HAND SANITIZER- alcohol gel Audy Global Enterprises 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.

Simply Natural Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 67%

Purpose

Antiseptic

Use

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

Warnings

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

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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 redness develop.

If condition persists for more than 72 hours.

Directions

- Place enough product in your palm to thoroughly cover your hands
- Children under 6 years of age should be supervised when using this product
- Rub hands together briskly until dry

Other information

Protect the product in this container

from excessive heat and direct sun.

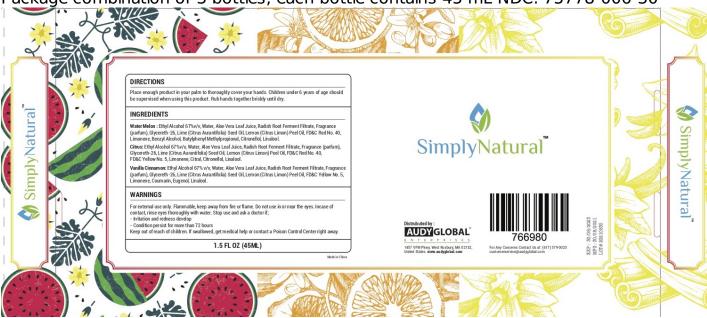
- Store below 104°F (40°C)
- May discolor certain fabrics.

Inactive ingredients

Water, Aloe Barbadensis Leaf Juice, Radish Root Ferment Filtrate, Fragrance (parfum), Glycereth-26, Lime (Citrus Aurantifolia) Seed Oil, Lemon (Citrus Limon) Peel Oil, FD&C Red No. 40, FD&C Yellow No. 5, Limonene, Citral, Citronellol, Linalool

Package Label - Principal Display Panel

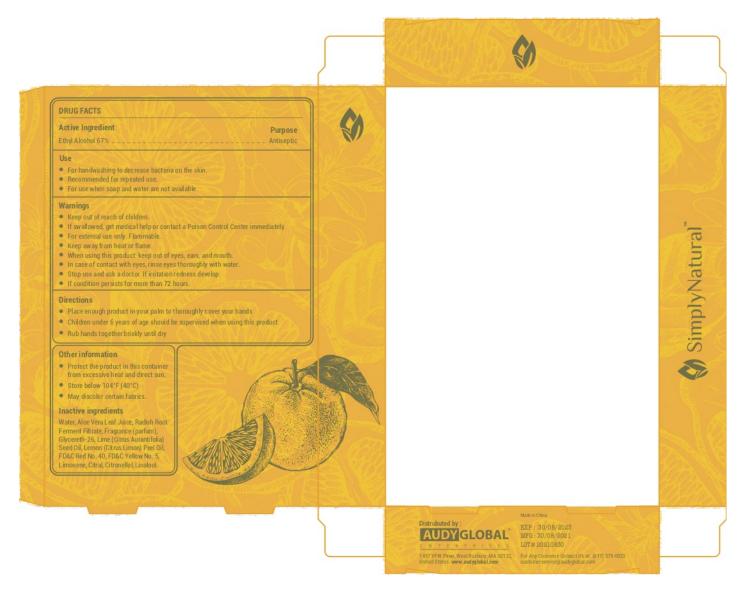
Package combination of 3 bottles, each bottle contains 45 mL NDC: 75778-006-30



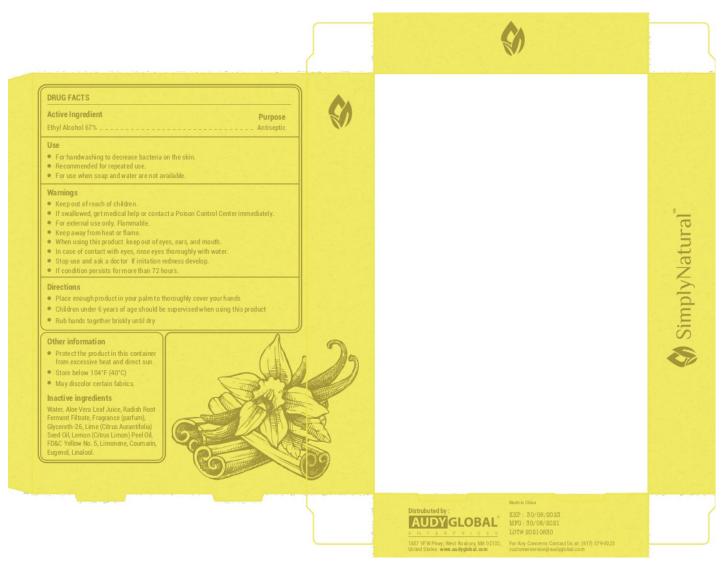
Bottle 1 of 3, Water Melon scent 45 mL NDC: 75778-006-30

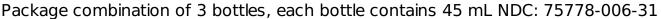


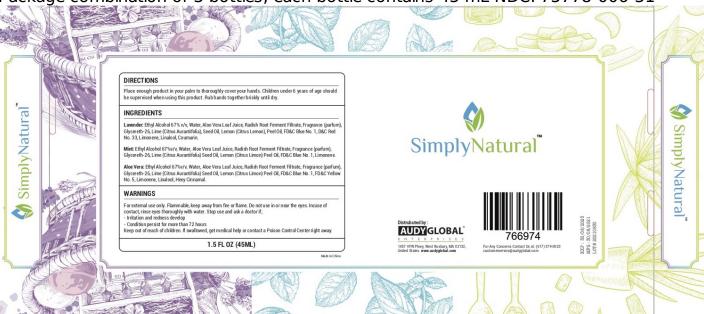
Bottle 2 of 3, Citrus scent 45 mL NDC: 75778-006-30



