

DARANJO- benzalkonium chloride solution

Matilde Gómez López

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.

Active Ingredient(s)

Alcohol 70% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

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 contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

purified water USP, alcohol, sodium nitrite.

Package Label - Principal Display Panel

65 mL NDC:78084-003-01

HandeSe

TAKE CLEAN WITH YOU

Antibacterial

Hands & Skin

2.20 fl. oz. (65 ml)

DRUG FACTS

Active ingredient	Purpose
Benzalkonium Chloride .13 % v/v	Antiseptic

Uses

- Sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use.

Warnings:

- For external use only.**
- When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- Stop use and ask a doctor if** irritation or rash appears and lasts.
- Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Place enough product in your palm thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised by an adult when used.

Inactive ingredients

- Water, Sodium Nitrite, 70% Ethyl Alcohol (.3%)



7 503013 750809

HECHO EN MEXICO

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120 mL NDC: 78084-003-02

HandeSe

TAKE CLEAN WITH YOU

Antibacterial

Hands & Skin

4.06 fl. oz. (120 ml)

DRUG FACTS

Active ingredient	Purpose
Benzalkonium Chloride .13% v/v	Antiseptic

Uses

- Sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use.

Warnings:

- **For external use only.**
- **When using this product** do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- **Stop use and ask a doctor if** irritation or rash appears and lasts.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Place enough product in your palm thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised by an adult when used.

Inactive ingredients

- Water, Sodium Nitrite, 70% Ethyl Alcohol (.3%)



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HandeSe

TAKE CLEAN WITH YOU

Antibacterial

Hands & Skin

8.12 fl. oz. (240 ml)

DRUG FACTS

Active ingredient	Purpose
Benzalkonium Chloride .13 % v/v	Antiseptic

Uses

- Sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use.

Warnings:

- For external use only.
- When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- Stop use and ask a doctor if irritation or rash appears and lasts.
- Keep out of reach of children. If swallowed, get medical get medical help or contact a Poison Control Center right away.

Directions:

- Place enough product in your palm thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised by an adult when used.

Inactive ingredients

- Water, Sodium Nitrite ,70% Ethyl Alcohol (.3%)



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HandeSe

TAKE CLEAN WITH YOU

Antibacterial

Hands & Skin

11.16 fl. oz. (330 ml)

DRUG FACTS

Active ingredient	Purpose
Benzalkonium Chloride .13% v/v	Antiseptic

Uses

- Sanitizer to help reduce bacteria on the skin that could cause disease.
- Recommended for repeated use.

Warnings:

- For external use only.
- When using this product do not use in or near the eyes. In case of contact, rinse eyes thoroughly with water.
- Stop use and ask a doctor if irritation or rash appears and lasts.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Place enough product in your palm thoroughly cover your hands.
- Rub hands together briskly until dry.
- Children under 6 years of age should be supervised by an adult when used.

Inactive ingredients

- Water, Sodium Nitrite ,70% Ethyl Alcohol (.3%)



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DARANJO

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:78084-003
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 g in 1000 mL	
Inactive Ingredients				
Ingredient Name		Strength		
SODIUM NITRITE (UNII: M0KG633D4F)		0.3 g in 1000 mL		
ALCOHOL (UNII: 3K9958V90M)		4 mL in 1000 mL		
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78084-003-01	65 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2020	
2	NDC:78084-003-02	120 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2020	
3	NDC:78084-003-03	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2020	
4	NDC:78084-003-04	330 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/07/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/07/2020		

Labeler - Matilde Gómez López (951577135)

Registrant - Matilde Gómez López (951577135)

Establishment

Name	Address	ID/FEI	Business Operations
Matilde Gómez López		951577135	manufacture(78084-003) , pack(78084-003) , label(78084-003)

Revised: 9/2020

Matilde Gómez López