

Components	Species	Test Results
4-CHLORO-M-CRESOL (CAS 59-50-7)		
Acute		
Oral		
LD50	Rat	1830 mg/kg
Subacute		
Oral		
NOAEL	Rat	400 mg/kg/day, 28 Day
Subchronic		
Oral		
NOAEL	Rat	150 ppm, 13 weeks, dietary study
CLOBETASONE BUTYRATE (CAS 25122-57-0)		
Acute		
Oral		
LD50	Rat	> 6000 mg/kg
Subacute		
Dermal		
TDL0	Rat	17.5 mg/kg, 5 weeks
Other		
TDL0	Rat	3 mg/kg, 30 Day, subcutaneous injection
Subchronic		
Other		
TDL0	Rat	15.6 mg/kg, 26 weeks, subcutaneous injection
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg

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

Skin corrosion/irritation Repeated contact may increase sensitivity of skin to bruising.

Corrosivity

4-CHLORO-M-CRESOL: 2 %, Literature data
Result: Irritant
Species: Human

Serious eye damage/eye irritation May be irritating to eyes.

Eye

4-CHLORO-M-CRESOL: 0.1 %, Literature data
Result: Severe Irritant
Species: Rabbit

Respiratory sensitization None known.

Skin sensitization Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.

Sensitization

4-CHLORO-M-CRESOL: OECD 406 - Maximisation test, Literature data
Result: Positive
Species: Guinea pig

Sensitization

CLOBETASONE BUTYRATE	SAR / QSAR, DEREK, Lhasa, UK Result: Positive SAR / QSAR, OECD QSAR Toolbox, Laboratory of Mathematical Chemistry, Bulgaria Result: Positive

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

4-CHLORO-M-CRESOL	125 mg/kg In vivo Micronucleus, Intra-peritoneal injection. Result: Negative Species: Mouse Organ: Bone marrow Ames Result: Equivocal
CLOBETASONE BUTYRATE	Ames Result: Negative
4-CHLORO-M-CRESOL	HPRT gene mutation in human lymphocytes Result: Negative
CLOBETASONE BUTYRATE	In vitro cytogenetics assay Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay Result: Negative Yeast mutation Result: Negative in vivo cytogenetics assay Result: Equivocal

Carcinogenicity Not classifiable as to carcinogenicity to humans.

4-CHLORO-M-CRESOL	104 mg/kg/day, Literature data Result: NOAEL for renal necrosis and fibrosis Species: Rat

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

CLOBETASONE BUTYRATE	Embryofetal Development Result: Developmental abnormalities. Species: Rabbit Embryofetal Development Result: Maternal toxicity; adverse foetal effects Species: Rat Fertility, Glucocorticoid Result: Effects on fertility, foetal toxicity Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure Adrenal glands. Bone tissue. Immune system. May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard Not established.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test Results
CLOBETASONE BUTYRATE (CAS 25122-57-0)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, Nominal, OECD 209
	NOEC	Residential sludge	100 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 0.43 mg/l, 48 hours, Measured. OECD 202
	NOEC	Water flea (Daphnia magna)	0.43 mg/l, 48 hours

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

Persistence and degradability Not available.

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

GLYCERIN	-1.76
4-CHLORO-M-CRESOL	2.78 - 3.1 3.1
CLOBETASONE BUTYRATE	3.63 (Measured).

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.

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.

US RCRA Hazardous Waste U List: Reference

4-CHLORO-M-CRESOL (CAS 59-50-7)	U039

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).

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

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

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.

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)

4-CHLORO-M-CRESOL (CAS 59-50-7)	LISTED

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

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 No

SARA 311/312 Hazardous chemical No

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.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

4-CHLORO-M-CRESOL (CAS 59-50-7)
GLYCERIN (CAS 56-81-5)

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

4-CHLORO-M-CRESOL (CAS 59-50-7) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

4-CHLORO-M-CRESOL (CAS 59-50-7)
GLYCERIN (CAS 56-81-5)

US. Rhode Island RTK

4-CHLORO-M-CRESOL (CAS 59-50-7)

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)	No
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 10-18-2013

Revision date 10-18-2013

Version # 11

Further information This material has not been assessed for HMIS or NFPA ratings.

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: Multiple Properties
Toxicological Information:
Transport Information: