

MoliCare Skin Barrier Cream

Issue date: 22 February 2019

Version No. 4.0 Supersedes: July 2017

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name: MoliCare Skin Barrier Cream

Art. No.: 995026/3; 995086/0; 995051/3

Recommended Use: Protects the skin from irritations, especially in intimate area.

Protects irritated skin areas from harmful substances and cares for the skin stressed by incontinence.

Apply very thinly. Use on intact skin.

Manufacturer/supplier

PAUL HARTMANN PTY LTD

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2. HAZARDS IDENTIFICATION

AUSTRALIAN CLASSIFICATION

(According to Approved Criteria for Classifying Hazardous Substances NOHSC:1008(2004))

Hazard Category: None allocated.

Hazard Classification: NON-HAZARDOUS SUBSTANCE, NON-DANGEROUS GOODS.

Risk Phrases: None allocated Safety Phrases: None allocated

Poison Schedule (Australia): Not scheduled. SUSMP Signal Word(s): None allocated

(According to Work Health and Safety Regulations 2011)

GHS Hazard Classification: None allocated.

GHS Signal Word: None allocated.

GHS Hazard Pictogram(s): None allocated.

Hazard Statements: None allocated.

Precautionary Statements: None allocated.

Hazard Statements: None allocated.

Precautionary statements:

<u>Prevention</u>: No prevention statements. <u>Response</u>: No response statements. <u>Storage</u>: No storage statements. <u>Disposal</u>: No disposal statements.

3. COMPOSITION / INFORMATION ON INGREDIENTS

SUBSTANCE NAME	CAS Number	Proportion
*Non-hazardous ingredients		100%



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* (Ingredients present at non-hazardous concentrations, according to criteria of SWAC (Australia) based on available information).

Further information:

MoliCare Skin Barrier Cream is preparation of solid matters in form of a water-in-oil emulsion

Composition of the impregnation liquid (INCI):

AQUA (WATER), PARAFFINUM LIQUIDUM, ISOPROPYL PALMITATE, CETEARYL ALCOHOL, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, PROPYLENE GLYCOL, CETEARYL GLUCOSIDE, C 12-15 ALKYL BENZOATE, STEARIC ACID, PETROLATUM, BISABOLOL, PEG-30 DIPOLYHYDROXYSTEARATE, PEG-40 STEARATE, CREATINE, PRUNUS AMYGDALUS DULCIS OIL, LINSEED ACID, 1,2-HEXANEDIOL, CAPRYLYL GLYCOL, TROPOLONE, PARFUM(FRAGRANCE), ROSMARINUS OFFICINALIS LEAF EXTRACT, SODIUM PCA, SODIUM LACTATE, ARGININE, ASPARTIC ACID, PCA, GLYCINE, ALANINE, SERINE, VALINE, PROLINE, THREONINE, ISOLEUCINE, HISTIDINE, PHENYLALANINE

4. FIRST AID MEASURES

Swallowed:

Do NOT induce vomiting. Rinse mouth with water. Never give anything by mouth if victim is semi-conscious or unconscious. If symptoms develop seek medical attention. Show this sheet to the doctor.

Eve:

If contact with the eye(s) occurs, hold eyelids apart and flush the eye continuously with running water holding eyelid(s) open. Take care not to rinse contaminated water into the non-affected eye. Remove contact lenses, if present and easy to do so. Continue rinsing. If symptoms persist seek medical attention. Show this sheet to the doctor.

Skin:

If irritation occurs, wash affected area thoroughly with soap and water. If symptoms persist obtain medical attention. Show this sheet to the doctor.

Inhaled:

Inhalation is not an expected route of exposure. If respiratory irritation or distress occurs remove victim to fresh air. Keep at rest. Apply artificial respiration if not breathing. Seek medical attention if respiratory irritation or distress continues. Show this sheet to the doctor.

First Aid Facilities:

Normal wash room facilities.

Advice to Doctor:

Treat symptomatically.

