# ICS3 PINK HEALTHCARE ANTISEPTIC HAND- benzalkonium chloride 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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Inopak - ICS3Pink - 162

#### Drug Facts Active Ingredient

Benzalkonium chloride 0.13% (w/w)

#### **Purpose**

Antiseptic

#### Keep out of reach of children.

• Keep out of reach of children.

#### Uses

For hand washing to decrease bacteria on the skin after changing diapers, after assisting ill persons or before contact with a person under medical care or treatment. Recommended for repeated use.

#### Warnings

- For external use only. Keep out of eyes, ears or mouth.
- Discontinue use if irritation occurs.

#### **Directions**

- Dispense a golf ball size amount of foam onto dry hands and rub vigorously for 15 seconds
- Rinse with water and towel dry.

#### **Inactive Ingredients**

Cetrimonium cloride, chlorhexidine glluconate, cocamidopropyl PG-dimonium chloride phosphate, D & C Red #33, decyl glucoside, ethyl alcohol, phenoxyethanol, polyquaternium 10, polyquarternium 11, water.

#### **ICS3 Pink label**

BIO-5077Q-FL 1000 34 FL OZ

Rev. 1.02 iCS3® (1000 mL)

INFECTION CONTROL SYSTEM 3 Bio-5077Q-FL

ANTISEPTIC HAND WASH

**Drug Facts** 

Active Ingredient Purpose

Benzalkonium chloride ...... Antiseptic

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#### **Inactive Ingredients**

Cetrimonium chloride, chlorhexidine gluconate, cocamidopropyl PG-dimonium chloride phosphate, D&C Red # 33, decyl glucoside, ethyl alcohol, isopropyl alcohol, phenoxyethanol, polyquaternium 11, water

888-497-7375

biocentris

info@biocentris.com

**PHARMACEUTICALS** 

www.biocentris.com

BIO-5077Q-FL1000 Rev. 1.2



34 FLOZ (1000 mL) Bio-5077Q-FL

INFECTION CONTROL SYSTEM 3

## ANTISEPTIC HAND WASH

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888-497-4375 info@biocentris.com www.biocentris.com



#### **ICS3 Pink Case**

iCS3®

1.0

INFECTION CONTROL SYSTEM 3

O 6 / 1000 mL Pouches BIO-5077Q-FL1000 040232 65000 0

ANTISEPTIC FOAM

HAND WASH

O 6/1000 mL Cartridges BIO-5077Q-OS1000 040232 65001 7

O 12 / 18 oz Bottles

O 24 / 50 mL Bottles

BIO-5076-CASE Rev.

BIO-5077Q-18 4375

040232 65002 4

BIO-5077Q-50

Call: 888-497-

040232 65003 1

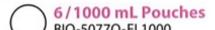
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www.biocentris.com

**Biocentris** 

#### **PHARMACEUTICALS**







6/1000 mL Cartridges BIO-5077Q-OS1000



BIO-5077Q-CASE Rev. 1.0

#### 12 / 18 oz Bottles BIO-5077Q-18



24/50 mL Bottles BIO-5077Q-50



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#### ICS3 PINK HEALTHCARE ANTISEPTIC HAND

benzalkonium chloride liquid

#### **Product Information**

Product Type HUMAN OTC DRUG

Item Code (Source)

NDC:58575-162

Route of Administration

TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BENZALKO NIUM CHLO RIDE</b> (UNII: F5UM2KM3W7) (BENZALKO NIUM - UNII:7N6 JUD5X6 Y)	BENZALKONIUM CHLORIDE	130 mg in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
CETRIMO NIUM CHLO RIDE (UNII: UC9 PE9 5 IBP)		
CHLORHEXIDINE GLUCONATE (UNII: MOR84MUD8E)		
CO CAMIDO PRO PYL PG-DIMO NIUM CHLO RIDE PHO SPHATE (UNII: H2KVQ74JM4)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
DECYL GLUCO SIDE (UNII: Z17H97EA6Y)		
ALCOHOL (UNII: 3K9958V90M)		
PHENOXYETHANOL (UNII: HIE492ZZ3T)		
POLYQUATERNIUM-10 (30000 MPA.S AT 2%) (UNII: C7RDC8 Y4JS)		
POLYQUATERNIUM-11 (1000000 MW) (UNII: 0B44BS5IJS)		
WATER (UNII: 059QF0KO0R)		

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:58575-162- 02	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 14		
2	NDC:58575-162- 18	532 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	11/0 1/20 14		
3	NDC:58575-162- 01	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/0 1/20 14		
4	NDC:58575-162- 10	$1000\ mL$ in $1BOTTLE,$ DISPENSING; Type 0: Not a Combination Product	11/0 1/20 14		
5	NDC:58575-162- 11	1000 mL in 1 POUCH; Type 0: Not a Combination Product	11/0 1/20 14		
6	NDC:58575-162- 12	1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	11/0 1/20 14		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	11/0 1/20 14		

# **Labeler -** Inopak, Ltd (194718243)

## Registrant - Inopak, Ltd (194718243)

Establishment				
Name	Address	ID/FEI	Business Operations	
Inopak, Ltd		194718243	manufacture(58575-162)	

Revised: 2/2020 Inopak, Ltd