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.

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

- Get a sufficient amount of products onto hands.
- Brisky 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)

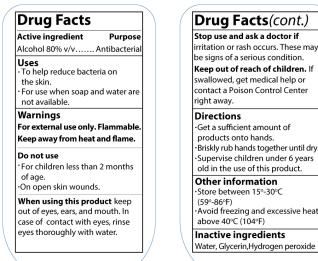
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

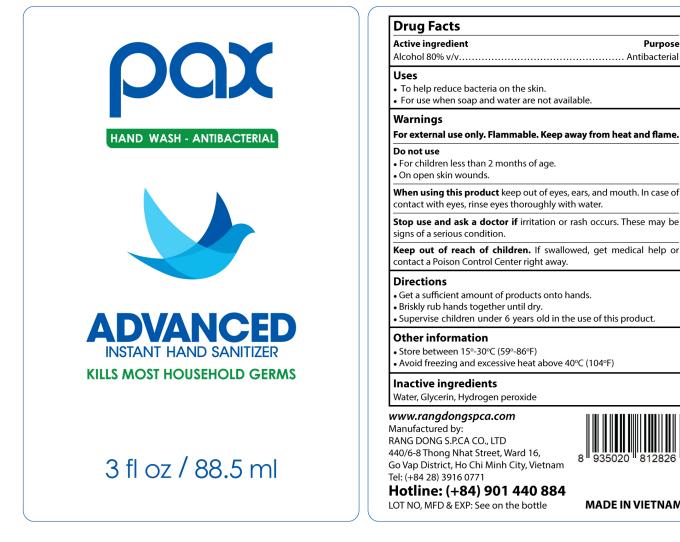
29.5 mL NDC: 80060-100-01







88.5 mL NDC: 80060-100-03



Drug Facts Drug Facts(cont.) Stop use and ask a doctor if Active ingredient Purpose irritation or rash occurs. These may Alcohol 80% v/v..... Antibacterial be signs of a serious condition. Uses • To help reduce bacteria on Keep out of reach of children. If swallowed, get medical help or the skin. For use when soap and water are contact a Poison Control Center not available. right away. Warnings Directions For external use only. Flammable Get a sufficient amount of products onto hands. Keep away from heat and flame. Briskly rub hands together until dry Do not use Supervise children under 6 years For children less than 2 months old in the use of this product. of age. Other information On open skin wounds. Store between 15°-30°C When using this product keep (59°-86°F) out of eyes, ears, and mouth. In Avoid freezing and excessive heat case of contact with eyes, rinse above 40°C (104°F) eyes thoroughly with water. Inactive ingredients Water, Glycerin, Hydrogen peroxide

MADE IN VIETNAM

Purpose



236.59 mL NDC: 80060-100-05

Drug Facts

Active ingredient

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.

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

- 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

www.rangdongspca.com

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 Hotline: (+84) 901 440 884

LOT NO, MFD & EXP: See on the bottle



Purpose



295 mL NDC: 80060-100-06

Drug Facts Active ingredient Purpose

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.

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

- 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





HAND WASH - ANTIBACTERIAL





10 fl oz / 295 ml

354 mL NDC: 80060-100-07

Drug Facts

Active ingredient

Alcohol 80% v/v.....

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.

..... Antibacterial

Do not use

• 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

- 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



Purpose







12 fl oz / 354 ml

500 mL NDC: 80060-100-08

Drug Facts

Active ingredient

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.

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

• 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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Hotline: (+84) 901 440 884 LOT NO, MFD & EXP: See on the bottle



Purpose



590 mL NDC: 80060-100-09

Drug Facts

Active ingredient

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.

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

- 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)
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Inactive ingredients Water, Glycerin, Hydrogen peroxide

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Hotline: (+84) 901 440 884 LOT NO, MFD & EXP: See on the bottle



Purpose





20 fl oz / 590 ml

Drug Facts

Active ingredient

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.

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

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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Hotline: (+84) 901 440 884

LOT NO, MFD & EXP: See on the bottle



Purpose

MADE IN VIETNAM



Drug Facts

Active ingredient

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.

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

- 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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Purpose

