

CELAVI HAND SANITIZING WET WIPES- benzalkonium chloride liquid
HAN KOOK CHEMICAL

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.

Drug Facts

ACTIVE INGREDIENT

Active Ingredients: Benzalkonium Chloride 0.1%

INACTIVE INGREDIENT

Inactive Ingredients:

Water, Glycerin, Sodium benzoate, Polysorbate 20, Disodium EDTA, Phenoxyethanol, Tocopheryl acetate, Citric acid

PURPOSE

Purpose: antiseptic

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children:

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

Uses

Uses:

- instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- instant hand antiseptic to decrease bacteria on the skin

WARNINGS

Warnings

For external use only

When using this product

- if following abnormal symptoms persist, discontinue use
Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes
- Stop immediately and consult a doctor if you experience
 - 1) Hypersensitivity symptoms such as erythema, itching and dermatitis.
 - 2) Skin Irritation
 - 3) Following Instructions when using medication
 - (1) For external use only (Do not use internally)
 - (2) Avoid getting into the eyes (if contact occurs, wash well with clean water)
- When used repeatedly in the same area, skin irritation may occur.
- Do not use the product for a long time in the same area as swelling, inflammation or sickness may

occur due to absorption through the skin.

It is not recommended to use this one areas that have been medically treated with a cast or bandage.

■ Do not use in combination with soap or antibacterial cleansing agents.

Directions

Directions:

■ Scrub and wipe off the hand and skin, which are used individually or if necessary.

Other information

Other information:

■ Read the directions and warnings before use ■ Avoid freezing and excessive heat above 40 ° (104 °)

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

celavi

HAND SANITIZING WET WIPES

30 WIPES

MADE IN KOREA/HECHO EN COREA

For Soft, Clean Hands

KILLS 99.9% OF BACTERIA & GERMS*

30 WIPES

MADE IN KOREA

Drug Facts

*Kills 99.9% of harmful bacteria
162g (30 ct)

Active Ingredients	Purpose
Benzalkonium Chloride 0.1%	antiseptic

Uses

- Instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease
- Instant hand antiseptic to decrease bacteria on the skin

Warning

For external use only
When using this product:

- If following abnormal symptoms persist, discontinue use. Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes
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 - 1) Hypersensitivity symptoms such as erythema, itching and dermatitis
 - 2) Skin Irritation
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 - (1) For external use only (Do not use internally)
 - (2) Avoid getting into the eyes (if contact occurs, wash well with clean water)
- When used repeatedly in the same area, skin irritation may occur.
- Do not use the product for a long time in the same area as swelling, inflammation or soreness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage.
- Do not use in combination with soap or antibacterial cleansing agents.

Directions

- Scrub and wipe off the hand and skin, which are used individually or if necessary.

Other Information

- read the directions and warnings before use
- avoid freezing and excessive heat above 40 degree C (104 degree F)

Inactive Ingredients

Water, Glycerin, Sodium benzoate, Polycarbonate 20, Disodium EDTA, Phenylethanol, Tocopheryl acetate, Citric acid

celavi
LOS ANGELES, CA 90023, USA
DISTRIBUTED BY: NO.1 INC.
WWW.CELAVIPRODUCTS.COM

ITEM# SF130

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MADE IN KOREA

USE BY 0000000

CELAVI HAND SANITIZING WET WIPES

benzalkonium chloride liquid

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:75770-0-10

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.16 g in 162 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75770-010-01	162 g in 1 CONTAINER; Type 0: Not a Combination Product	04/01/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/01/2020	

Labeler - HAN KOOK CHEMICAL (689059312)**Registrant** - HAN KOOK CHEMICAL (689059312)**Establishment**

Name	Address	ID/FEI	Business Operations
FIRSTCHAM CO., LTD		689905446	manufacture(75770-010)

Revised: 4/2020

HAN KOOK CHEMICAL