Poisons Information:

For advice, contact a Poisons Information Centre (e.g. phone Australia 13 1126; New Zealand 0800 764 766) or a doctor (at once).

5. FIRE-FIGHTING MEASURES

Extinguishing Media:

Suitable: Foam, carbon dioxide (CO2), dry chemical, water-spray

Unsuitable: Full water jet.



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Specific Hazards Arising from the Chemical:

No unusual fire or explosion hazards. Combustible, following evaporation of the water. For further information, refer to section 10: "Stability and Reactivity".

On combustion or on thermal decomposition (pyrolysis) releases oxides of Carbon (CO + CO₂), and oxides of Nitrogen (NOx).

Precautions for Fire Fighters and Special Protective Equipment:

Fire fighters to wear full protective clothing and self-contained breathing apparatus (SCBA) in confined spaces, oxygen deficient atmospheres or if exposed to products of decomposition. If safe to do so, move undamaged containers from fire area. Stay upwind. Evacuate the personnel away from the fumes. If possible to do so safely, shut off fuel to fire. In case of fire close by, cool down the containers/equipment exposed to heat with a water spray. Product will burn under fire conditions. Do not dispose of fire-fighting water in the environment.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

High risk of slipping due to leakage/spillage of product. Avoid contact with eyes

Environmental Precautions:

Is not allowed to be released into the sewerage/surface water/groundwater in larger quantities.

Method for Cleaning or Taking Up:

Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder). Send in suitable container for recovery or disposal

Disposal:

Dispose of all contaminated materials in accordance with local regulations. (Refer to section 13 "Disposal Considerations").

Emergency information (Transport):

Dangerous Goods - Initial Emergency Response Guide (IERG) (SAA/SNZ HB76) Not applicable.

Reference to Other Sections:

Observe protective instructions (see Sections 7 and 8). Information for disposal (see section 13).

7. HANDLING AND STORAGE

Precautions for Safe Handling:

Avoid contact with eyes. Does not require any specific or particular measures. In industrial situations, wear protective equipment to prevent eye contact, as outlined under section 8 "Exposure Controls / Personal Protection". When using do not eat, drink or smoke. Handle and use in accordance with good occupational hygiene and safety practice.

Conditions for Safe Storage:

Keep containers tightly closed in a cool, well-ventilated place from incompatible materials (see Section 10 "Stability and Reactivity).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION



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No exposure standards assigned to this specific material by the Safe Work Australia Council (SWAC). However, exposure standards for ingredients are stated below:

Control parameters:

Exposure limits (EH40)

	CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
I	57-55-6	Propane-1,2-diol,	-	10		TWA (8 h)	WEL
		particulates	-	-		STEL (15 min)	WEL

Further information:

TWA - the Time-Weighted Average airborne concentration over an eight-hour working day, for a five-day working week over an entire working life.

STEL (Short Term Exposure Limit) - the average airborne concentration over a 15 minute period which should not be exceeded at any time during a normal eight-hour workday.

These Exposure Standards are guides to be used in the control of occupational health hazards. All atmospheric contamination should be kept to as low a level as is workable. Exposure Standards should not be used as fine dividing lines between safe and dangerous concentrations of chemicals. They are not a measure of relative toxicity.

Surveillance procedures:

The recommended limits SHOULD NOT be exceeded. The user is responsible for monitoring the working environment in accordance with local laws and regulations.

Biological Limit Values:

None allocated.

Engineering Controls

Ensure sufficient ventilation to keep airborne concentrations below exposure limits and as low as practicable. Local exhaust ventilation may be required.

Eye/Face Protection:

Not required under normal use. In industrial situations, safety glasses with side shields, or splash proof chemical goggles, and/or a full-face shield as appropriate. Final choice of appropriate eye/face protection will vary according to individual circumstances i.e. methods of handling or engineering controls and according to risk assessments undertaken. Eye protection should conform with Australian/New Zealand Standard AS/NZS 1337.1 Personal eye protection - Eye and face protectors for occupational applications.

