

**PROFESSIONAL CHOICE GOLD HAND CLEANER- 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.*

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**Professional Choice Gold Hand Cleaner 404**

**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 using**

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

**Keep away from Children**

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

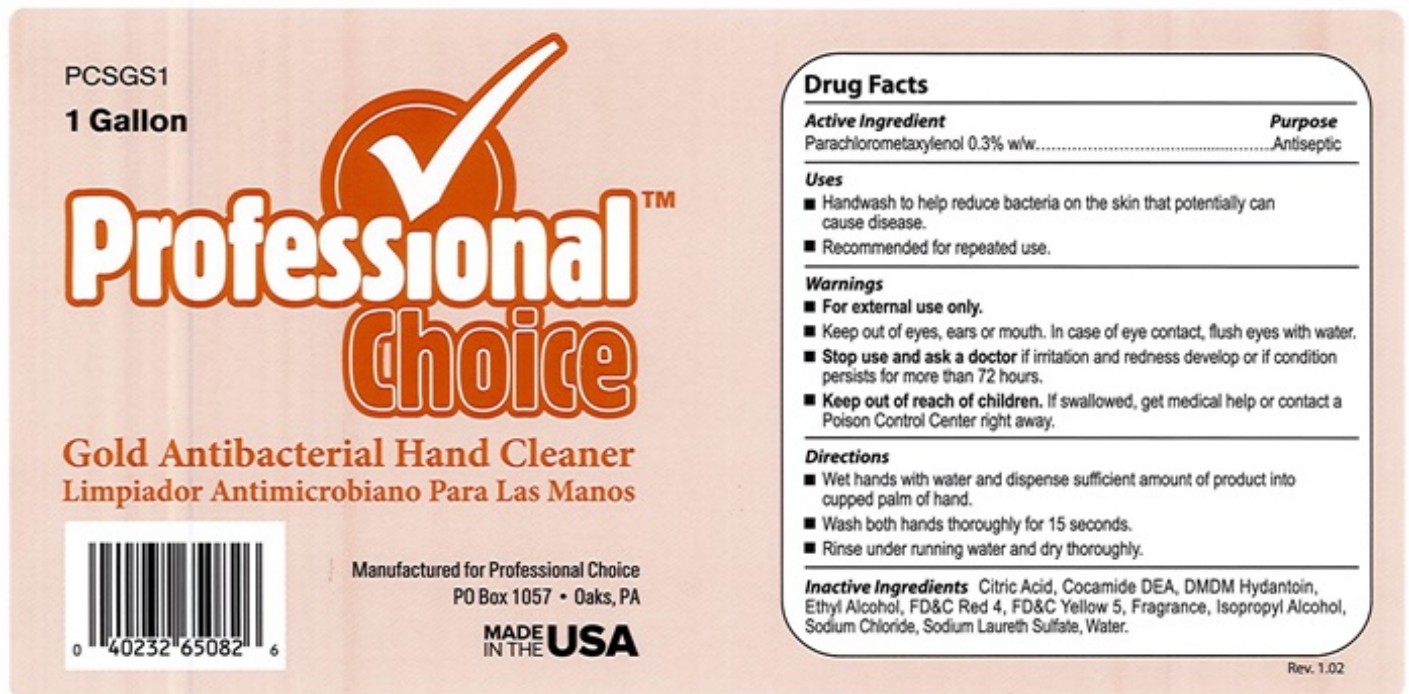
**Directions**

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

**Inactive Ingredient**

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

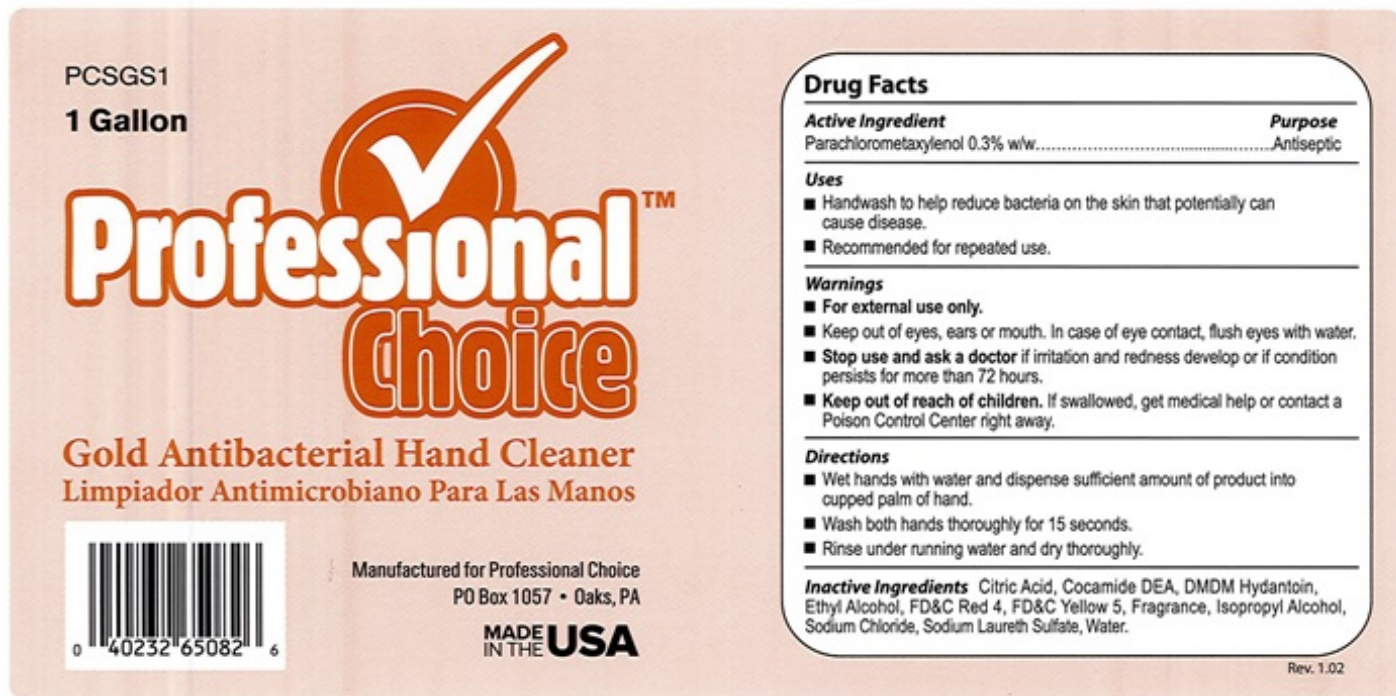
**Professional Choice Gallon Label**



<p>PCSGS1 1 Gallon Professional<sup>TM</sup> Choice Gold Antibacterial Hand Cleaner Limpiador Antimicrobiano Para Las Manos</p>	<p><b>Drug Facts</b></p> <table border="0"> <tr> <td>Active Ingredient</td> <td>Purpose</td> </tr> <tr> <td>Parachlorometaxylenol 0.3% w/w.....</td> <td>Antiseptic</td> </tr> </table> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>• Handwash to help reduce bacteria on the skin that potentially can cause disease.</li> <li>• Recommended for repeated use.</li> </ul> <p><b>Warnings</b></p> <ul style="list-style-type: none"> <li>• For external use only.</li> <li>• Keep out of eyes, ears, or mouth. In case of eye contact, flush eyes with water.</li> <li>• Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• Wet hands with water and dispense sufficient amount of product into cupped palm of hand.</li> </ul>	Active Ingredient	Purpose	Parachlorometaxylenol 0.3% w/w.....	Antiseptic
