PLANEAIRE HANDS HAND SANITIZER- ethyl alcohol gel EverywhereAire LLC

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.

PlaneAire Hands gel Lemon Carrotseed hand sanitizer

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) (70%, 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
- c. Sterile distilled water or boiled cold water
- d. Other inactive ingredients.

Active Ingredient(s)

Alcohol 70% v/v.

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

on open wounds or near eyes.

In case of contact with eyes, rinse eyes thoroughly with water.

Stop use if irritation or rash occurs. If conditon persists for more than 72 hours, consult a doctor

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

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Directions

- Wet hands thoroughly with product, rub hands, and allow to dry without wiping
- For children under 6 years of age, use only under adult supervision to avoid swallowing
- not recommended for infants

Other information

- store between 15-30C (59-86F)
- do not store above 105F
- avoid freezing
- may discolor some fabrics
- may be harmful to some wood finishes and plastics

Inactive ingredients

aloe vera inner leaf, green tea extract, carbomer, glycerin, lemon oil, carrot seed oil, sodium hydroxide, water

Package Label - Principal Display Panel

Antiseptic

Made With Aloe Vera and **Green Tea Extract**

REFRESHING LEMON CARROT SCENT

2 FL. OZ (60mL)

60 mL NDC: 80335-106-02

Drug Facts

Active Ingredient

Purpose

Ethyl Alcohol 70% v/v...... Antiseptic

Uses ■ helps reduce bacteria that potentially can cause disease for use when soap and water are not available.

Warnings

For external use only—on hands.

Flammable. Keep away from heat and flame.

Do not use ■ on open wounds or near eyes. In case of contact with eyes, rinse thoroughly with water.

Discontinue use if ■ irritation or redness develops. ■ If condition persists for more than 72 hours, consult a doctor.

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

Directions

■ Wet hands thoroughly with product, rub hands, and allow to dry without wiping. ■ For children under 6 years of age, use only under adult supervision to avoid swallowing. ■ not recommended for infants

Other Information

- store between 15-30°C (59-86°F). ■do not store above 105°F ■ avoid freezing ■ may discolor some fabrics
- may be harmful to some wood finishes and plastics

Inactive Ingredients

Aloe Vera (Inner Leaf), Carbomer, Glycerin, Green Tea Extract (Camellia Sinensis Leaf), Lemon Carrot Seed Oil Blend (Citrus Limon and Daucus Carota L. Oils), Sodium Hydroxide, Water (Aqua)



Manufactured for EverywhereAire LLC, Princeton, NJ

Made in the USA

PlaneAire.com 1-800-572-5805

PLANEAIRE HANDS HAND SANITIZER

TOPICAL

ethyl alcohol gel

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Route of Administration

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80335-106

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	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)		
LEMON OIL (UNII: 19GRO824LL)		
CARROT SEED OIL (UNII: 595AO13F11)		
CARBOMER 980 (UNII: 4Q93RCW27E)		
SODIUM HYDROXIDE (UNII: 55X04QC32I)		
GLYCERIN (UNII: PDC6A3C0OX)		
ALOE VERA LEAF POLYSACCHARIDES (UNII: W210437517)		
WATER (UNII: 059QF0KO0R)		

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
			60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	12/21/2020	

Marketing In	Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	12/21/2020		

Labeler - EverywhereAire LLC (117635273)

Registrant - EverywhereAire LLC (117635273)

Revised: 10/2021 EverywhereAire LLC