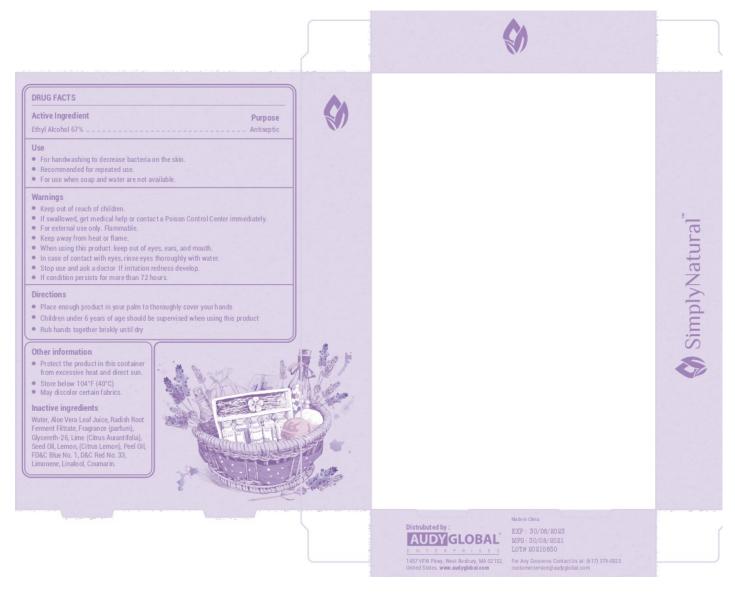
Bottle 3 of 3, Vanilla Cinnamon scent 45 mL NDC: 75778-006-30



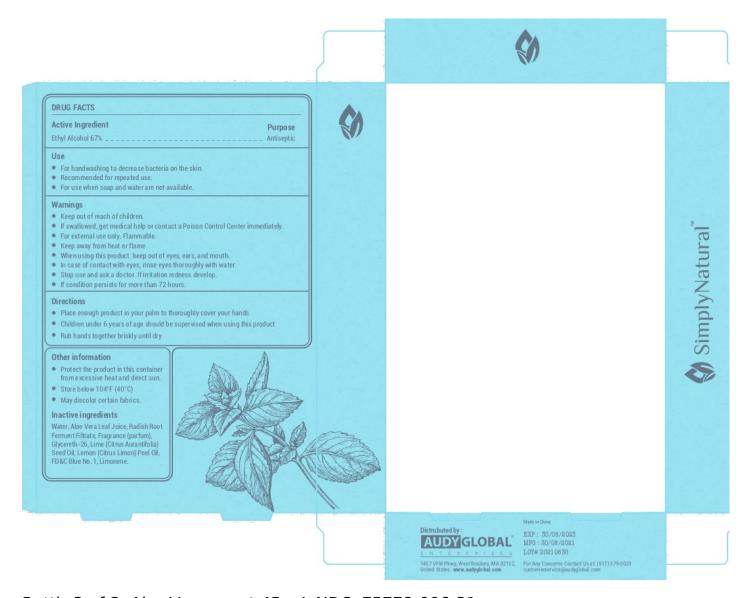




Bottle 1 of 3, Lavender scent 45 mL NDC: 75778-006-31



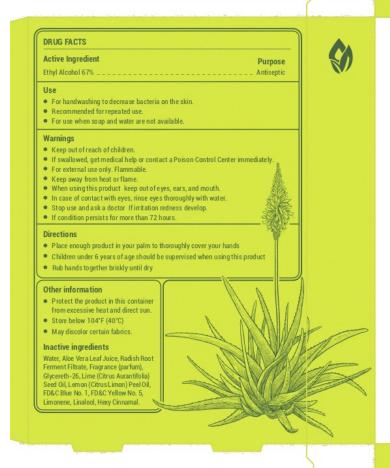
Bottle 2 of 3, Mint scent 45 mL NDC: 75778-006-31



Bottle 3 of 3, Aloe Vera scent 45 mL NDC: 75778-006-31









HAND SANITIZER

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:75778-006

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M) ALCOHOL 67 mL in 100 mL

Inactive Ingredients

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Ingredient Name	Strength			
LIMONENE, (+)- (UNII: GFD7C86Q1W)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
LEUCONOSTOC/RADISH ROOT FERMENT FILTRATE (UNII: D2QHA03458)				

WATER (UNII: 059QF0KO0R)	
CITRUS AURANTIFOLIA SEED OIL (UNII: EW089HAI77)	
LEMON OIL, TERPENELESS (UNII: X69W83NI7V)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERETH-26 (UNII: NNE56F2N14)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
CITRAL (UNII: T7EU0O9VPP)	
.BETACITRONELLOL, (R)- (UNII: P010UT964K)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:75778-006- 30	1 in 1 PACKAGE, COMBINATION	10/25/2021			
1		3 in 1 PACKAGE				
1		45 mL in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:75778-006- 31	1 in 1 PACKAGE, COMBINATION	10/25/2021			
2		3 in 1 PACKAGE				
2		45 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	05/14/2021			

Labeler - Audy Global Enterprises Inc. (079171473)

Establishment					
Name	Address	ID/FEI	Business Operations		
Zhongrong Technology Corporation Ltd.		529575698	manufacture(75778-006)		

Revised: 10/2021 Audy Global Enterprises Inc.