

**PLUS BRASEPT- benzalkonium chloride 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.

PLUS BRASEPT 6265 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Benzalkonium Chloride 2.5%

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, glycerin, isopropyl alcohol, disodium cocoamphodipropionate, hydroxyethylcellulose, lauramine oxide,

PEG-75 lanolin, citric acid, FD and C red no.4

PLUS BRASEPT 6265

PLUS BRASEPT

Antiseptic Handwash

This product is an effective one-step cleaner/sanitizer for use in food processing plants and restaurants by personnel prior to handling food and/or food-processing equipment. Based on quaternary ammonium chlorides, this viscous formulation is more cost-efficient than traditional PCMX-based products.

This formulation effectively reduces the bacterial flora of the skin. When tested via the Modified Available Chlorine Germicidal Equivalent Concentration Test it demonstrates equal sanitizing activity to 50 ppm of free chlorine against Staphylococcus aureus and Salmonella typhi.

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

Antiseptic Handwash

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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	
Active Ingredients	Purpose
Benzalkonium Chloride 2.5%	Antiseptic
Use for hand-washing to decrease bacteria on the skin	
Warnings	
For external use only	
When using this product	
<ul style="list-style-type: none"> do not get into eyes if contact occurs, rinse eyes thoroughly with water 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> irritation and redness develop 	
Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away	
Directions	
<ul style="list-style-type: none"> wet hands and forearms apply 5 milliliters (teaspoonful) or palmful to hands and forearms scrub thoroughly for 1 minute and rinse this product must be dispensed from adequate dispensers located a sufficient distance from processing lines to prevent accidental product contamination 	
Inactive Ingredients water, glycerin, isopropyl alcohol, disodium cocoamphodipropionate, hydroxyethyl cellulose, lauramine oxide, PEG-75 lanolin, citric acid, FD & C red #4	

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USA

Sold by: **Newdrop North America LLC**
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(470) 275-3196

08941110000100202

PLUS BRASEPT

benzalkonium chloride soap

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83318-265
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	25 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
HYDROXYETHYL CELLULOSE (1500 MPA.S AT 1%) (UNII: L605B5892V)	
DISODIUM COCOAMPHODIPROPIONATE (UNII: 6K8PRP397M)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
PEG-75 LANOLIN (UNII: 09179OX7TB)	
GLYCERIN (UNII: PDC6A3C0OX)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
FD&C RED NO. 4 (UNII: X3W0AM1JLX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83318-265-41	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	03/23/2023	

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(83318-265)

Revised: 3/2023

NEWDROP NORTH AMERICA LLC