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Parachlorometaxylenol 0.3% w/w.....	Antiseptic				
<p>040232 65082 6 Manufactured for Professional Choice PO Box 1057 • Oaks, PA MADE IN THE USA</p>					

- Wash both hands thoroughly for 15 seconds.
  - Rinse under running water and dry thoroughly.
- Inactive ingredients** Citric Acid, Cocamide DEA, DMDM Hydantoin, Ethyl Alcohol, FD&C Red 4, FD&C Yellow 5, Fragrance, Isopropyl Alcohol, Sodium, Water

Rev. 1.02



**Professional Choice Gallon Case Label**

40232 65084

√

Professional™

Choice

Gold Antibacterial Hand Cleaner

Limpiador Antimicrobiano Para Las Manos

PCSGS1

Manufactured for Professional Choice

4/Gallon

PO Box 1057 • Oaks, PA

MADE USA

IN THE



# Professional Choice™

## Choice

**Gold Antibacterial Hand Cleaner**  
**Limpiador Antimicrobiano Para Las Manos**

**PCSGS1**  
**4/Gallon**

Manufactured for Professional Choice  
 PO Box 1057 • Oaks, PA

**MADE  
 IN THE USA**

### Professional Choice Single Container Box Front

**404-1-PCSGS800**

**Rev.01**

#### Drug Facts

Active Ingredient	Purpose
Parachlorometaxyleneol 0.3% w/w....	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.