Hand Protection

Not required under normal use. In industrial situations, impermeable protective gloves must be chosen according to the function of the work station: other chemicals which may be handled, physical protection necessary (resistance to cutting, puncture, heat), dexterity required. Gloves must be inspected prior to use. Observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. The selection of gloves must take into account the extent and duration of use at the workstation. Final choice of appropriate gloves will vary according to individual circumstances i.e. methods of handling or according to risk assessments undertaken. It is advisable that a local supplier of personal protective clothing is consulted regarding the choice of material. Reference should be made to AS/NZS 2161.1: Occupational protective gloves - Selection, use and maintenance.

Respiratory Protection



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Not required under normal use. In industrial situations, if engineering controls are not effective in controlling airborne exposure then respiratory protective equipment should be used suitable for protecting against airborne contaminants. Final choice of appropriate gloves will vary according to individual circumstances i.e. methods of handling, extent and duration of use at workstation, other chemicals which may be handled, physical protection necessary (resistance to cutting, puncture, heat), dexterity required, and risk assessments undertaken. Reference should be made to Australian/New Zealand Standards AS/NZS 1715, Selection, Use and maintenance of Respiratory Protective Devices; and AS/NZS 1716, Respiratory Protective Devices.

Skin and Body Protection

Choose body protection according to the amount and concentration of the hazardous chemical at the work place. Consideration must be given to both durability as well as permeation resistance. Launder contaminated clothing before reuse. It is advisable that a local supplier of personal protective clothing is consulted regarding the choice of material.

Selection Criteria:

Protective equipment must be chosen according to current AS/NZS standards and in cooperation with the supplier of protective equipment. Personal protective equipment must be defined after risk assessment for the workstation. Selection of appropriate personal protective equipment should be based on an evaluation of the performance characteristics of the protective equipment relative to the task(s) to be performed, conditions present, duration of use, and the potential hazards and/or risks that may occur during use.

Workplace Hygiene Measures:

Personal hygiene is an important work practice exposure control measure and the following general measures should be taken when working with or handling this material:

Regular cleaning of equipment, work area and clothing. Use clean, well-maintained personal protection equipment. Keep personal protective equipment in a clean place, away from the work area. Contaminated work clothing should not be allowed out of the workplace. Before reuse, thoroughly clean personal protection equipment. Wash hands before breaks and immediately after handling the product. Shower or bathe at the end of working. When using do not eat, drink or smoke.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White, homogenous, glossy, shiny cream.

Colour: White

Odour: Characteristic.
Odour threshold: No data available

pH Value: 5.5 - 6.5

Melting point/freezing point: No data available.

Initial boiling point and boiling range: ~ 100°C Flash Point: > 100°C

Evaporation rate: No data available. Flammability (solid, gas): No data available. Upper/lower flammability: No data available. Vapour Pressure: Not available. Vapour density: No data available. Relative density: No data available. Density (at 20 °C): No data available **Specific Gravity:** No data available. Solubility in Water: No data available Solubility in Organic Solvents: Not available. Partition coefficient: n-octanol/water: No data available.



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Auto-ignition temperature:No data available.Decomposition temperature:No data availableViscosity:No data availableOxidising Properties:Not available.

10. STABILITY AND REACTIVITY

Reactivity:

No decomposition if stored and applied as directed.

Chemical Stability:

Stable under normal conditions of use.

Conditions To Avoid:

To avoid thermal decomposition, do not overheat.

Incompatible Materials:

No materials to be especially mentioned..

Hazardous Decomposition Products:

No decomposition if stored and used as directed.

On combustion or on thermal decomposition (pyrolysis) releases oxides of Carbon (CO + CO₂), and oxides of Nitrogen (NOx).

Hazardous Reactions:

Hazardous polymerisation will not occur.

11. TOXICOLOGICAL INFORMATION

Acute Health Effects:

Ingested:

Ingestion of this product may irritate the gastric tract causing nausea and vomiting.

