

# SAFETY DATA SHEET

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

### 1.1. Product identifier

Trade name or designation of the mixture	EUMOCREAM
Registration number	-
Synonyms	EUMOCREAM CONCENTRATED REHYDRATION CREAM * EUMOBASE COSMETIC EMOLLIENT CREAM * FORMULA PTSRL9960 * SPECTRO ECZEMACARE INTENSE REHYDRATION CREAM * SPECTRO KIDS ECZEMACARE INTENSE MOISTURIZING CREAM
Issue date	05-December-2014
Version number	07
Revision date	05-December-2014

### 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](mailto:msds@gsk.com)  
Website: [www.gsk.com](http://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

#### 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.

### 2.3. Other hazards

This product will support combustion at elevated temperatures.

Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

## 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		-	-
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
CETOSTEARYL ALCOHOL	< 5	67762-27-0 267-008-6		-	-
<b>Classification:</b>	<b>DSD:</b> Xi;R36/38				
	<b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319				
POLYETHYLENE GLYCOL STEARATE	1 - < 3	9004-99-3 -		-	-
<b>Classification:</b>	<b>DSD:</b> Xi;R36/37/38				
	<b>CLP:</b> Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				
Paraffin wax	< 2.5	8002-74-2 232-315-6		-	-
<b>Classification:</b>	<b>DSD:</b> -				
	<b>CLP:</b> -				
4-CHLORO-M-CRESOL	< 0.25	59-50-7 200-431-6			604-014-00-3
<b>Classification:</b>	<b>DSD:</b> Xn;R21/22, Xi;R41, R43, N;R50				
	<b>CLP:</b> Acute Tox. 4;H302, Acute Tox. 4;H312, Skin Sens. 1;H317, Eye Dam. 1;H318, Aquatic Acute 1;H400				

Other components below reportable levels 60 - &lt; 70

**List of abbreviations and symbols that may be used above**

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**

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.

**4.1. Description of 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 centre immediately. Do not induce vomiting without advice from poison control center.

**4.2. Most important symptoms and effects, both acute and delayed**

None known.

**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 current prescribing information or to the local poison control information centre.

## SECTION 5: Firefighting measures

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

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

<b>For non-emergency personnel</b>	Keep unnecessary personnel away. Keep upwind. Keep out of low areas. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. For personal protection, see section 8.
<b>For emergency responders</b>	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
<b>6.2. Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.
<b>6.3. Methods and material for containment and cleaning up</b>	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.
<b>6.4. Reference to other sections</b>	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

## SECTION 7: Handling and storage

<b>7.1. Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Keep away from heat, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
<b>7.3. Specific end use(s)</b>	Medicinal Product.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

##### GSK

Not established

#### UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m <sup>3</sup>	Mist.
Paraffin wax (CAS 8002-74-2)	STEL	6 mg/m <sup>3</sup>	Fume.
	TWA	2 mg/m <sup>3</sup>	Fume.

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

**Recommended monitoring procedures** Follow standard monitoring procedures.

**Derived no-effect level (DNEL)** Not available.

**Predicted no effect concentrations (PNECs)** Not available.

#### Exposure guidelines

### 8.2. Exposure controls

<b>Appropriate engineering controls</b>	General ventilation normally adequate. 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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>General information</b>	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.
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended. (e.g. EN 166). Not normally needed.
<b>Skin protection</b>	
<b>- Hand protection</b>	For prolonged or repeated skin contact use suitable protective gloves. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time). Not normally needed.
<b>- Other</b>	Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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). No personal respiratory protective equipment normally required.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>Hygiene measures</b>	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.

#### **Environmental exposure controls**

<b>Hazard guidance and control recommendations</b>	Environmental manager must be informed of all major releases.
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## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

#### **Appearance**

<b>Physical state</b>	Liquid.
<b>Form</b>	Cream.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	> 191 °C (> 375.8 °F) Closed cup (Estimation based on components).
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.

#### **Upper/lower flammability or explosive limits**

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Not available.
<b>Solubility (other)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

<b>10.1. Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>10.2. Chemical stability</b>	Material is stable under normal conditions.
<b>10.3. Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>10.4. Conditions to avoid</b>	Keep away from heat, sparks and open flame. Contact with incompatible materials.
<b>10.5. Incompatible materials</b>	Strong oxidising agents.
<b>10.6. Hazardous decomposition products</b>	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

## SECTION 11: Toxicological information

<b>General information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
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### Information on likely routes of exposure

<b>Inhalation</b>	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Ingestion</b>	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.
<b>Symptoms</b>	None known.

