

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
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

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	-	-	
Classification:	DSD: -				
	CLP: -				
CETOSTEARYL ALCOHOL	< 5	67762-27-0 267-008-6	-	-	
Classification:	DSD: Xi;R36/38				
	CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319				
POLYETHYLENE GLYCOL STEARATE	1 - < 3	9004-99-3 -	-	-	
Classification:	DSD: Xi;R36/37/38				
	CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, STOT SE 3;H335				
Paraffin wax	< 2,5	8002-74-2 232-315-6	-	-	
Classification:	DSD: -				
	CLP: -				
4-CHLORO-M-CRESOL	< 0,25	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				

Other components below reportable levels 60 - < 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

General fire hazards	This product will support combustion at elevated temperatures.
5.1. Extinguishing media	
Suitable extinguishing media	Foam. Dry chemical powder. Carbon dioxide (CO2).
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	Move containers from fire area if you can do so without risk.
Specific methods	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	
For non-emergency personnel	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.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
6.2. Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	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.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13 of the SDS.

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, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).
7.3. Specific end use(s)	Medicinal Product.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters	
Occupational exposure limits	
GSK	Not established
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	
Appropriate engineering controls	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.
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. (e.g. EN 166). Not normally needed.

Skin protection**- Hand protection**

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.

- Other

Wear suitable protective clothing as protection against splashing or contamination. (EN 14605 for splashes, EN ISO 13982 for dust). Not normally needed.

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. No personal respiratory protective equipment normally required.

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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

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)

Solubility (water) Not available.

Solubility (other) 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 Keep away from heat, sparks and open flame. Contact with incompatible materials.

10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's 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

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	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.

Symptoms None known.

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

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
CETOSTEARYL ALCOHOL (CAS 67762-27-0)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
GLYCERIN (CAS 56-81-5)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg

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

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

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

Serious eye damage/eye irritation Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

Eye

4-CHLORO-M-CRESOL	0,1 %, Literature data Result: Severe Irritant Species: Rabbit
-------------------	--

Respiratory sensitisation Due to partial or complete lack of data the classification is not possible.

Skin sensitisation Health injuries are not known or expected under normal use. Contains a potential skin sensitizer.

Sensitisation

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

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

Mutagenicity

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

Carcinogenicity

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

Reproductive toxicity

Contains no ingredient listed as toxic to reproduction

Specific target organ toxicity - single exposure

None known.

Specific target organ toxicity - repeated exposure

None known.

Aspiration hazard

Not established.

Mixture versus substance information

No information available.

Other information

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)

Aquatic*Acute*

Species	EC50	Test results
Algae	EC50	Green algae (<i>Scenedesmus subspicatus</i>) 4,2 mg/l, 72 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 2 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult <i>Pimephales promelas</i>) 7,6 mg/l, 96 hours Flow-through test

CETOSTEARYL ALCOHOL (CAS 67762-27-0)

Aquatic*Acute*

Species	EC50	Test results
Algae	EC50	Green algae (<i>Scenedesmus subspicatus</i>) 235 mg/l, 96 hours
Crustacea	EC50	Water flea (<i>Daphnia magna</i>) 1666 mg/l, 48 hours
	NOEC	Water flea (<i>Daphnia magna</i>) 0,98 mg/l, 21 days
Fish	LC50	Bluegill sunfish (Adult <i>Lepomis macrochirus</i>) > 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

Percent degradation (Aerobic biodegradation-ready)

Paraffin wax < 50 %

12.3. Bioaccumulative potential Not available.**Partition coefficient****n-octanol/water (log Kow)**

4-CHLORO-M-CRESOL	2,78 - 3,1 3,1
GLYCERIN	-1,76

Bioconcentration factor (BCF)

CETOSTEARYL ALCOHOL

> 1000 Measured

12.4. Mobility in soil**Adsorption****Soil/sediment sorption - log K_{oc}**

CETOSTEARYL ALCOHOL

3,58 - 4,67 Estimated

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). Avoid discharge into water courses or onto the ground.

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

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(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.