

HAND SANITIZER- hand sanitizer gel
Raining Rose, 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.

Ethanol 70%

Antimicrobial

Hand Sanitizer to help reduce bacteria on the skin. Recommended for repeated use.

Warnings• For external use only

- Flammable, keep away from fire or flame
- Do not use in eyes. In case of eye contact flush thoroughly with water and seek medical attention.
- Stop use and ask doctor if irritation and redness develop and persists for more than 72 hours.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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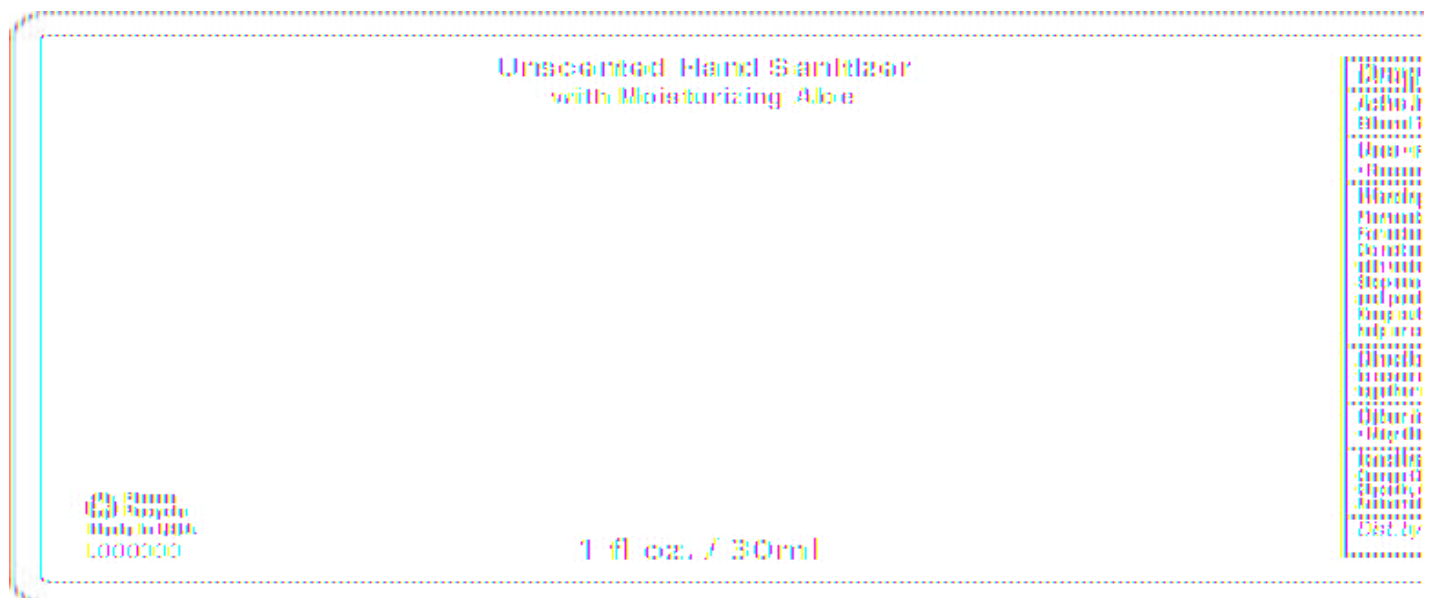
Directions

- Dispense an adequate amount in your palm to cover all surfaces of hands completely.
- Rub hands together until dry. • Does not require rinsing.

Other Information

- Do not store above 105°F.
- May discolor some fabrics.

Inactive Ingredients: Water (Aqua), Isopropyl Alcohol, Orange Oil, Acrylates/C10-30 Akyl Acrylate Crosspolymer, Glycerin, Aloe Barbadensis Leaf Juice, Panthenol, Aminomethyl Propanol.



HAND SANITIZER
hand sanitizer gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65692-2050
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
ORANGE OIL (UNII: AKN3KSD11B)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PANTHENOL (UNII: WV9CM0O67Z)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CITRUS	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:65692-2050-1	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	04/30/2020	

Labeler - Raining Rose, Inc (083819404)**Registrant** - Raining Rose, Inc (083819404)**Establishment**

Name	Address	ID/FEI	Business Operations
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Aire-Master America, Inc.		057897381	manufacture(65692-2050)
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Establishment

Name	Address	ID/FEI	Business Operations
Raining Rose, Inc		083819404	label(65692-2050) , pack(65692-2050)

Revised: 4/2020

Raining Rose, Inc