Eye

Eye contact may cause redness, itching and irritation.

Skin:

Non-irritating to skin.

Inhaled[.]

If misted or sprayed, inhalation may irritate the nose, throat and respiratory system.

Chronic Health Effects:

No information available.

Acute Toxicity:

Based on available data, the classification criteria are not met.

No toxicological data available

Skin corrosion/irritation:

Not classified

Serious eye damage/irritation:



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Not classified

Respiratory or skin sensitisation:

Not classified

Germ cell mutagenicity:

Not classified

Carcinogenicity:

Not classified

Reproductive toxicity:

Not classified

Specific Target Organ Toxicity (STOT) - single exposure:

Not classified

Specific Target Organ Toxicity (STOT) - repeated exposure:

Not classified

Aspiration hazard:

Not classified

Other information

Empirical data on effects on humans

This product has proved good skin compatibility properties in human-experimental tests and in practical use. Contact with eyes may cause irritation.

Further information:

Classification / Safety Aspects

In the Federal Republic of Germany MoliCare Skin Barrier Cream is classified as cosmetic product.

The product is in compliance with the latest amendments of the European Directive on Cosmetics (EEC Council Directive 76/768 with Technical Adaptations an Amendments).

The product contains only ingredients which are permitted resp. which are not prohibited for cosmetic use according to the EEC Directive on Cosmetics.

The skin tolerance was dermatologically tested on predamaged (scarified) skin of human subjects with the result "very good".

MoliCare Skin Barrier Cream was tested in a nursing home on persons suffering from incontinence under supervision of a medical specialist. The application of the product resulted in an improvement of the skin condition. Furthermore the very good skin tolerance and the protection effect of MoliCare Skin Barrier Cream against harmful substances in faeces and urine could be attested.

12. ECOLOGICAL INFORMATION

Ecotoxicity:

No data available.

Persistence / Degradability:

No data available.

Bioaccumulative potential:

No data available.



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Mobility in soil:

No data available.

Other adverse effects

According to Regulation (EC) No 1907/2006 (REACH) none of the substances, contained in this product are a PBT / vPvB substance.

Further information:

Ecological injuries are not known or expected under normal use.

Do not release into the aquatic environment. Do not flush into surface water or sanitary sewer system. Collect spillages. (See Section 6: Accidental Release Measures).

Product is not allowed to be discharged into aquatic environment. (See section 6 "Accidental Release Measures" and section 13 "Disposal Considerations").

13. DISPOSAL CONSIDERATIONS

Residues from Product

Prohibition: Discharging waste into the aquatic environment is forbidden.

Destruction/Disposal:

Can be incinerated, when in compliance with local regulations.

Where possible recycling is preferred to disposal.

Contaminated packaging

Empty containers should be taken for local recycling, recovery or waste disposal.

Further Information:

In accordance with ADG7 regulations containers or tankers which have not been cleaned or deodorized and which previously contained a hazardous product, must either be labelled or have hazard signs.

NOTE: The user's attention is drawn to the possible existence of local regulations regarding disposal.

14. TRANSPORT INFORMATION

UN Number: No hazardous material as defined by the transport regulations.

Proper Shipping Name: No hazardous material as defined by the transport regulations **Transport hazard Class:** No hazardous material as defined by the transport regulations

Subsidiary risk: None allocated

Packing Group: No hazardous material as defined by the transport regulations

Hazchem Code: None allocated

Road and Rail Transport: (Australia-ADG)

Not classified as a Dangerous Good according to the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code) for transport by road and rail.

Land Transport: (New Zealand):

Not classified as Dangerous Goods according to NZS 5433:2007 Transport of Dangerous Goods on Land.

Sea (IMDG):

Not classified as a Dangerous Good according to the International Maritime Organization Rules (Maritime Dangerous Goods Code - IMDG Code) for transport by sea.

