INODERM STYLE ANTIBACTERIAL- chloroxylenol liquid
Inopak, Ltd

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.

Inopak Style Antibacterial Liquid Soap

Drug Facts

Active ingredient

Chloroxylenol 0.3% w/w

Purpose

Antiseptic

Uses

- For handwashing to help reduce bacteria on the skin.
- Recommended for repeat use.

Warnings

For external use only.

When using this product, keep away from eyes. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develop or if condition persists for more than 72 hours.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Wet hands with water and dispense sufficient amount of product into cupped palm of hand.
- Lather vigorously for at least 15 seconds.
- Rinse with water and dry thoroughly.

Inactive ingredients

Water, Sodium Laureth Sulfate, Sodium Chloride, Cocamide DEA, DMDM Hydantoin, Alcohol, Fragrance, Isopropyl Alcohol, Citric Acid, FD&C Yellow 5, FD&C Red 4.

Inopak, LTD.

Ringwood, NJ 07456

1-800-762-7725 • www.inopak.com

INODERM®

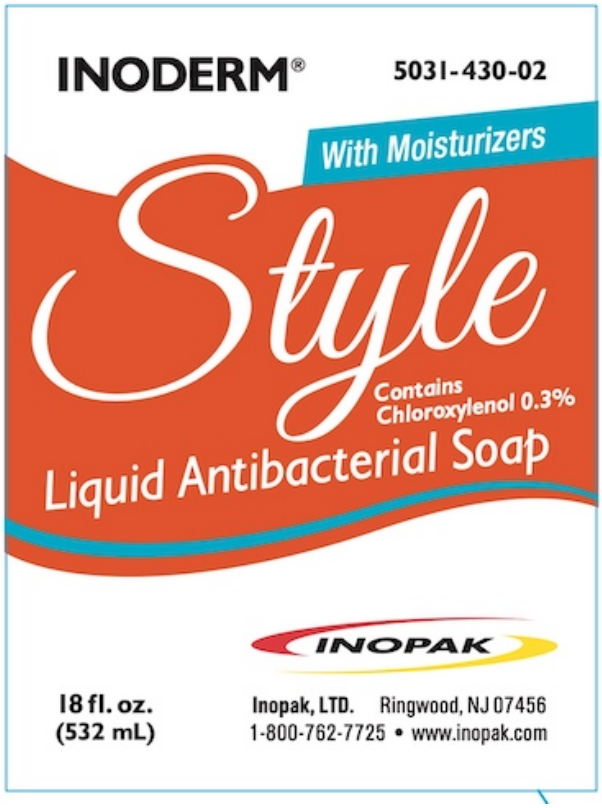
With Moisturizers

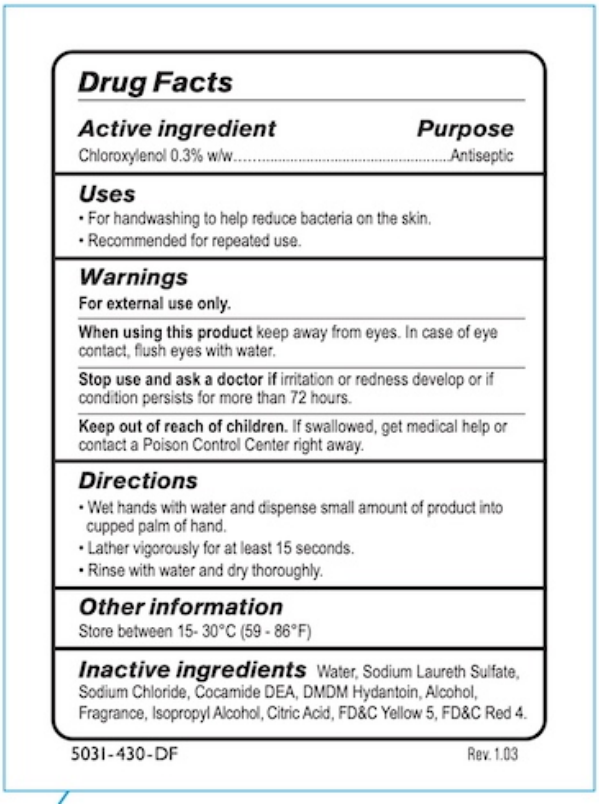
Style

Contains Chloroxylenol 0.3%

Liquid Antibacterial Soap

18 fl. oz. (532 mL)





INODERM STYLE ANTIBACTERIAL

chloroxylenol liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58575-523
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	0.3 g in 100 mL

Inactive Ingredients	
Ingredient Name	**Strength**
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCO DIETHANOLAMIDE (UNII: 92005F972D)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-523-42	3800 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2021	07/22/2024
2	NDC:58575-523-07	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2021	10/08/2023
3	NDC:58575-523-17	532 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2021	07/19/2024
4	NDC:58575-523-80	1 in 1 BOX	04/20/2021	01/28/2024
4		800 mL in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:58575-523-82	2000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/20/2021	04/21/2024
6	NDC:58575-523-10	1000 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	04/20/2021	11/06/2023

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/20/2021	07/22/2024

Labeler - Inopak, Ltd (194718243)

Establishment

Name	Address	ID/FEI	Business Operations
Inopak, Ltd		194718243	manufacture(58575-523)

Revised: 2/2023 Inopak, Ltd