

HAND SANITIZER- alcohol gel

RANG DONG S.P.CA MANUFACTURING - CONSTRUCTION - TRADING COMPANY LIMITED

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) (80%, 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 (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. 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 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria on the skin. 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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away.

Directions

- Get a sufficient amount of products onto hands.
- Briskly rub hands together until dry.
- Supervise children under 6 years old in the use of this product.

Other information

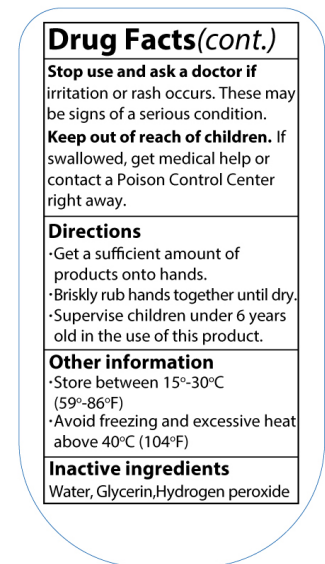
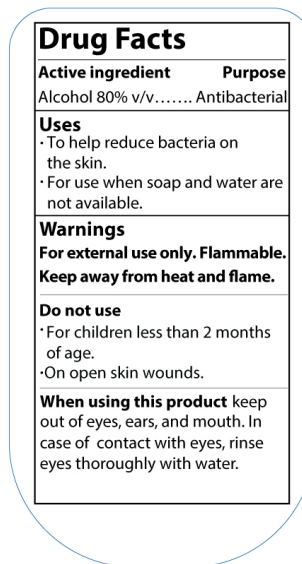
- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

29.5 mL NDC: 80060-100-01



59 mL NDC: 80060-100-02



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

2 fl oz / 59 ml

MADE IN VIETNAM
Hotline: (+84) 901 440 884



Manufactured by:
RANG DONG S.P.CA
CO., LTD
440/6-8 Thong Nhat
Street, Ward 16,
Go Vap District, Ho
Chi Minh City,
Vietnam.
Tel:
(+84 28) 3916 0771

www.rangdongspca.com
LOT NO, MFD & EXP: See on the bottle

Drug Facts	
Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial
Uses	
<ul style="list-style-type: none"> To help reduce bacteria on the skin. For use when soap and water are not available. 	
Warnings	
For external use only. Flammable. Keep away from heat and flame.	
Do not use	
<ul style="list-style-type: none"> For 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.	

Drug Facts(cont.)	
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	
<ul style="list-style-type: none"> Get a sufficient amount of products onto hands. Briskly rub hands together until dry. Supervise children under 6 years old in the use of this product. 	
Other information	
<ul style="list-style-type: none"> Store between 15°-30°C (59°-86°F) Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients	
Water, Glycerin, Hydrogen peroxide	

88.5 mL NDC: 80060-100-03




ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

3 fl oz / 88.5 ml

Drug Facts	
Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial
Uses	
<ul style="list-style-type: none"> To help reduce bacteria on the skin. For use when soap and water are not available. 	
Warnings	
For external use only. Flammable. Keep away from heat and flame.	
Do not use	
<ul style="list-style-type: none"> For 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.	
Directions	
<ul style="list-style-type: none"> Get a sufficient amount of products onto hands. Briskly rub hands together until dry. Supervise children under 6 years old in the use of this product. 	
Other information	
<ul style="list-style-type: none"> Store between 15°-30°C (59°-86°F) Avoid freezing and excessive heat above 40°C (104°F) 	
Inactive ingredients	
Water, Glycerin, Hydrogen peroxide	

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LOT NO, MFD & EXP: See on the bottle



8 935020 812826

MADE IN VIETNAM

118 mL NDC: 80060-100-04

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

4 fl oz / 118 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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Do not use

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- Briskly rub hands together until dry.
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Other information

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

Inactive ingredients

Water, Glycerin, Hydrogen peroxide

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LOT NO, MFD & EXP: See on the bottle



MADE IN VIETNAM

236.59 mL NDC: 80060-100-05

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

8 fl oz / 236.59 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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

Do not use

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

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Directions

- Get a sufficient amount of products onto hands.
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- Supervise children under 6 years old in the use of this product.