Hotline: (+84) 901 440 884 LOT NO, MFD & EXP: See on the bottle

MADE IN VIETNAM

			Drug Facts			
			Active ingredient			Purpo
		λ	Uses • To help reduce back			Antibacte
			For use when soap and water are not available.			
HAND	WASH - ANTIBAG	CTERIAL	Warnings For external use only. Flammable. Keep away from heat and flame.			
			Do not use • For children less tha • On open skin wound			
			When using this pro eyes thoroughly with		d mouth. Ir	a case of contact with eyes, rinse
				doctor if irritation or rash occ	urs. These	may be signs of a serious
~			Keep out of reach	of children. If swallowed, get	t medical	help or contact a Poison Contro
			Center right away. Directions			
			 Get a sufficient amo Briskly rub hands tog 	ount of products onto hands. gether until dry. under 6 years old in the use of 1	this produ	ct.
			Other informatio • Store between 15°-3	on 30°C (59°-86°F)		
INSTANT HAND SANITIZER KILLS MOST HOUSEHOLD GERMS			Inactive ingredie		°F)	
			Water, Glycerin, Hydro www.rangdongsp		11	
			Manufactured by: RANG DONG S.P.CA CO			
		4	440/6-8 Thong Nhat S Go Vap District, Ho Ch	Street, Ward 16,		
169	floz/5	Litro	Tel: (+84 28) 3916 077 Hotline: (+84)	1	8	935020 812901
			LOT NO, MFD & EXP: S			MADE IN VIETN/
	ZER					
ılcohol gel						
HAND SANITIZ alcohol gel Product Informati Product Type		HUMAN OTC DRUG	Ite m Code	e (Source)	ND	C:80060-100
alcohol gel Product Informati Product Type	on		Item Code	e (Source)	ND	PC:80060-100
nlcohol gel Product Informati	on	HUMAN OTC DRUG TOPICAL	Item Code	e (Source)	ND	PC:80060-100
alcohol gel Product Informati Product Type	on	TOPICAL	Item Code	(Source)	ND	DC:80060-100
lcohol gel Product Informati Product Type Route of Administrati	on on Active Moie	TOPICAL	Item Code	e (Source) Basis of Stren		0C:80060-100 Strength
llcohol gel Product Informati Product Type Route of Administrati Active Ingredient /	on ion Active Moie Ingred	TOPICAL	Item Code			
llcohol gel Product Informati Product Type Route of Administrati Active Ingredient /	on ion Active Moie Ingred	TOPICAL ety lient Name	Item Code	Basis of Stren		Strength
Ncohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99)	on ion Active Moid Ingred 58 V90M) (ALC	TOPICAL ety lient Name	Item Code	Basis of Stren		Strength
llcohol gel Product Informati Product Type Route of Administrati Active Ingredient /	on on Active Moie Ingred 58 V90M) (ALC	TOPICAL ety lient Name COHOL - UNII:3K9958V90M)	Item Code	Basis of Stren	gth	Strength 80 mL in 100 mL
Ilcohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99) Inactive Ingredien	on ion Active Moie Ingred 58 V90 M) (ALC Its Ing	TOPICAL ety lient Name	Item Code	Basis of Stren ALCOHOL	g th St	Strength 80 mL in 100 mL trength
Ilcohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99 Inactive Ingredien GLYCERIN (UNII: PDC6	on on Active Moie Ingred 58 V90M) (ALC Its Ing A3C00X)	TOPICAL ety lient Name COHOL - UNII:3K9958V90M) gredient Name	Item Code	Basis of Stren ALCOHOL 1.45 mL in	gth St n 100 m	Strength 80 mL in 100 mL trength nL
Ilcohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99) Inactive Ingredien	on ion Active Moid Ingred 58 V90M) (ALC its Ing A3C0OX) E (UNII: BBX06	TOPICAL ety lient Name COHOL - UNII:3K9958V90M) gredient Name	Item Code	Basis of Stren ALCOHOL	gth St n 100 m	Strength 80 mL in 100 mL trength
Ilcohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99) Inactive Ingredien GLYCERIN (UNII: PDC6 HYDRO GEN PERO XIDI	on ion Active Moid Ingred 58 V90M) (ALC its Ing A3C0OX) E (UNII: BBX06	TOPICAL ety lient Name COHOL - UNII:3K9958V90M) gredient Name	Item Code	Basis of Stren ALCOHOL 1.45 mL in	gth St n 100 m	Strength 80 mL in 100 mL trength
Ilcohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99 Inactive Ingredien GLYCERIN (UNII: PDC6 HYDROGEN PEROXIDI WATER (UNII: 059QF0F	on ion Active Moid Ingred 58 V90M) (ALC its Ing A3C0OX) E (UNII: BBX06	TOPICAL ety lient Name COHOL - UNII:3K9958V90M) gredient Name	Item Code	Basis of Stren ALCOHOL 1.45 mL in	gth St n 100 m	Strength 80 mL in 100 mL trength
lcohol gel Product Informati Product Type Route of Administrati Active Ingredient/ ALCOHOL (UNII: 3K99) Inactive Ingredien GLYCERIN (UNII: PDC6 HYDRO GEN PERO XIDI	on ion Active Moid Ingred 58 V90M) (ALC its Ing A3C0OX) E (UNII: BBX06	TOPICAL ety lient Name COHOL - UNII:3K9958V90M) gredient Name	Item Code	Basis of Stren ALCOHOL 1.45 mL in	gth St n 100 n in 100	Strength 80 mL in 100 mL trength nL

29.5 mL in 1 BOTTLE; Type 0: Not a Combination Product 08/11/2020

 NDC:80060-100-

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								
N	Aarketing Categor	y Application Number or Monograph Citation	Marketing Start Date	Marketing End Date				
ОТ	°C monograph not fina	al part333A	08/11/2020					

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

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

Establishment						
Name	Address		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