

RUBZAN- isopropyl alcohol gel
Prime Eco Group, Inc.

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.

RUBZAN Hand Gel Sanitizer

Drug Facts

Active ingredient[s]

Isopropyl alcohol 70% v/v

Purpose

Antiseptic

Use[s]

Antiseptic hand rub and sanitizing gel 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

- on 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 small 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 59 - 86°F (15-30°C)
- Avoid freezing and excessive heat above 104°F (40°C)

Inactive ingredients

glycerin, polyacrylic crosspolymer, hydrogen peroxide, purified water USP.

RUBZAN +

- **Contains 70% v/v isopropyl alcohol**
- Hygienic Hand Rub
- Kills germs and bacteria
- Fragrance Free

Leaves hands feeling soft while killing 99.99% of germs

PRIME ECO GROUP, INC.

WHARTON TX 77488

WWW.PRIMEECOGROUP.COM

MADE IN USA

Packaging

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 70% v/v	Antiseptic
Use[s]	
Antiseptic hand rub and sanitizing gel 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	
<ul style="list-style-type: none"> on 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 small 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"> Store between 59 - 86 F (15 - 30°C) Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
glycerin, polyacrylic crosspolymer, hydrogen peroxide, purified water USP.	

RUBZAN

Hand Gel
Sanitizer

Leaves hands
feeling
soft while
killing
99.99% of
germs

PRIME ECO GROUP, INC.
WHARTON TX 77488
WWW.PRIMEECOGROUP.COM

MADE IN USA

RUBZAN
+

- Contains 70% v/v isopropyl alcohol
- Hygienic Hand Rub
- Kills germs and bacteria
- Fragrance Free

16 fl oz (473mL)

DRUG FACTS LABEL

Drug Facts	
Active ingredient[s]	Purpose
Isopropyl alcohol 70% v/v	Antiseptic
Use[s]	
Antiseptic hand rub and sanitizing gel 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	
<ul style="list-style-type: none"> on 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 small 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"> Store between 59 - 86°F (15-30°C) Avoid freezing and excessive heat above 104°F (40°C) 	
Inactive ingredients	
glycerin, polyacrylic crosspolymer, hydrogen peroxide, purified water USP.	

RUBZAN

isopropyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75549-770
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name		Basis of Strength	Strength	
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)		ISOPROPYL ALCOHOL	70 L in 100 L	
Inactive Ingredients				
Ingredient Name			Strength	
GLYCERIN (UNII: PDC6A3C0OX)				
POLYACRYLIC ACID (8000 MW) (UNII: 73861X4K5F)				
HYDROGEN PEROXIDE (UNII: BBX060AN9V)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75549-770-16	0.473 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
2	NDC:75549-770-01	3.785 L in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/27/2020	
3	NDC:75549-770-05	18.927 L in 1 PAIL; Type 0: Not a Combination Product	04/27/2020	
4	NDC:75549-770-55	208.198 L in 1 DRUM; Type 0: Not a Combination Product	04/27/2020	
5	NDC:75549-770-75	1040.99 L in 1 CONTAINER; Type 0: Not a Combination Product	04/27/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final		part333A	04/27/2020	

Labeler - Prime Eco Group, Inc. (097411727)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Eco Group, Inc.		097411727	manufacture(75549-770)

Revised: 4/2020

Prime Eco Group, Inc.