

HYDROCLEAN HAND SANITIZER- benzalkonium chloride 0.13% gel
Telebrands Corp

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.

HydroClean Hand Sanitizer

Active ingredient

Benzalkonium Chloride 0.13% w/w

Purpose

Benzalkonium Chloride 0.13% w/w.....Antiseptic

Uses

Antiseptic cleansing of hands and body to decrease bacteria on skin without soap and water.

Warnings

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of eye contact, flush eyes with water.

Stop use and ask doctor if

- irritation or rash occurs. These might be signs of a serious condition.
- 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

- Apply a small amount of gel into palm of hand. Rub thoroughly over all surfaces of both hands for 15 seconds. Allow hands to dry without wiping.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

Store tightly closed in a cool dry place.

Inactive ingredients

Water/Aqua/Eau, Aloe Barbadensis Leaf Extract, Sodium Hyaluronate, Cocos Nucifera (Coconut) Oil, Cannabis Sativa (Hemp) Seed Oil, Hydroxyethylcellulose, Polysorbate 20, Disodium EDTA, Sodium Citrate, Sodium Hydroxide, Citric Acid, Blue 1 (CI 42090), Yellow 5 (CI 19140).

Questions?

Call (855) 877-4503 (M-F, 9am-5pm EST)

Handvana

Odor Free

HydroClean

Hand Sanitizer

Benzalkonium Chloride 0.13%

KILLS 99.9% OF GERMS*

Sanitize + ***Soften Hands***

With Moisturizing

Coconut Oil

Aloe Vera

Hyaluronic Acid

VALUE SIZE

OVER 1lb

17 fl oz (503 mL)

Made in the USA

Handvänä™

Odor Free

HYDROCLEAN™ HAND SANITIZER

Benzalkonium Chloride 0.13%

KILLS 99.9% OF GERMS*

Sanitize + Soften Hands

With Moisturizing

Coconut Oil

Aloe Vera

Hyaluronic Acid

VALUE SIZE
OVER
1 lb
17 fl oz (503 mL)



Handvänä™

Drug Facts

Active ingredient

Benzalkonium Chloride 0.13% w/w

Uses

Antiseptic cleansing of hands and body to deodorize without soap and water.

Warnings

For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, nose, and mouth. In case of eye contact, flush eyes with water.

Stop use and ask a doctor if

- irritation or rash occurs. These might be signs of an allergic reaction.
- condition persists for more than 72 hours

Keep out of reach of children. If swallowed, call Poison Control Center right away.

Directions

- Apply a small amount of gel into palm of hand and rub over all surfaces of both hands for 15 seconds. Allow hands to dry.
- Supervise children under 6 years of age when using.

Other Information Store tightly closed in original container.

Inactive Ingredients Water/Aqua/Eau, Aloe Vera, Sodium Hyaluronate, Cocos Nucifera (Coconut) Seed Oil, Hydroxyethylcellulose, Polysorbate 20, Citric Acid, Sodium Hydroxide, Citric Acid, Blue 1 (CI 42090)

Questions? Call (855) 877-4503 (M-F, 9am-5pm)

*Kills 99.9% of Common Germs



HYDROCLEAN HAND SANITIZER

benzalkonium chloride 0.13% gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73287-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
WATER (UNII: 059QF0KO0R)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
HYDROXYETHYL CELLULOSE, UNSPECIFIED (UNII: T4V6TWG28D)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
CANNABIS SATIVA SEED OIL (UNII: 69VJ1LPN1S)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
COCONUT OIL (UNII: Q9L0O73W7L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73287-007-01	1 in 1 CARTON	04/08/2020	
1		503 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
2	NDC:73287-007-02	1 in 1 CARTON	05/15/2020	
2		3785 mL in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:73287-007-03	1 in 1 CARTON	05/15/2020	
3		946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		
4	NDC:73287-007-04	1 in 1 CARTON	05/15/2020	
4		59 mL in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:73287-007-05	1 in 1 CARTON	05/15/2020	
5		236 mL in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	04/08/2020	

Labeler - Telebrands Corp (177266558)

Establishment

Name	Address	ID/FEI	Business Operations
Neutraderm, Inc.		146224444	manufacture(73287-007)

Establishment

Name	Address	ID/FEI	Business Operations
A.I.G. Technologies Incorporated		171837367	manufacture(73287-007)

