

HAND SANITIZER- alcohol gel
CROWN (YANGZHOU) HEALTH & BEAUTY 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.

Active Ingredient(s)

(Ethyl) Alcohol 75% 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.

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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

Water, aminomethyl propanol, carbomer, propanediol, tocopheryl acetate, isopropyl myristate, glycerin, fragrance

Package Label - Principal Display Panel





59mL NDC: 75328-001-01



Drug Facts	
Active ingredient	Purpose
alcohol 75%	Antiseptic
Uses	
<ul style="list-style-type: none"> • Hand sanitizer to help reduce bacteria that potentially can cause disease • For use when soap and water are not available 	
Warnings	
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Do not use	
<ul style="list-style-type: none"> • In children less than 2 months of age • On open skin wounds 	
When using this product avoid contact with eyes. In case of eye contact, flush eyes with water.	
Stop use and ask a doctor if irritation or redness develops, or if 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.	
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Designed from U.S.A.
Distributed by
Max Power Product Group
Los Angeles, CA
Made in China / Hecho en China

473mL NDC: 75328-001-02

<p>RAIN'S SECRET™</p> <h1>Hand Sanitizer</h1>  <p>Kills 99.99% of GERMS</p> <p>16 FL.OZ. / 473ml</p>	<table border="1"> <thead> <tr> <th colspan="2">Drug Facts</th> </tr> <tr> <th>Active ingredient</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Ethyl alcohol 75%</td> <td>Antiseptic</td> </tr> <tr> <td colspan="2">Uses</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Hand sanitizer to help reduce bacteria that potentially can cause disease • For use when soap and water are not available </td> </tr> <tr> <td colspan="2">Warnings</td> </tr> <tr> <td colspan="2">For external use only. Flammable. Keep away from heat or flame.</td> </tr> <tr> <td colspan="2">Do not use</td> </tr> <tr> <td colspan="2">near or in the eyes. If contact occurs, rinse eyes with water thoroughly.</td> </tr> <tr> <td colspan="2">Stop use and ask a physician if irritation, rash, or redness develops.</td> </tr> <tr> <td colspan="2">Keep out of reach of children</td> </tr> <tr> <td colspan="2">If swallowed get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2">Directions</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • 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. </td> </tr> <tr> <td colspan="2">Other information</td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> • Should be stored below 110°F(43°C) • Can discolor surfaces and some fabrics </td> </tr> <tr> <td colspan="2">Inactive ingredients deionized water, aminomethyl propanol, carbomer, propanediol, tocopheryl acetate, isopropyl myristate, glycerin, fragrance, water</td> </tr> </tbody> </table>	Drug Facts		Active ingredient	Purpose	Ethyl alcohol 75%	Antiseptic	Uses		<ul style="list-style-type: none"> • 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		near or in the eyes. If contact occurs, rinse eyes with water thoroughly.		Stop use and ask a physician if irritation, rash, or redness develops.		Keep out of reach of children		If swallowed get medical help or contact a Poison Control Center right away.		Directions		<ul style="list-style-type: none"> • 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		<ul style="list-style-type: none"> • Should be stored below 110°F(43°C) • Can discolor surfaces and some fabrics 		Inactive ingredients deionized water, aminomethyl propanol, carbomer, propanediol, tocopheryl acetate, isopropyl myristate, glycerin, fragrance, water		  <p>Made in China</p> 
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HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75328-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
WATER (UNII: 059QF0K00R)	
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
PROPANEDIOL (UNII: 5965N8W85T)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75328-001-01	59 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	
2	NDC:75328-001-02	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

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

Labeler - CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD (542978427)**Establishment**

Name	Address	ID/FEI	Business Operations
CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD		542978427	manufacture(75328-001)

Revised: 7/2020

CROWN (YANGZHOU) HEALTH & BEAUTY CO., LTD