

**AMERIWASH- parachlorometaxyleneol liquid
SHIELD LINE LLC**

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

AMERIDERM AMERIWASH PCMX 0.3%

Drug Facts

Active Ingredient

Parachlorometaxyleneol 0.3% w/w

Purpose

Antimicrobial

Uses

- Handwash to help reduce bacteria on the skin that potentially can cause disease
- Recommended for repeat use

Warnings

- **FOR EXTERNAL USE ONLY**

When using this product

- Do not use in or near the eyes
- In case of eye contact rinse the eyes thoroughly with water

Stop use and ask a doctor if

- Irritation or rash appears or lasts

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- Wet hands
- Apply a small amount of product and work into lather
- Rinse well and dry hands completely

Inactive Ingredients

Alpha Hexylcinnamaldehyde, Citric Acid Monohydrate, Cocamidopropyl Betaine, Coco Diethanolamide, D&C Red No. 33, DMDM Hydantoin, Edetate Disodium Anhydrous, FD&C Yellow No.5, FD&C Yellow No.6, PEG-7 Glyceryl Cocoate, Sodium Chloride, Sodium Laureth Sulfate, Sulisobenzone, Water

AMERIWASH DRUG FACT PANEL

NDC: 52410-8038-5
AmeriDerm
AmeriWashTM
 Antimicrobial Lotion Hand Soap with PCMX

Reorder No: 210 1 Gallon (3.78 Liters)

| Drug Facts | |
|--|----------------|
| Active ingredient | Purpose |
| Parachlorometaxlenol 0.3% w/w..... | Antiseptic |
| Uses | |
| <ul style="list-style-type: none"> ■ Handwash to help decrease bacteria on the skin ■ Recommended for repeated use | |
| Warnings | |
| FOR EXTERNAL USE ONLY | |
| When using this product | |
| <ul style="list-style-type: none"> ■ Do not use in or near the eyes ■ In case of contact, rinse eyes thoroughly with water | |
| Stop use and ask a doctor if Irritation or rash appears and lasts | |
| Keep out of reach of children swallowed, get medical help or contact a Poison Control Center right away | |
| Directions | |
| <ul style="list-style-type: none"> ■ Wet hands ■ Apply a small amount of product and work into a lather ■ Rinse well and dry hands completely | |
| Inactive Ingredients | |
| Alpha Hexylcinnamaldehyde, Citric Acid Monohydrate, Cocamidopropyl Betaine, Coco Diethanolamide, D&C Red No. 33, DMDM Hydantoin, Edetate Disodium Anhydrous, FD&C Yellow No.5, FD&C Yellow No.6, PEG-7 Glyceryl Cocoate, Sodium Chloride, Sodium Laureth Sulfate, Sulisobenzone, Water | |

Made in Turkey

3 524 10 80385 7

AMD-80385
 Manufactured for:
 Shield Line LLC,
 Hackensack, NJ 07601
 USA
 www.ameriderm.com

Label Size: 6.125" x 4.625" (.1 in rounded corner)
 No varnish on Patient Name / Room # Strip

AMERIWASH

parachlorometaxlenol liquid

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52410-8038 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|------------------|
| CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q) | CHLOROXYLENOL | 0.003 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| COCO DIETHANOLAMIDE (UNII: 92005F972D) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | |
| FD&C YELLOW NO. 5 (UNII: I753WB2F1M) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| SODIUM LAURETH SULFATE (UNII: BPV390UAP0) | |
| WATER (UNII: 059QF0KO0R) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| SULISOBENZONE (UNII: 1W6L629B4K) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| PEG-7 GLYCERYL COCOATE (UNII: VNX7251543) | |
| .ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:52410-8038-3 | 800 mL in 1 POUCH; Type 0: Not a Combination Product | 08/01/2017 | |
| 2 | NDC:52410-8038-4 | 1000 mL in 1 POUCH; Type 0: Not a Combination Product | 08/01/2017 | |
| 3 | NDC:52410-8038-5 | 3780 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/01/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 08/01/2017 | |

Labeler - SHIELD LINE LLC (078518916)