

REBOM HAND SANITIZER- power gel, 70% alcohol gel
A&H Branded Products, LLC

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.

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (70%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.00% v/v).
- c. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

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

glycerin, purified water USP

Package Label - Principal Display Panel

110 mL NDC: 76910-010-01




Hand Sanitizer
Alcohol Antiseptic 70%
Topical, Non-sterile Gel



3.71 fl. oz / 110 ml

Drug Facts

Active Ingredients	Purpose
Alcohol 70% v/v	Antiseptic

Use Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.

Do not use

- On children less than 2 months of age
- On open skin wounds

Warnings

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

When using this product keep out of eyes, ears and mouth. In case of eye contact immediately flush eyes thoroughly with water.

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

Keep out of reach of children. In case of accidental ingestion, contact a doctor or Poison Control Center immediately.

Directions

- Place enough product on your 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°-30 °C (59°- 89°F) ■ Avoid freezing and excessive heat above 40 °C (104°F) ■ May discolor fabrics or surfaces

Inactive Ingredients carbomer, glycerin, triethanolamine, water



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reBom Co., Ltd., 6 Myeonghaksandanse-ro, Yeondong-myeon, Sejong, 30068 Republic of Korea PRODUCT OF KOREA
Distributed by A&H Branded Products LLC Rochester Hills, MI 48309
Questions or Concerns: Go to www.ahbranded.com Item: E-371

500 mL NDC: 76910-010-02

reBom



16.9 fl. oz / 500 ml

Drug Facts

Active Ingredients Alcohol 70% v/v	Purpose Antiseptic
Use Hand Sanitizer to help reduce bacteria on the skin. For use when soap and water are not available.	
Do not use <ul style="list-style-type: none"> On children less than 2 months of age On open skin wounds 	
Warnings For external use only. Flammable. Keep away from heat or flame.	
When using this product Keep out of eyes, ears and mouth. In case of eye contact immediately flush eyes thoroughly with water.	
Stop use and ask a doctor if irritation or rash occurs. These may be the signs of a serious condition.	
Keep out of reach of children. In case of accidental ingestion, contact a doctor or Poison Control Center immediately.	
Directions <ul style="list-style-type: none"> Place enough product on your 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 15°-30 °C (59°- 89°F) Avoid freezing and excessive heat above 40 °C (104°F) May discolor fabrics or surfaces 	
Inactive Ingredients carbomer, glycerin, triethanolamine, water	

reBom Co., Ltd., 6 Myeonghaksandanse-ro, Yeondong-myeon, Sejong, 30068 Republic of Korea PRODUCT OF KOREA
 Distributed by A&H Branded Products LLC Rochester Hills, MI 48309
 Questions or Concerns: Go to www.ahbranded.com Item: E-169



REBOM HAND SANITIZER

power gel, 70% alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:769 10-0 10
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:769 10-0 10-01	110 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2020	
2	NDC:769 10-0 10-02	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/29/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC mono graph not final	part333A	03/29/2020	

Labeler - A&H Branded Products, LLC (803413942)

Establishment

Name	Address	ID/FEI	Business Operations
A&H Branded Products, LLC		803413942	manufacture(76910-010)

Revised: 4/2020

A&H Branded Products, LLC