

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	EUMOVATE CREAM
Registration number	-
Synonyms	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
Issue date	18-October-2013
Version number	11
Revision date	18-October-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES:
UK In-country toll call: + (44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards

Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.
This product will support combustion at elevated temperatures.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
GLYCERIN	20 - < 30	56-81-5 200-289-5	-	-	
Classification:	DSD: -				
	CLP: -				
GLYCERYL MONOSTEARATE	5 - < 10	31566-31-1 250-705-4	-	-	
Classification:	DSD: -				
	CLP: -				
4-CHLORO-M-CRESOL	< 0.2	59-50-7 200-431-6	-	604-014-00-3	
Classification:	DSD: Xn;R21/22, Xi;R41, R43, N;R50				
	CLP: Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Sens. 1;H317, Eye Dam. 1;H318, Aquatic Acute 1;H400				
CLOBETASONE BUTYRATE	0.05	25122-57-0 246-635-9	-	-	
Classification:	DSD: Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21, R53				
	CLP: Repr. 1B;H360D, Repr. 2;H361f, STOT RE 2;H373, Aquatic Chronic 4;H413				
HYDROUS CITRIC ACID	< 0.1	5949-29-1 201-069-1	-	-	
Classification:	DSD: Xi;R37/38-41				
	CLP: Skin Irrit. 2;H315, Eye Dam. 1;H318, STOT SE 3;H335				

Other components below reportable levels 60 - < 70

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information

Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse. 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.

4.1. Description of 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. Call a POISON CENTRE or doctor/physician if you feel unwell.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Ingestion

Call a POISON CENTRE or doctor/physician if you feel unwell. If swallowed, rinse mouth with water (only if the person is conscious).

4.2. Most important symptoms and effects, both 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).

4.3. Indication of any 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.

SECTION 5: Firefighting measures

General fire hazards	This product will support combustion at elevated temperatures.
5.1. Extinguishing media	
Suitable extinguishing media	Alcohol resistant foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Water.
5.2. Special hazards arising from the substance or mixture	During fire, gases hazardous to health may be formed.
5.3. Advice for firefighters	
Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures	
For non-emergency personnel	Keep unnecessary personnel away. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material 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 vapours or divert vapour cloud drift. 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.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Observe good industrial hygiene practices.
7.2. 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).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK Components	Type	Value	Note
CLOBETASONE BUTYRATE (CAS 25122-57-0)	8 HR TWA	20 mcg/m ³	
	OHC	3	Skin
		3	Reproductive hazard
HYDROUS CITRIC ACID (CAS 5949-29-1)	8 HR TWA	5000 mcg/m ³	
	OHC	1	
UK. EH40 Workplace Exposure Limits (WELs)			
Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m ³	Mist.

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection

If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- 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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other

Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection

Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures

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.

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.

Environmental exposure controls

Hazard guidance and control recommendations

Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Liquid.

Form Cream.

Colour Not available.

Odour Not available.

Odour threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point > 191 °C (> 375.8 °F) 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.

Vapour pressure Not available.

Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid heat, sparks, open flames and other ignition sources. Avoid temperatures exceeding the flash point. Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
----------------------------	--------------------------------------------------------------------------------------------------------------

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	Harmful in contact with skin. 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	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).
-----------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

11.1. 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		
<i>Oral</i>		
LD50	Rat	1830 mg/kg
Subacute		
<i>Oral</i>		
NOAEL	Rat	400 mg/kg/day, 28 Day
Subchronic		
<i>Oral</i>		
NOAEL	Rat	150 ppm, 13 weeks, dietary study
CLOBETASONE BUTYRATE (CAS 25122-57-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 6000 mg/kg
Subacute		
<i>Dermal</i>		
TDL0	Rat	17.5 mg/kg, 5 weeks
<i>Other</i>		
TDL0	Rat	3 mg/kg, 30 Day, subcutaneous injection

Components	Species	Test results
Subchronic <i>Other</i> TDLO	Rat	15.6 mg/kg, 26 weeks, subcutaneous injection
GLYCERIN (CAS 56-81-5)		
Acute <i>Oral</i> LD50	Rat	> 2000 mg/kg
GLYCERYL MONOSTEARATE (CAS 31566-31-1)		
Acute <i>Oral</i> 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 sensitisation	None known.	
Skin sensitisation	Allergic skin reactions might occur following repeated contact with this material in susceptible individuals.	
Sensitisation 4-CHLORO-M-CRESOL		OECD 406 - Maximisation test, Literature data Result: positive Species: Guinea pig
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.	
Germ cell mutagenicity		
Mutagenicity 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 4-CHLORO-M-CRESOL	Not classifiable as to carcinogenicity to humans. 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.

Reproductive toxicity

Reproductivity

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.

Mixture versus substance information No information available.

Other information Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity 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			
<i>Acute</i>			
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.

12.2. Persistence and degradability Not available.

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CLOBETASONE BUTYRATE 20 %, 8 days Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log Kow)

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

12.4. Mobility in soil Not available.

Mobility in general Not available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste	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.
EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.
Special precautions	Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I**
Not listed.
- Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II**
Not listed.
- Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended**
Not listed.
- Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended**
Not listed.
- Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry**
Not listed.
- Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA**
Not listed.

Authorisations

- Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended**
Not listed.

Restrictions on use

- Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended**
Not listed.
- Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work**
Not listed.
- Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding**
Not listed.

Other EU regulations

- Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances**
Not listed.
- Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work**
4-CHLORO-M-CRESOL (CAS 59-50-7)

Directive 94/33/EC on the protection of young people at work

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

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	<p>R21/22 Harmful in contact with skin and if swallowed.</p> <p>R37/38 Irritating to respiratory system and skin.</p> <p>R41 Risk of serious damage to eyes.</p> <p>R43 May cause sensitization by skin contact.</p> <p>R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin.</p> <p>R50 Very toxic to aquatic organisms.</p> <p>R53 May cause long term adverse effects in the aquatic environment.</p> <p>R61 May cause harm to the unborn child.</p> <p>R62 Possible risk of impaired fertility.</p> <p>H302 Harmful if swallowed.</p> <p>H312 Harmful in contact with skin.</p> <p>H315 Causes skin irritation.</p> <p>H317 May cause an allergic skin reaction.</p> <p>H318 Causes serious eye damage.</p> <p>H335 May cause respiratory irritation.</p> <p>H360D May damage the unborn child.</p> <p>H361f Suspected of damaging fertility.</p> <p>H373 May cause damage to organs through prolonged or repeated exposure.</p> <p>H400 Very toxic to aquatic life.</p> <p>H413 May cause long lasting harmful effects to aquatic life.</p>
Revision information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: TOXICOLOGICAL INFORMATION: TRANSPORT INFORMATION:
Training information	Follow training instructions when handling this material.
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.