

**PURESAN ANTIBACTERIAL LIQUID- parachlorometaxyleneol 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.

Puresan Antibacterial liquid soap 408

Active Ingredient

Parachlorometaxyleneol 0.3% w/w

Purpose

Antiseptic

Uses

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

Warnings

- For external use only.
- Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes with water.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

When using

Keep out of eyes, ears, or mouth.

Stop use

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

Children

Keep out of reach of children.

Directions

- Wet hands with water and dispense sufficient amount of product into cupped palm of hand.
- Wash both hands thoroughly for 15 seconds.

- Rinse under running water and dry thoroughly.

Inactive Ingredient

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

Puresan antibacterial liquid soap single label

MADE
IN THE USA

Antibacterial
Liquid Soap
With Moisturizers
1000 ml
Refill Bag LIQUID
Item# s1000

puresan
cleaning innovations

Drug Facts

Active
Ingredient
Purpose
Parachlorometaxlenol 0.3%
w/w.... Antiseptic

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Rev. 1.01
PO Box 170, Sparta NJ 07871
855.500.8080 • puresanusa.com

Antibacterial Liquid Soap

With Moisturizers

1000 mL
Refill Bag LIQUID
Item# s1000



MADE
IN THE USA

Drug Facts

Active Ingredient

Parachlorometaxyleneol 0.3% w/w.....Antiseptic

Purpose

Uses

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

Warnings

- For external use only.
- Keep out of eyes, ears or mouth. In case of eye contact, flush eyes with water.
- Stop use and ask a doctor if irritation and 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.
- Wash both hands thoroughly for 15 seconds.
- Rinse under running water and dry thoroughly.

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

Rev. 1.01

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Puresan Case label

Puresan
Cleaning innovations
ITEM 3 S1000AB-D-C8
PURESAN Antibacterial LOTION soap
1000ml case of 8 refills
QTY 8
1000ml refills per case
AVRO-S1000-CS

Rev: 1.0

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ITEM # S1000AB-D-C8

PURESAN Antibacterial LOTION soap
1000ml case of 8 refills



QTY 8
1000ml refills per case

AVRO-S1000-CS

Rev: 1.0

PURESAN ANTIBACTERIAL LIQUID

parachlorometaxylenol liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58575-408
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLOROXYLENOL (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
CO CAMIDO PROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
ALCOHOL (UNII: 3K9958V90M)	
FD&C RED NO. 4 (UNII: X3W0AMIJLX)	
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:58575-408-01	1000 mL in 1 BAG; Type 0: Not a Combination Product	01/01/2018	
2	NDC:58575-408-02	8000 mL in 1 CASE; Type 0: Not a Combination Product	01/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/01/2018	

Labeler - Inopak, Ltd. (194718243)

Establishment

Name	Address	ID/FEI	Business Operations
Inopak, Ltd.		194718243	manufacture(58575-408)

Revised: 2/2020

Inopak, Ltd.