SAFETY DATA SHEET

1. Identification

Product identifier **EUMOCREAM**

Other means of identification

Synonyms EUMOCREAM CONCENTRATED REHYDRATION CREAM * EUMOBASE COSMETIC EMOLLIENT CREAM * FORMULA PTSRL9960 * SPECTRO ECZEMACARE INTENSE REHYDRATION CREAM * SPECTRO KIDS ECZEMACARE INTENSE MOISTURIZING CREAM

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

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
GLYCERYL MONOSTEARATE	OCTADECANOIC ACID, MONOESTER WITH 1,2,3-PROPANETRIOL * GLYCEROL MONOSTEARATE * STEARIC ACID MONOGLYCERIDE * STEARIC MONOGLYCERIDE * CEFATIN	31566-31-1	< 10
CETOSTEARYL ALCOHOL	ALCOHOLS, C16-C19 * CETEARYL ALCOHOL * CETYLSTEARYL ALCOHOL * LANETTE WAX * CETOSTEARYL ISONONANOATE	67762-27-0	< 5

Chemical name	Common name and synonyms	CAS number	%
POLYETHYLENE GLYCOL STEARATE	POLY(OXY-1,2-ETHANEDIYL), ALPHA-(1-OXOOCTADECYL)-OMEGA-HYD ROXY- * GLYCOLS, POLYETHYLENE, MONOSTEARATE * POLYOXYL 8 STEARATE * POLYETHYLENE GLYCOL 400 MONOSTEARATE * POLYETHOXYLATED MONOSTEARATE * POLYETHYLENE GLYCOL MONOSTEARATE * POLYETHYLENE OXIDE MONOSTEARATE	9004-99-3	1 - < 3
PARAFFIN WAX	PARAFFIN * HARD PARAFFIN * PARAFFIN WAXES AND HYDROCARBON WAXES * WHITE SOFT PARAFFIN	8002-74-2	< 2.5
4-CHLORO-M-CRESOL	PHENOL, 4-CHLORO-3-METHYL- * 4-CHLORO-3-METHYLPHENOL * 3-METHYL-4-CHLOROPHENOL * 6-CHLORO-M-CRESOL * 6-CHLORO-3-HYDROXYTOLUENE * 4-CHLORO-1-HYDROXY-3-METHYLBENZE NE * CHLOROCRESOL * P-CHLOROCRESOL	59-50-7	< 0.25
CITRIC ACID ANHYDROUS	BETA-HYDROXYTRICARBALLYLIC ACID * ANHYDROUS CITRIC ACID * 2-HYDROXY-1,2,3-PROPANETRICARBOX YLIC ACID * CITIRIC ACID	77-92-9	< 0.1
Other components below reportable levels			50 - < 60

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

4. 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 center immediately. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed None known.

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 current prescribing information or to the local poison control information center.

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.

5. Fire-fighting measures

Suitable extinguishing media 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 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.

General fire hazards This product will support combustion at elevated temperatures.

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 SDS.

Methods and materials 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. For waste disposal, see section 13 of the SDS.

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, sparks and open flame. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value
CITRIC ACID ANHYDROUS (CAS 77-92-9)	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
GLYCERYL MONOSTEARATE (CAS 31566-31-1)	TWA	10 mg/m3	
PARAFFIN WAX (CAS 8002-74-2)	TWA	2 mg/m3	Fume.

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
PARAFFIN WAX (CAS 8002-74-2)	TWA	2 mg/m3	Fume.

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

Exposure guidelines

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

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

Skin protection

Hand protection For prolonged or repeated skin contact use suitable protective gloves.

Other Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations 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.

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)

Solubility (water)	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	Keep away from heat, sparks and open flame. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics	None known.

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		
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
CETOSTEARYL ALCOHOL (CAS 67762-27-0)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
CITRIC ACID ANHYDROUS (CAS 77-92-9)		
Acute		
Oral		
LD50	Rat	3000 mg/kg
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 Health injuries are not known or expected under normal use.

Corrosivity

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

Irritation Corrosion - Skin: P.I.I. value

CITRIC ACID ANHYDROUS	OECD 404 Result: Mild to moderate irritant. Species: Rabbit

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
CITRIC ACID ANHYDROUS	Acute ocular irritation; OECD 405 Result: Severe Irritant Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Not available.

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

Sensitization

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

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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.

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

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
4-CHLORO-M-CRESOL (CAS 59-50-7)			
Aquatic			
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)			
Aquatic			
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
CITRIC ACID ANHYDROUS (CAS 77-92-9)			
Aquatic			
Acute			
Algae	NOEC	Green algae (Scenedesmus quadricauda)	425 mg/l, 8 days Static Test
Crustacea	EC50	Water flea (Daphnia magna)	120 mg/l, 72 hours Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	1516 mg/l, 96 hours Static test

Components	Species	Test Results
	Golden ide/orfe (Adult Leuciscus idus)	440 - 760 mg/l, 96 hours Static test

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

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CETOSTEARYL ALCOHOL	56 - 100 %, 28 days BOD
CITRIC ACID ANHYDROUS	98 %, 2 days Modified Zahn-Wellens, Activated sludge

Bioaccumulative potential

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

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CETOSTEARYL ALCOHOL	3.58 - 4.67 Estimated

Mobility in general Not available.

Volatility

Henry's law

CITRIC ACID ANHYDROUS	< 0 atm m^3/mol Calculated, 25 °C

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

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.

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). 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.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

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.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

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

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Chemical name	CAS number	% by wt.
4-CHLORO-M-CRESOL	59-50-7	< 0.25

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.

US state regulations

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

4-CHLORO-M-CRESOL (CAS 59-50-7)
GLYCERIN (CAS 56-81-5)
PARAFFIN WAX (CAS 8002-74-2)

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

4-CHLORO-M-CRESOL (CAS 59-50-7)
GLYCERIN (CAS 56-81-5)
PARAFFIN WAX (CAS 8002-74-2)

US. Pennsylvania Worker and Community Right-to-Know Law

4-CHLORO-M-CRESOL (CAS 59-50-7)
GLYCERIN (CAS 56-81-5)
PARAFFIN WAX (CAS 8002-74-2)

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)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
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	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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	12-05-2014
Revision date	12-05-2014
Version #	07
Further information	HMIS® is a registered trade and service mark of the NPCA.
HMIS® ratings	Health: 2* Flammability: 1 Physical hazard: 0
NFPA ratings	Health: 2 Flammability: 1 Instability: 0
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: Undisclosed Ingredient Statement Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States GHS: Classification