

## **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.*

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### **Bortek Foaming Hand Soap 508**

#### **Active Ingredient**

Parachlorometaxylenol 0.3%

#### **Purpose**

Antiseptic

#### **Use**

Handwash to help reduce bacteria on the skin that can potentially 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 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.

#### **When using**

Do not get into eyes. In case of eye contact, flush eyes with water.

#### **Stop Use**

- 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**

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 minutes.
- Rinse under running water and dry thoroughly.

#### **Inactive ingredients**

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

**Individual label**

**Rev 1.0**

**A FAMILY COMPANY SINCE 1967**

**800.626.7835**

**Part#: 5063-Bortek**

**sweeperland.com**

**Bortek®**

**INDUSTRIES, INC.**

FOAMING HAND SOAP

Antibacterial Hand Wash with Moisturizers

YOUR CLEANING SOLUTIONS RESOURCE

**Drug Facts**

**Active Ingredient**

**Purpose**

Parachlorometaxyleneol 0.3% w/w

Antiseptic

**Uses**

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**Questions? Call 800-626-7835 or visit our website sweeperland.com**

Reorder Item #28130103

Net Contents: 1000 ml

Rev 1.0  
Part #: 5063-Bortek

A FAMILY COMPANY SINCE 1967

800.626.7835  
sweeperland.com



FOAMING HAND SOAP



Antibacterial Hand Wash with Moisturizers

YOUR CLEANING SOLUTIONS RESOURCE

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Parachlorometaxylenol 0.3% w/w.....	Antiseptic

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Reorder Item #: 28130103

Net Contents: 1000 ml

**Multi-pack label**

Rev 1.0

A FAMILY COMPANY SINCE 1967

800.626.7835

Part#: 5063-BortekCS

sweeperland.com

Bortek®

INDUSTRIES, INC.

FOAMING HAND SOAP

Antibacterial Hand Wash with Moisturizers

MADE IN THE USA

YOUR CLEANING SOLUTIONS RESOURCE

Corporate Headquarters

4713 Gettysburg Road

Mechanicsburg, PA 17055

EQUIPMENT    PARTS    RENTALS                    SERVICE                    SUPPLIES

### **Drug Facts**

#### **Active Ingredient**

Parachlorometaxlenol 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**

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**Questions? Call 800-626-7835 or visit our website [sweeperland.com](http://sweeperland.com)**

Reorder Item #28130103

Net Contents: 6 x 1000 ml

ANTIBACTERIAL

Rev 1.0  
Part #: 5063-Bortek CS

A FAMILY COMPANY SINCE 1967

800.626.7835  
sweeperland.com



# FOAMING HAND SOAP

Antibacterial Hand Wash with Moisturizers



MADE IN THE USA

YOUR CLEANING SOLUTIONS RESOURCE

## Corporate Headquarters

4713 Gettysburg Road  
Mechanicsburg, PA 17055

EQUIPMENT PARTS RENTALS SERVICE SUPPLIES

Drug Facts	
<b>Active Ingredient</b> Parachlorometaxylenol 0.3% w/w	<b>Purpose</b> Antiseptic
<b>Uses</b> ■ Handwash to help reduce bacteria on the skin that can potentially cause disease. ■ Recommended for repeated use.	<ul style="list-style-type: none"> <li>■ Keep out of eyes, ears or mouth. In case of eye contact, flush eyes with water.</li> <li>■ Stop use and ask a doctor if irritation persists for more than 72 hours.</li> <li>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>
<b>Warnings</b> ■ For external use only.	<p>amount of product into cupped palm of hand. Wash both hands thoroughly for 15 seconds. Rinse under running water and dry thoroughly.</p> <p><b>Inactive Ingredients</b> Citric Acid, Cocamide DEA, DMDM Hydantoin, Ethyl Alcohol, Fragrance, Isopropyl Alcohol, Phenoxyethanol, FD&amp;C Red No. 4, Sodium Laureth Sulfate, Water.</p> <p>Questions? Call 800.626.7835 or visit our website sweeperland.com</p>
<b>Directions</b> Wet hands with water and dispense sufficient	

Reorder Item #: 28130103

Net Contents: 6 x 1000 ml

**ANTIBACTERIAL**

## ANTIBACTERIAL

chloroxylenol liquid

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58575-508
<b>Route of Administration</b>	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 MONOHYDRATE (UNII: 2968PHW8QP)	
CO CAMIDO PROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
Alcohol (UNII: 3K9958V90M)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

<b>FD&amp;C RED NO. 4</b> (UNII: X3W0AM1JLX)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-508-01	1000 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	01/01/2018	
2	NDC:58575-508-02	4000 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(58575-508)

Revised: 2/2020

Inopak, Ltd