#### 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.

√  
 Professional Choice™  
 Gold Limpiador  
 Antibacterial Antimicrobiano  
 Hand Para  
 Cleaner Las Manos  
 Broad Contains  
 Spectrum .3% P.C.M.X.  
 Germ  
 Control  
 MADE PCSGS800  
 IN THE 800 ml  
 USA



**Inactive ingredients** Citric Acid, Cocamide DEA, DMOM Hydantoin,  
Ethyl Alcohol, FD&C Yellow 5, Fragrance, Isopropyl Alcohol, Sodium  
Chloride, Sodium Laureth Sulfate, TEA-Lauryl Sulfate, Water.  
Manufactured for Professional Choice  
PO Box 1057 • Oaks, PA

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404-1-PCSGS800  
Rev. 01

### Drug Facts

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

### Uses

- Handwash to decrease 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 thoroughly for 15 seconds.
- Rinse under running water and dry thoroughly.

### Inactive Ingredients

Citric Acid, Cocamide DEA, DMDM Hydantoin, Ethyl Alcohol, FD&C Red No. 4, FD&C Yellow No. 5, Fragrance, Isopropyl Alcohol, Sodium Chloride, Sodium Laureth Sulfate, Water.



# Professional Choice™

Gold  
Antibacterial  
Hand  
Cleaner

Limpiador  
Antimicrobiano  
Para  
Las Manos

Broad Spectrum  
Germ Control

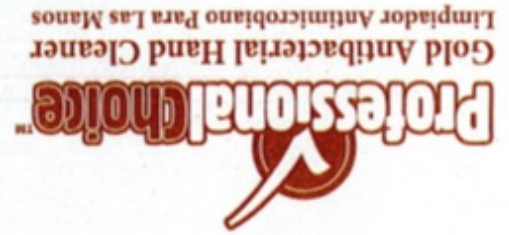
Contains  
.3% P.C.M.X.

Manufactured for Professional Choice  
PO Box 1057 • Oaks, PA

MADE  
IN THE **USA**

PCSGS800  
800ml

Professional Choice Single Box Back

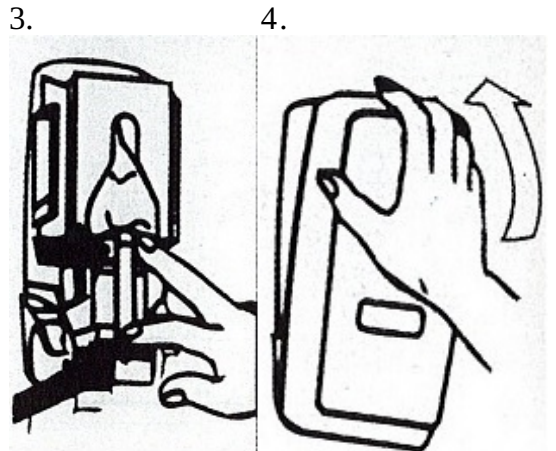
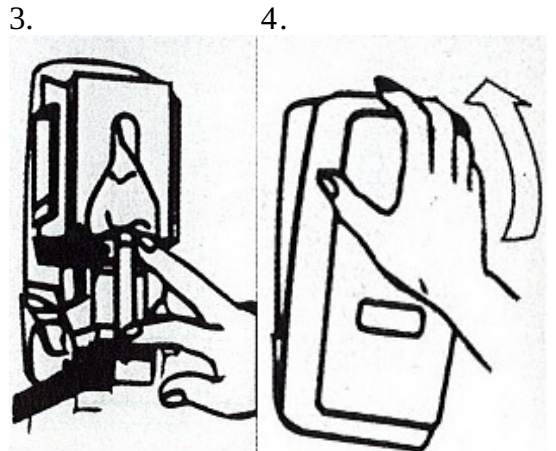
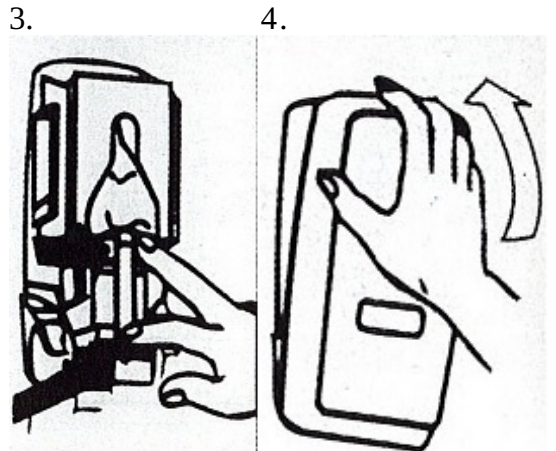
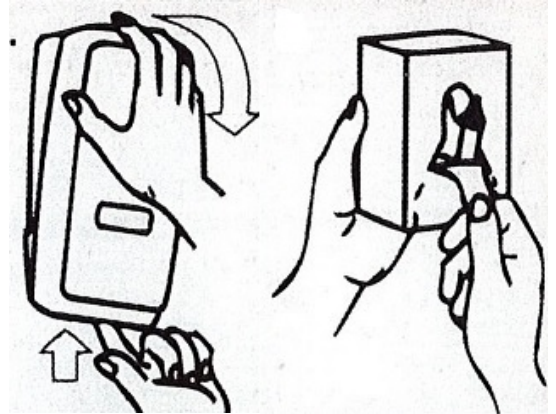