### 11.1. Information on toxicological effects

<b>Acute toxicity</b>	Expected to be a low hazard for usual industrial or commercial handling by trained personnel.
<b>Components</b>	<b>Species</b> <b>Test results</b>

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

<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	1830 mg/kg
<b>Subacute</b>		
<i>Oral</i>		
NOAEL	Rat	400 mg/kg/day, 28 Day
<b>Subchronic</b>		
<i>Oral</i>		
NOAEL	Rat	150 ppm, 13 weeks dietary study

#### CETOSTEARYL ALCOHOL (CAS 67762-27-0)

<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg

#### GLYCERIN (CAS 56-81-5)

<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
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<b>Corrosivity</b>		
4-CHLORO-M-CRESOL	2 %, Literature data	

<b>Serious eye damage/eye irritation</b>	Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.
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<b>Eye</b>		
4-CHLORO-M-CRESOL	0.1 %, Literature data	

<b>Respiratory sensitisation</b>	Due to partial or complete lack of data the classification is not possible.
<b>Skin sensitisation</b>	Health injuries are not known or expected under normal use. Contains a potential skin sensitizer.
<b>Sensitisation</b> 4-CHLORO-M-CRESOL	OECD 406 - Maximisation test, Literature data Result: positive Species: Guinea pig
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.
<b>Mutagenicity</b> 4-CHLORO-M-CRESOL	125 mg/kg In vivo Micronucleus, Intra-peritoneal injection. Result: negative Species: Mouse Organ: Bone marrow Ames Result: Equivocal HPRT gene mutation in human lymphocytes Result: negative
<b>Carcinogenicity</b>	Carcinogenic effects are not expected as a result of occupational exposure. Not classifiable as to carcinogenicity to humans. Contains a material (4-Chloro-M-cresol) classified as a carcinogen by external agencies. These effects are linked only to high doses of this substance; lower doses did not cause this adverse effect.
4-CHLORO-M-CRESOL	104 mg/kg/day, Literature data Result: NOAEL for renal necrosis and fibrosis Species: Rat
<b>Reproductive toxicity</b>	Contains no ingredient listed as toxic to reproduction
<b>Specific target organ toxicity - single exposure</b>	None known.
<b>Specific target organ toxicity - repeated exposure</b>	None known.
<b>Aspiration hazard</b>	Not established.
<b>Mixture versus substance information</b>	No information available.
<b>Other information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

## SECTION 12: Ecological information

**12.1. Toxicity** Not expected to be harmful to aquatic organisms.

Components	Species	Test results
4-CHLORO-M-CRESOL (CAS 59-50-7)		
<b>Aquatic</b>		
Acute		
Algae	EC50	Green algae (Scenedesmus subspicatus) 4.2 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna) 2 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas) 7.6 mg/l, 96 hours Flow-through test
CETOSTEARYL ALCOHOL (CAS 67762-27-0)		
<b>Aquatic</b>		
Acute		
Algae	EC50	Green algae (Scenedesmus subspicatus) 235 mg/l, 96 hours
Crustacea	EC50	Water flea (Daphnia magna) 1666 mg/l, 48 hours
	NOEC	Water flea (Daphnia magna) 0.98 mg/l, 21 days
Fish	LC50	Bluegill sunfish (Adult Lepomis macrochirus) > 1000 mg/l, 96 hours

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

**12.2. Persistence and degradability**

**Biodegradability**

**Percent degradation (Aerobic biodegradation-inherent)**

CETOSTEARYL ALCOHOL

56 - 100 %, 28 days BOD

<b>Biodegradability</b>	
Percent degradation (Aerobic biodegradation-ready)	
Paraffin wax	< 50 %
<b>12.3. Bioaccumulative potential</b>	Not available.
<b>Partition coefficient</b>	
<b>n-octanol/water (log Kow)</b>	
4-CHLORO-M-CRESOL	2.78 - 3.1
	3.1
GLYCERIN	-1.76
<b>Bioconcentration factor (BCF)</b>	
CETOSTEARYL ALCOHOL	> 1000 Measured
<b>12.4. Mobility in soil</b>	
<b>Adsorption</b>	
Soil/sediment sorption - log Koc	
CETOSTEARYL ALCOHOL	3.58 - 4.67 Estimated
<b>Mobility in general</b>	Not available.
<b>12.5. Results of PBT and vPvB assessment</b>	Not available.
<b>12.6. Other adverse effects</b>	Not available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Residual waste</b>	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.
<b>Contaminated packaging</b>	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.
<b>EU waste code</b>	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Disposal methods/information</b>	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.
<b>Special precautions</b>	Dispose in accordance with all applicable regulations.

## SECTION 14: Transport information

<b>ADR</b>	Not regulated as dangerous goods.
<b>IATA</b>	Not regulated as dangerous goods.
<b>IMDG</b>	Not regulated as dangerous goods.
<b>14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b>	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

<b>Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I</b>
Not listed.
<b>Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II</b>
Not listed.
<b>Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended</b>
Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended</b>
Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended</b>
Not listed.
<b>Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended</b>
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(10) 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**

R21/22 Harmful in contact with skin and if swallowed.

R36/37/38 Irritating to eyes, respiratory system and skin.

R36/38 Irritating to eyes and skin.

R41 Risk of serious damage to eyes.

R43 May cause sensitization by skin contact.

R50 Very toxic to aquatic organisms.

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H318 Causes serious eye damage.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H400 Very toxic to aquatic life.

#### **Revision information**

Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Undisclosed Ingredient Statement

Physical & Chemical Properties:

Transport Information: Agency Name and Packaging Type/Transport Mode Selection

Regulatory Information: United States

GHS: Classification

#### **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.