Other information

- Store between 15°-30°C (59°-86°F)
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Inactive ingredients

Water, Glycerin, Hydrogen peroxide

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LOT NO, MFD & EXP: See on the bottle



8 935020 812765

MADE IN VIETNAM

295 mL NDC: 80060-100-06

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

10 fl oz / 295 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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

Do not use

- For children less than 2 months of age.
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Other information

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

Inactive ingredients

Water, Glycerin, Hydrogen peroxide

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Hotline: (+84) 901 440 884

LOT NO, MFD & EXP: See on the bottle

MADE IN VIETNAM

354 mL NDC: 80060-100-07

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

12 fl oz / 354 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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

Do not use

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Directions

- Get a sufficient amount of products onto hands.
- Briskly rub hands together until dry.
- Supervise children under 6 years old in the use of this product.

Other information

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

Inactive ingredients

Water, Glycerin, Hydrogen peroxide

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LOT NO, MFD & EXP: See on the bottle



MADE IN VIETNAM

500 mL NDC: 80060-100-08

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

17 fl oz / 500 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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Do not use

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Other information

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Inactive ingredients

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Hotline: (+84) 901 440 884

LOT NO, MFD & EXP: See on the bottle

MADE IN VIETNAM

590 mL NDC: 80060-100-09

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

20 fl oz / 590 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
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Warnings

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Do not use

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Inactive ingredients

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LOT NO, MFD & EXP: See on the bottle

MADE IN VIETNAM

975 mL NDC: 80060-100-10

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

33 fl oz / 975 ml

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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Do not use

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Other information

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- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

Water, Glycerin, Hydrogen peroxide

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Hotline: (+84) 901 440 884

LOT NO, MFD & EXP: See on the bottle

MADE IN VIETNAM

5000 mL NDC: 80060-100-11

pax

HAND WASH - ANTIBACTERIAL



ADVANCED
INSTANT HAND SANITIZER
KILLS MOST HOUSEHOLD GERMS

169 fl oz / 5 Litre

Drug Facts

Active ingredient	Purpose
Alcohol 80% v/v.....	Antibacterial

Uses

- To help reduce bacteria on the skin.
- For use when soap and water are not available.

Warnings

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

Do not use

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Other information

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- Avoid freezing and excessive heat above 40°C (104°F)

Inactive ingredients

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Hotline: (+84) 901 440 884

LOT NO, MFD & EXP: See on the bottle



MADE IN VIETNAM

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80060-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	80 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80060-100-01	29.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	

2	NDC:80060-100-02	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
3	NDC:80060-100-03	88.5 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
4	NDC:80060-100-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
5	NDC:80060-100-05	236.59 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
6	NDC:80060-100-06	295 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
7	NDC:80060-100-07	354 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
8	NDC:80060-100-08	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
9	NDC:80060-100-09	590 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
10	NDC:80060-100-10	975 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	
11	NDC:80060-100-11	5000 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/11/2020	

Labeler - RANG DONG S.P.CA MANUFACTURING - CONSTRUCTION - TRADING COMPANY LIMITED (555830568)

Registrant - RANG DONG S.P.CA MANUFACTURING - CONSTRUCTION - TRADING COMPANY LIMITED (555830568)

Establishment

Name	Address	ID/FEI	Business Operations
RANG DONG S.P.CA MANUFACTURING - CONSTRUCTION - TRADING COMPANY LIMITED		555830568	manufacture(80060-100)

Revised: 10/2020

RANG DONG S.P.CA MANUFACTURING - CONSTRUCTION - TRADING COMPANY LIMITED