

CLEAN DISINFECTANT WIPES- benzalkonium chloride liquid

Clean One Co., Ltd.

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

Benzalkonium Chloride

INACTIVE INGREDIENTS

Water, Citric Acid

PURPOSE

Antiseptic

WARNINGS

For external use only.

Do not use

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

When using this product

- avoid getting into the eyes (if contact occurs, wash well with clean water)

Stop use and ask a doctor

- hypersensitivity symptoms such as erythema, itching and dermatitis happen
- skin irritation happens

KEEP OUT OF REACH OF CHILDREN

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

Uses

Hand sanitizing wipes to help reduce bacteria that potentially can cause disease.

Directions

- Wet hands thoroughly with product and allow to dry without wiping
- Do not flush
- Children under 2 years ask a doctor before use

Other information

- Read the directions and warnings before use

- Store between 15-30°(59-89°)
- Avoid freezing and excessive heat above 40°(104 °)

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Warnings For external use only. Do not use ■ in children less than 2 months of age ■ on open skin wounds When using this product ■ avoid getting into the eyes (if contact occurs, wash well with clean water) Stop use and ask a doctor ■ hypersensitivity symptoms such as erythema, itching and dermatitis happen ■ skin irritation happens Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
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Inactive ingredients Water, Citric Acid	
Manufacturer: Clean One Co., Ltd. 12-8, Sinpyeong-ro 16-gil, Dong-gu, Daegu, Republic of Korea	

CLEAN DISINFECTANT WIPES			
benzalkonium chloride liquid			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78506-001
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.0054 g in 3.6 g
Inactive Ingredients			
Ingredient Name			Strength
WATER (UNII: 059QF0KO0R)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
Packaging			
#	Item Code	Package Description	Marketing Start Date Marketing End Date
1	NDC:78506-001-01	3.6 g in 1 PACKET; Type 0: Not a Combination Product	09/08/2020
Marketing Information			
Marketing Category		Application Number or Monograph Citation	Marketing Start Date Marketing End Date
OTC monograph not final		part333E	09/08/2020

Labeler - Clean One Co., Ltd. (688986083)

Registrant - Clean One Co., Ltd. (688986083)

Establishment			
Name	Address	ID/FEI	Business Operations
Clean One Co., Ltd.		688986083	manufacture(78506-001)