

HAND SANITIZER- alcohol gel
SKYMAX VIETNAM 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.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Recommended for repeated use.

For handwashing to decrease bacteria on the skin.

Warnings

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

Do not use

- in the eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a doctor if irritation and redness develop and persist for more than 72 hours.

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

- We hands thoroughly with product
- Brisky rub hands together until dry
- Supervise children under 6 years in the use of this product.

Other information

- May discolor certain fabrics
- Store at the normal temperature

Inactive ingredients

aqua, carbomer 940, trolamine, hydro peroxide, glycerin, fragrance, vitamin e

Package Label - Principal Display Panel

100 mL NDC: 81650-100- 01



250 mL NDC: 81650-100- 02



SKY CLEAN

Drug facts

Active ingredient	Purpose
Alcohol	72%

User - Recommended for repeated use.
- For handwashing to decrease bacteria on the skin.

Warnings
For external use only

Flammable, keep away from heat and flame.
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Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

Direction - Wet hands thoroughly with product
- Briskly rub hands together until dry - Supervise children under 6 years in the use of this product.

Other information - May discolor certain fabrics
- Store at the normal temperature.

Inactive ingredients

Aqua	20,78%
Carbomer FD 2015	0,33%
Triethanolamine	0,19%
Hydro peroxide	0,41%
Glycerin	0,15%
Fragrance	0,12%
Vitamin E	0,02%

BRANCH SKYMAX VIETNAM Co., Ltd
22A Phan Van Bay Street - Hiep Phuoc Industrial Park
Ho Chi Minh City - Vietnam
Web: skyclean.vn | E: info@skyclean.vn
Tel: (+8428) 66501091 - 66501092

SKYMAX[®]

Hotline: (+8428) 66501091 Made in VIETNAM
LOT NO: EXP: MFG:

8 935262 15000171

Consider registration number
VIETNAM MEDICINE-CHEMICAL-368-8

500 mL NDC: 81650-100- 03



SKY CLEAN

Drug facts

Active ingredient	Purpose
Alcohol	72%

User - Recommended for repeated use.
- For handwashing to decrease bacteria on the skin.

Warnings
For external use only

Flammable, keep away from heat and flame.
Do not use in the eyes. In case of contact, rinse eyes thoroughly with water.
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Keep out of reach of children if swallowed, get medical help or contact a Poison Control Center right away.

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VIETNAM MEDICINE-CHEMICAL-368-8

1000 mL NDC: 81650-100- 04


NEW
SKYCLEAN

ANTIBACTERIAL HAND SANITIZER

HAND WASH GEL
WASH FOR HANDS

99,9%

Clean Hands
Pleasant Scent
Antimicrobial
Deodorant


CHERRY FLAVOR

Capacity 35.2 fl.OZ/1000ml

SKYCLEAN

Drug facts

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LOT NO: EXP: MFG:



Circulation registration number
VIETNAM MEDICINE-CHEMICAL-08-06-28

HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81650-100
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	0.02 mL in 100 mL
TROLAMINE (UNII: 9O3K93S3TK)	0.19 mL in 100 mL
CARBOMER 940 (UNII: 4Q93RCW27E)	0.33 mL in 100 mL
GLYCERIN (UNII: PDC6A3C0OX)	0.15 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.41 mL in 100 mL
WATER (UNII: 059QF0K00R)	20.78 mL in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81650-100-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2021	
2	NDC:81650-100-02	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2021	
3	NDC:81650-100-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2021	
4	NDC:81650-100-04	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/01/2021	

Labeler - SKYMAX VIETNAM COMPANY LIMITED (555655220)

Registrant - SKYMAX VIETNAM COMPANY LIMITED (555655220)

Establishment

Name	Address	ID/FEI	Business Operations
SKYMAX VIETNAM COMPANY LIMITED		556548577	manufacture(81650-100)

Revised: 3/2021

SKYMAX VIETNAM COMPANY LIMITED