

**ANTIBACTERIAL HAND SHEA BUTTER SCENTED- chloroxylenol liquid
PANROSA ENTERPRISES, INC.**

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.

Antibacterial Hand Soap Shea Butter Scented

Drug Facts

Active ingredient

Chloroxylenol 0.25%

Purpose

Antibacterial

Uses

- for handwashing to decrease bacteria on the skin

Warnings

For external use only

When using this product

- Avoid contact with eyes. In case of eye contact, flush with water.

Stop use and ask a doctor if

- irritation and redness develops.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

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

Directions

- pump into hands, wet as needed
- lather vigorously for at least 15 seconds
- wash skin, rinse and dry thoroughly

Inactive Ingredients:

Water, Sodium Laureth Sulfate, Cocamidopropyl Betaine, Cocamide MEA, Glycerin, Glycol Stearate, Sodium Chloride, Peg-150 Distearate, Citric Acid, Fragrance, Methylisothiazolinone Methylchlorisothiazolinone, Disodium EDTA

Package Labeling:



ANTIBACTERIAL HAND SHEA BUTTER SCENTED

chloroxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50302-520
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	2.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
COCO MONOETHANOLAMIDE (UNII: C80684146D)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCOL STEARATE (UNII: 0324G66D0E)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50302-520-00	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/20/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/20/2016	

Labeler - PANROSA ENTERPRISES, INC. (859957578)

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PANROSA ENTERPRISES, INC.