

ALOEGUARD - chloroxylenol soap
HealthLink

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.

AloeGuard 6729 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Chloroxylenol 0.5% w/w

Drug Facts Box OTC-Purpose Section

Antimicrobial

Drug Facts Box OTC-Indications & Usage Section

Specially formulated for the sensitive skin of today's healthcare professional
broad-spectrum antimicrobial hand cleaner
for repeated washings on a daily basis

Drug Facts Box OTC-Warnings Section

For external use only

Drug Facts Box OTC-When Using Section

do not use in or near eyes

Drug Facts Box OTC-Keep Out of Reach of Children Section

In case of accidental ingestion, seek medical attention or contact a poison control center immediately.

Drug Facts Box OTC-Dosage & Administration Section

wet hands

apply AloeGuard

wash hands vigorously

rinse thoroughly

Drug Facts Box OTC-General Precautions Section

store at room temperature

Drug Facts Box OTC-Inactive Ingredient Section

Water, TEA lauryl sulfate, Cocamide DEA, Urea, Aloe vera gel, Fragrance, Polyquaternium 7, Glycol Stearate, DMDM hydantoin, Sodium chloride, Methyl paraben, Methylchloroisothiazolinone, Methylisothiazolinone, Tetrasodium EDTA, Propyl paraben, FDC Blue 1, FDC Green 8, FDC Orange 4

AloeGuard 6729 18oz

672918P6318.jpg AloeGuard 18oz

| Drug Facts | |
|---|---------------|
| Active Ingredient | Purpose |
| Chloroxyleneol 0.5% w/w..... | Antimicrobial |
| Uses | |
| <ul style="list-style-type: none"> ■ Specially formulated for the sensitive skin of today's healthcare professional ■ broad-spectrum antimicrobial hand cleaner ■ for repeated washings on a daily basis | |
| Warnings | |
| For external use only | |
| When using this product | |
| <ul style="list-style-type: none"> ■ do not use in or near eyes | |
| Keep out of reach of children. In case of accidental ingestion, seek medical attention or contact poison control center immediately. | |



Antimicrobial Soap
Net Contents 18oz (1lb 2oz) 510gm



| Drug Facts continued | |
|--|--|
| Directions | |
| <ul style="list-style-type: none"> ■ wet hands ■ apply AloeGuard® ■ wash hands vigorously ■ rinse thoroughly | |
| Other information | |
| <ul style="list-style-type: none"> ■ store at room temperature | |
| Inactive ingredients: | |
| Water, TEA lauryl sulfate, Cocamide DEA, Urea, Aloe vera gel, Fragrance, Polyquaternium 7, Glycol stearate, DMDM hydantoin, Sodium chloride, Methyl paraben, Methylchloroisothiazolinone, Methylisothiazolinone, Tetrasodium EDTA, Propyl paraben, FD&C Blue #1, FD&C Green #8, D&C Orange #4. | |

Manufactured Exclusively For



672918P6318_0908

Reorder Number 7760

ALOE GUARD

chloroxyleneol soap

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:63843-729 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|------------------|
| CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q) | CHLOROXYLENOL | 0.005 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PROPYL PARABEN (UNII: Z8IX2SC10H) | |
| DIGLYCOL STEARATE (UNII: 94YQ11Y95F) | |
| TROLAMINE LAURYL SULFATE (UNII: E8458C1KAA) | |
| UREA (UNII: 8W8T17847W) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| D&C GREEN NO. 8 (UNII: I2W85YOX9L) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------|----------------------|--------------------|
| 1 | NDC:63843-729-06 | 1 in 1 BOX | | |
| 1 | | 800 mL in 1 BAG | | |
| 2 | NDC:63843-729-17 | 532 mL in 1 BOTTLE, PLASTIC | | |
| 3 | NDC:63843-729-14 | 3785 mL in 1 BOTTLE, PLASTIC | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333 | 07/31/2009 | |

Labeler - HealthLink (807714126)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|---------------------|
| ABC Compounding Co., Inc. | | 003284353 | manufacture |

Revised: 3/2010

HealthLink