

VIRAPRO KIDS HAND CLEANSER- benzalkonium chloride gel
ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI

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.

Hand Sanitizer Bubble Gum

Active Ingredient(s)

Benzalkonium Chloride 0.01% w/w

Purpose

Antiseptic Hand Sanitizer

Use

Used for general purpose hand and skin sanitization. Suitable for children. Can be used at home, school, kindergarten, or hospital. Keeps hands soft with its moisturizer content.

Warnings

For external use only.

When using this product, avoid contact with the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Keep out of reach of children under 3 years of age. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

Squeeze a drop onto the palm of your hands. Rub your hands well and let them dry.

Inactive ingredients

Aqua, Glycerin, Triethanolamine, Carbomer, PEG-40 Hydrogenated Castor Oil, Parfum (non-allergic)

Other information

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

Shelf life of the product is 2 years. Once opened, use within 3 months.

Dispose of contents/bottle in accordance with local regulations.

Package Label - Principal Display Panel

virapro

Dermal Disinfectant

Hand Cleanser Gel

For External Use Only

KIDS

BUBBLE GUM

ALCOHOL FREE 0%

U.S. Contact: ViraPro North America

550 Albion Ave. Schaumburg Chicago, IL 60193

Phone: +1 (312) 340-0288

www.viapro.com

Manufacturer: All One Kozmetik

Sutluce, Imrahor Cd. No:36, 34445 Beyoglu/Istanbul

Phone: (0212) 501 19 00

<https://www.allone.com.tr/>

MADE IN EUROPE





VIRAPRO KIDS HAND CLEANSER

benzalkonium chloride gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75348-004
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.01 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
GLYCERIN (UNII: PDC6A3C0OX)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	
CARBOMER 980 (UNII: 4Q93RCW27E)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75348-004-01	50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75348-004-02	100 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	



Active Ingredient: Benzalkonium Chloride 0.01% w/w **Purpose:** Antiseptic hand sanitizer. **Use:** Used for general purpose hand and skin sanitization. Suitable for children. Can be used at home, school, kindergarten, or hospital. Keeps hands soft with its moisturizer content. **Warnings:** For external use only. When using this product, avoid contact with the eyes. In case of contact with eyes, rinse eyes thoroughly with water. Keep out of reach of children under 3 years of age. If swallowed, get medical help or contact a Poison Control Center right away. **Directions:** Squeeze a drop onto the palm of your hands. Rub your hands well and let them dry. **Inactive ingredients:** Aqua, Glycerin, Triethanolamine, Carbomer, PEG-40 Hydrogenated Castor Oil, Parfum (non-allergic). **Other information:** Store between 15-30 °C (59-86 °F). Avoid freezing or excessive heat above 40 °C (104 °F). Shelf life of the product is 2 years. Once opened, use within 3 months. **Disposal:** Dispose of contents/bottle in accordance with local regulations.

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50ml e 1,6 fl. oz. 5 055866 825040

PRD: 02.11.2020
EXP: 02.11.2022



Active Ingredient: Benzalkonium Chloride 0.01% w/w **Purpose:** Antiseptic hand sanitizer. **Use:** Used for general purpose hand and skin sanitization. Suitable for children. Can be used at home, school, kindergarten, or hospital. Keeps hands soft with its moisturizer content. **Warnings:** For external use only. When using this product, avoid contact with the eyes. In case of contact with eyes, rinse eyes thoroughly with water. Keep out of reach of children under 3 years of age. If swallowed, get medical help or contact a Poison Control Center right away. **Directions:** Squeeze a drop onto the palm of your hands. Rub your hands well and let them dry. **Inactive ingredients:** Aqua, Glycerin, Triethanolamine, Carbomer, PEG-40 Hydrogenated Castor Oil, Parfum (non-allergic). **Other information:** Store between 15-30 °C (59-86 °F). Avoid freezing or excessive heat above 40 °C (104 °F). Shelf life of the product is 2 years. Once opened, use within 3 months. **Disposal:** Dispose of contents/bottle in accordance with local regulations.

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100ml e 3.38 fl. oz. 5 055866 825071

PRD: 02.11.2020
EXP: 02.11.2022

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI (519983719)

Registrant - HARDAL GLOBAL CONSULTING LLC. (123584960)

Establishment

Name	Address	ID/FEI	Business Operations
ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI		519983719	manufacture(75348-004)

Revised: 10/2020

ALL ONE KOZMETIK SANAYI DIS TICARET ANONIM SIRKETI