ENVIROMED HAND SANITIZER- benzalkonium chloride solution Unysource Enterprise

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.

Environmed Hand Sanitizer Alcohol free

DRUG FACTS

Active Ingredient

Benzalkonium chloride 0.15%

Purpose

Antiseptic

Uses

For hand sanitizing. To decrease bacteria on the skin.

Warnings

For external use only.

Do not use in the eyes.

In case of eye contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

if irritation or redness develops, or if condition persists more than 72 hours.

Keep out of reach of children.

Instruct children on proper use. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Apply small amount to wetted hands and wash vigorously for 15 seconds, make sure to get between fingers and under finger nails. Rinse with warm, clean water. Repeat as necessary.

Inactive Ingredients

Tea tree oil, Cocamidopropyl Betaine, Sweet Orange, Glycerin, Panthenol, Water

Purpose

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PRINCIPAL DISPLAY PANEL





20ml NDC 79505-012-01

PRINCIPAL DISPLAY PANEL



Alcohol Free Hand Sanitizer

KILLS 99.9% OF GERMS

60mL

Drug Facts		
Active Ingredient(s) Benzalkonium Chloride 0.15%		Purpose Antibacterial
Use[s] For hand washing to decrease bacteria on t	he skin	
Warnings For external use only.		
When using this product keep out of eyes, In case o	f contact with eyes, rinse eyes thoroughly w	6th water.
Stop use and ask a doctor if irritation or redness de	velops and persists.	
Keep out of reach of children. If swallowed, get me	dical help promptly and contact Poison Cont	trol.
Directions Wet hands thoroughly with product and allow to d	ry without wiping. For adults anc children 2	years and older.
Other information		
Store under 105° F.		
Inactive Ingredients Water, glycein, sweet orange	r, Panthenol, Cocamidoptopyl Betaine, Tea tree	
Manufactured by: UnySource Enterprise 20 Melford Drive Unit 5 Scarberough, ON MIB 20K, CANADA	MFG: EXP: LOTA: NDC#:	6 28011 ¹ 53604

Principal Display Panel



Alcohol Free Hand Sanitizer

KILLS 99.9% OF GERMS

250mL

Drug Facts		
Active Ingredient(s) Benzalkonium Chloride 0.15%		Purpose Antibacterial
Use(s) For hand washing to decrease bacteria on th	ne skin	
Wernings For external use only.		
When using this product keep out of eyes, in case of	contact with eyes, rinse eyes thoroughly w	jth water
Stop use and ask a doctor if irritation or redness de-	velops and persists.	
Keep out of reach of children. If swallowed, get med	dical help promptly and contact Poison Cont	trol.
Directions		
Wet hands thoroughly with product and allow to di	ry without wiping. For adults and children 2	years and older.
Other information		
Store under 105° F.		
Inactive ingredients Water, glycerin, sweet crange	, Panthenol, Cocamidoptopyl Betaine, Tea tree	
Manufactured by: UnySource Enterprise	MFG:	10000000
20 Melford Drive Unit 5	EXP:	1000000
Scarborough, ON	LOTA:	
M1B 2X6, CANADA	NDC#:	6 28011*53605**

250 ml NDC 79505-012-03

Principal Display Panel



Alcohol Free Hand Sanitizer

KILLS 99.9% OF GERMS

500 mL

Drug Facts		
Active ingredient(s) Benzalkonium Chloride 0.15%		Purpose Antibacterial
Use(s) For hand washing to decrease bacteria on t	he skin	
Warnings For external use only.		
When using this product keep out of eyes, in case o	f contact with eyes, rinse eyes thoroughly	with water.
Stop use and ask a doctor if irritation or redness de	velops and persists.	
Keep out of reach of children. If swallowed, get me	dical help promptly and contact Poison Co	ntrol.
Directions Wet hands thoroughly with product and allow to d	ry without wiping. For adults anc children	2 years and older.
Other information		
Store under 105° F.		
Inactive ingredients Water plycerin, sweet orange	e, Panthenol, Cocamidoptopyl Betaine, Tea tree	
Manufactured by: UnySource Enterprise 20 Melford Drive Unit S Scarborough, ON MTB 206, CANADA	MFG: EXP: LOTF: NDC#:	6 -28011153606

500 mL NDC 79505-012-04

Principal Display Panel



Alcohol Free Hand Sanitizer

KILLS 99.9% OF GERMS

1000mL

Drug Facts		
Active Ingredient[s] Benzalkonium Chloride 0.15%		Purpose Antibacterial
Use[s] For hand washing to decrease bacteria on th	ne skin	
Warnings For external use only.		
When using this product keep out of eyes, in case of	contact with eyes, rinse eyes thoroughly	with water.
Stop use and ask a doctor if irritation or redness dev	velops and persists.	
Keep out of reach of children. If swallowed, get med	fical help promptly and contact Poison Co	ntrol.
Directions Wet hands thoroughly with product and allow to dr	ry without wiping. For adults anc children	2 years and older.
Other information		
Store under 105° F.		
Inactive ingredients Water, glycerin, sweet orange	, Panthenol, Cocamidoptopyl Betaine, Tea tree	
Manufactured by: UnySource Enterprise 20 Melford Drive Unit S Scarborough, ON MIB 2506, CANADA	MFG: EXP: LOT#: NDC#:	28011*53607

1000ml NDC 79505-012-05

Principal Display Panel



Alcohol Free Hand Sanitizer

KILLS 99.9% OF GERMS

4000mL

Drug Facts		
Active Ingredient(s) Benzalkonium Chloride 0.15%		Purpose Antibacterial
Use(s) For hand washing to decrease bacteria on th	he skin	
Warnings For external use only.		
When using this product keep out of eyes, in case of	f contact with eyes, rinse eyes thoroughly	with water.
Stop use and ask a doctor if irritation or redness de-	velops and persists.	
Keep out of reach of children. If swallowed, get med	dical help promptly and contact Poison Co	nêrol.
Directions Wet hands thoroughly with product and allow to di	ry without wiping. For adults anc children	2 years and older.
Other information		
Store under 105° F.		
Inactive ingredients Water, plycerin, sweet orange	e, Panthenol, Cocamidoptopyl Betaine, Tea tree	
Manufactured by: UnySource Enterprise 20 Melford Drive Unit 5 Scarborough, ON M18 206, CANADA	MFG: EXP: LOTA: NDC#:	6 28011 53608

4000 mL NDC 79505-012-06

ENVIROMED HAND SANITIZER

benzalkonium chloride solution

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79505-012
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0015 g in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
TEA TREE OIL (UNII: VIF565UC2G)		
ORANGE OIL (UNII: AKN3KSD11B)		
PANTHENOL (UNII: WV9CM0O67Z)		
CO CAMIDO PRO PYL BETAINE (UNII: 50 CF3011KX)		

GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:79505-012- 01	20 mL in 1 POUCH; Type 0: Not a Combination Product	07/30/2020		
2	NDC:79505-012- 02	60 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020		
3	NDC:79505-012- 03	250 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020		
4	NDC:79505-012- 04	500 mL in 1 BOTTLE, DISPENSING; Type 0: Not a Combination Product	07/30/2020		
5	NDC:79505-012- 05	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/30/2020		
6	NDC:79505-012- 06	4000 mL in 1 JAR; Type 0: Not a Combination Product	07/30/2020		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/30/2020	

Labeler - Unysource Enterprise (204167139)

Establishment				
Name	Address	ID/FEI	Business Operations	
Unysource Enterprise		204167139	manufacture(79505-012)	

Revised: 12/2020 Unysource Enterprise