

**PLUS BRASEPT THD- chloroxylenol soap  
NEWDROP NORTH AMERICA LLC**

*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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**PLUS BRASEPT THD 6544 Drug Facts and Label**

**Drug Facts Box OTC-Active Ingredient Section**

Chloroxylenol 0.3%

**Drug Facts Box OTC-Purpose Section**

Antiseptic

**Drug Facts Box OTC-Indications & Usage Section**

for hand-washing to decrease bacteria on the skin

**Drug Facts Box OTC-Warnings Section**

For external use only

**Drug Facts Box OTC-When Using Section**

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

**Drug Facts Box OTC-Stop Use Section**

irritation and redness develop

**Drug Facts Box OTC-Keep Out of Reach of Children Section**

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

**Drug Facts Box OTC-Dosage & Administration Section**

- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

**Drug Facts Box OTC-Inactive Ingredient Section**

water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, sodium chloride, citric acid, DMDM hydantoin, fragrance, FD and C yellow no.5, food red 10

## PLUS BRASEPT THD

### PLUS BRASEPT THD

#### Antiseptic Hand Soap

An effective antibacterial hand soap for use in:

- Food Service Facilities
- Athletic Facilities
- Business/office Buildings
- Factories
- Locker Rooms
- Shower and Bath Areas
- Public Restrooms
- Daycare Centers
- Hotels
- Correctional Facilities
- Dressing Rooms
- Institutional Facilities
- Nurseries
- Public Facilities
- Schools
- Campgrounds.

Formulated with skin conditioners for extra mildness.

This product is designed exclusively for industrial and institutional use by trained personnel. This product is sold "as is" and the manufacturer makes no warranty, expressed or implied, of merchantability, and/or fitness for a particular purpose or otherwise.

# PLUS BRASEPT THD

## Antiseptic Hand Soap

**NEWDROP**  
USA

**CAUTION: KEEP OUT OF REACH OF CHILDREN**

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand this label, find someone to explain it to you in detail.)

NET CONTENTS: 1 GALLON (3.8 L)

Drug Facts	
<b>Active Ingredient</b>	<b>Purpose</b>
Chloroxylenol 0.3%	Antiseptic
<b>Uses</b> for hand-washing to decrease bacteria on the skin	
<b>Warnings</b>	
For external use only	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>■ do not get into eyes</li> <li>■ if contact occurs, rinse eyes thoroughly with water</li> </ul>	
<b>Stop use and ask a doctor if</b>	
<ul style="list-style-type: none"> <li>■ irritation and redness develop</li> </ul>	
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>■ wet hands and forearms</li> <li>■ apply 5 milliliters (teaspoonful) or palmful to hands and forearms</li> <li>■ scrub thoroughly for 1 minute and rinse</li> </ul>	
<b>Inactive Ingredients</b>	
water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, DMDM hydantoin, sodium chloride, citric acid, fragrance, FD&C yellow no. 5, food red 10.	

**NEWDROP**  
USA

Sold by: **Newdrop North America LLC**  
2480 Oakcreek Rd, Suite D2, Doraville, GA, 30340  
(470) 275-3196

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## PLUS BRASEPT THD

chloroxylenol soap

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83318-544
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>CHLOROXYLENOL</b> (UNII: 0F32U78V2Q) (CHLOROXYLENOL - UNII:0F32U78V2Q)	CHLOROXYLENOL	3 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SODIUM LAURETH SULFATE</b> (UNII: BPV390UAP0)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>DECYL GLUCOSIDE</b> (UNII: Z17H97EA6Y)	
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	
<b>DMDM HYDANTOIN</b> (UNII: BYR0546TOW)	
<b>COCO MONOISOPROPANOLAMIDE</b> (UNII: 21X4Y0VTB1)	
<b>FD&amp;C YELLOW NO. 5</b> (UNII: I753WB2F1M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83318-544-41	3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/24/2023	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	03/24/2023	

**Labeler** - NEWDROP NORTH AMERICA LLC (094392481)

**Registrant** - ABC Compounding Co., Inc. (003284353)

### Establishment

Name	Address	ID/FEI	Business Operations
ABC Compounding Co., Inc.		003284353	manufacture(83318-544)

Revised: 3/2023

NEWDROP NORTH AMERICA LLC