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 of the chemical and restrictions on use

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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

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

Label elements, including precautionary statements

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

Other hazards which do not result in classification

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

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
GLYCERIN Glycerol GLYCERIN ANHYDROUS Glycerine GLYCERITOL GLYCYL ALCOHOL 1,2,3-Propanetriol PROPANETRIOL GLYROL GLYSANIN TRIHYDROXYPROPANE 1,2,3-TRIHYDROXYPROPANE OSMOGLYN	56-81-5	20 - < 30

CETOSTEARYL ALCOHOL ALCOHOLS, C16-C19 CETEARYL ALCOHOL CETYLSTEARYL ALCOHOL LANETTE WAX CETOSTEARYL ISONONANOATE	67762-27-0	< 5
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-METHYLBENZENE CHLOROCRESOL P-CHLOROCRESOL	59-50-7	< 0.25
Other components below reportable levels		60 - < 70

4. First-aid measures

Description of necessary 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.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	None known.
Medical attention and special treatment	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.

5. Fire-fighting measures

Extinguishing media

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 fire fighters	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.
Hazchem Code	Not available.
General fire hazards	This product will support combustion at elevated temperatures.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

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

7. Handling and storage

Precautions for safe handling	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 and personal protection

Control parameters Follow standard monitoring procedures.

Occupational exposure limits

GSK
Not established

Australia. National Workplace OELs (Workplace Exposure Standards for Airborne Contaminants, Appendix A)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Inhalable mist.
Paraffin wax (CAS 8002-74-2)	TWA	2 mg/m3	Fume.

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Inspirable dust.
Paraffin wax (CAS 8002-74-2)	TWA	2 mg/m3	Fume.

US. ACGIH Threshold Limit Values

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

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	10 mg/m3	Mist.
Paraffin wax (CAS 8002-74-2)	STEL	6 mg/m3	Fume.
	TWA	2 mg/m3	Fume.

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	TWA	50 mg/m3	Inhalable fraction.

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, for example personal protective equipment (PPE)

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	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
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.

9. 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.
Explosive limit - lower (%)	Not available.
Explosive limit – upper (%)	Not available.
Vapour pressure	Not available.
Vapour 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 oxidising 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 possible 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 exposure	None known.
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
GLYCERIN (CAS 56-81-5)		
Acute		
Oral		
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/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 or skin sensitisation

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

Mutagenicity

4-CHLORO-M-CRESOL	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.

Other 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

* 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

Percent degradation (Aerobic biodegradation-ready)

Paraffin wax	< 50 %

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 No data available for this product.

Adsorption

Soil/sediment sorption - log Koc

CETOSTEARYL ALCOHOL	3.58 - 4.67 Estimated

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal methods 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.

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.

14. Transport information

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 Not available.

15. Regulatory information

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

4-CHLORO-M-CRESOL (CAS 59-50-7)	For advice, contact a Poisons information Centre (Phone eg Australia 131 - 126; New Zealand 03 - 4747 - 000) or a doctor (at once)., If swallowed, do NOT induce vomiting., If in eyes, hold eyelids apart and flush the eye continuously with running water. Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes., If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water. Continue flushing with water until advised

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

4-CHLORO-M-CRESOL (CAS 59-50-7)	Exception was applied to data.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

GLYCERIN (CAS 56-81-5)	1000 - 9999 TONNES See the regulation for additional information.
Paraffin wax (CAS 8002-74-2)	100000 - 999999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

Not listed.

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

Not applicable.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Country(s) or region	Inventory name	On inventory (yes/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	Yes
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

Issue date 05-December-2014

Revision date 05-December-2014

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: Product and Company Identification
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