✓  
Professional Choice™  
Gold Antibacterial Hand Cleaner  
Limpiador Antimicrobiano Para Las Manos

- Antibacterial soap can help reduce bacteria on the hands that cause disease
- PH balanced
- Produced in an FDA registered facility
- cGMP facility
- Mild formula for multiple handwashing without stripping the skin of its natural oils

40232 65081

✓  
Professional Choice™  
Dispenser Loading Instructions  
1. 2.





5031

  
**ProfessionalChoice™**

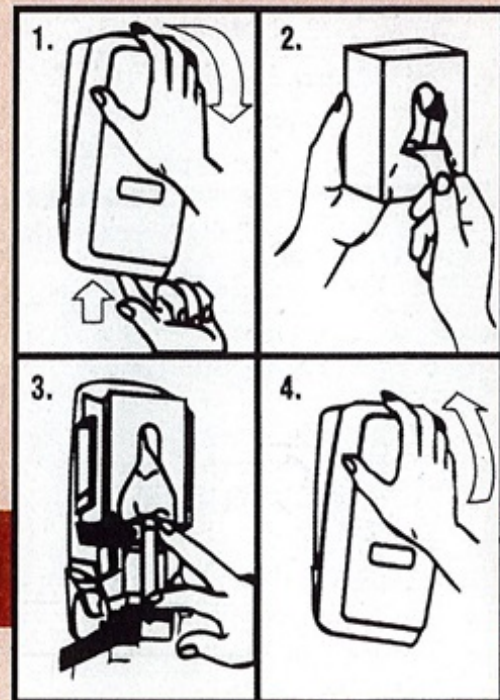
**Gold Antibacterial Hand Cleaner**  
Limpiador Antimicrobiano Para Las Manos

- Antibacterial soap can help reduce bacteria on the hands that cause disease
- PH balanced
- Produced in an FDA registered facility
- cGMP facility
- Mild formula for multiple handwashing without stripping the skin of its natural oils



**ProfessionalChoice™**  
Gold Antibacterial Hand Cleaner  
Limpiador Antimicrobiano Para Las Manos

  
**ProfessionalChoice™**  
Dispenser Loading Instructions





4032 65083

✓

Professional™

Choice

Gold Antibacterial Hand Cleaner

Limpiador Antimicrobiano Para Las Manos

PCSGS1800

Manufactured for Professional Choice

12/800

PO Box 1057 • Oaks, PA

MADE USA

IN THE



<b>PROFESSIONAL CHOICE GOLD HAND CLEANER</b>			
parachlorometaxlenol liquid			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58575-404
<b>Route of Administration</b>	TOPICAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>

<b>CHLOROXYLENOL</b> (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)		<b>CHLOROXYLENOL</b>	0.3 mg in 1 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>				<b>Strength</b>
WATER (UNII: 059QF0K00R)				
CITRIC ACID ACETATE (UNII: DSO12WL7AU)				
CO CAMIDO PROPYL DIMETHYLAMINE (UNII: L36BM7DG2T)				
DMDM HYDANTOIN (UNII: BYR0546TOW)				
ALCOHOL (UNII: 3K9958V90M)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				
ISOPROPYL ALCOHOL (UNII: ND2M416302)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
TRIETHANOLAMINE LAURYL SULFATE (UNII: E8458C1KAA)				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58575-404-01	3785 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2018	
2	NDC:58575-404-02	15140 mL in 1 CASE; Type 0: Not a Combination Product	01/01/2018	
3	NDC:58575-404-03	800 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/01/2018	
4	NDC:58575-404-04	9600 mL in 1 CASE; Type 0: Not a Combination Product	01/01/2018	
<b>Marketing Information</b>				
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(58575-404)

Revised: 2/2020

Inopak, Ltd.