Marine pollutant: NO



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Air (IATA):

Not classified as a Dangerous Good according to the International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA) Dangerous Goods Regulations for transport by air.

NOTE: The above regulatory prescriptions are those valid on the date of publication of this SDS. Given the possible evolution of transport regulations for hazardous materials, it would be advisable to check their validity with your sales office.

15. REGULATORY INFORMATION

Poison Schedule (Australia): Not scheduled.

Inventory Status Australia (AICS) Y

Y = All ingredients are on the inventory.

E = All ingredients are on the inventory or exempt from listing.

P = One or more ingredients fall under the polymer exemption or are on the no longer polymer list. All other ingredients are on the inventory or exempt from listing.

N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing.

EU regulatory information

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

2004/42/EC (VOC): < 1%

Employment restrictions: Observe employment restrictions for young people. Observe employment restrictions for child bearing mothers and nursing.

National regulatory information

Water contaminating class (D): 1 - slightly water contaminating

Chemical safety assessment

For this substance a chemical safety assessment has not been carried out.

NOTE:

The regulatory information given above only indicates the principal regulations specifically applicable to the product described in the Safety Data Sheet. The user's attention is drawn to the possible existence of additional provisions which complete these regulations. Refer to all applicable national, international and local regulations or provisions.

16. OTHER INFORMATION

Reason For Revision

- 1) Review against current SWA/GHS and NZ EPA/HSNO criteria and latest information from manufacturer/supplier.
- 2) Changes and /or additional information made to all Sections.
- 3) Change the name from Menalind to MoliCare
- 4) Remove zinc oxide from composition and make adjustments accordingly.



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The customer is advised to consult the product Technical Data Sheets for further information including advice on suitable equipment. SDSs are updated frequently. Please ensure that you have a current copy.

Key Legend Information:

ACGIH - American Conference of Governmental Industrial Hygienists [US]

AICS - Australian Inventory of Chemical Substances [Aust]

CAS - Chemical Abstracts Service [US]

EPA - Environmental Protection Agency [Int]

EU - European Union [EU]

GHS - United Nations - Globally Harmonized System of Classification and Labelling of Chemicals [Int]

HSNO - Hazardous Substances and New Organisms [NZ]

IACR - International Agency for Research on Cancer [Int]

IATA - International Aviation Transport Authority [Int]

ICAO - International Civil Aviation Organization [Int]

IMDG - International Maritime Dangerous Goods [Int]

IMO - International Maritime Organisation. [Int]

NTP - National Toxicology Program

NIOSH - National Institute for Occupational Safety and Health [US]

NOHSC - National Occupational Health & Safety Commission [Aust]

NZ EPA New Zealand Environmental Protection Agency [NZ] [formerly ERMANZ]

NZIoC - New Zealand Inventory of Chemicals [NZ]

OSHA - Occupational Safety and Health Administration [US]

SUSMP - Standard for the Uniform Scheduling of Medicines and Poisons [Aust][Formerly SUSDP]

STEL - Short Term Exposure Limit [Int]

SWAC - Safe Work Australia Council [Formerly ASCC]

TWA - Time Weighted Average [Int]

WES - Workplace Exposure Standard [NZ]

[Aust/NZ] = Australia/New Zealand

[Int] = International

[US] = United States of America

Principal References:

Safety Data Sheet (SDS) - MoliCare Skin Barrier Cream

Revision date: 13.02.2017 Revision No: 1,1

Technical Data Sheet - MoliCare Skin Barrier Cream

Spec.-No.: D 9.0163 Department: COH-IDI Date: 14 Sep 2017

Information supplied by manufacturer, reference sources including the public domain.

END OF SAFETY DATA SHEET

Disclaimer:

Data of Sections 4 to 8, as well as 10 to 12, relate mainly to the release of major amounts in the case of accidents or irregularities in industrial situations. For instructions on the regular use and application of this product refer to the product label and product information sheet. The information in this document describes the safety requirements for the product(s) and is based on the present level of knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.