DRGRAFHANDSANITIZER- alcohol solution Cospro Development Corp

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 rub manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Rub Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand rub 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%, 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.

Active Ingredient(s)

Alcohol 70%. Purpose: Antiseptic

Purpose

Antiseptic, Hand Rub

Use

Hand Sanitizer to help reduce bacteria on the skin

Warnings

For external use only. Flammable. Keep away from fire and flame

Do not use

• in or near eyes.

When using this product do not use in or near eyes. If contact occurs, rinse eyes thoroughly with water. Stop use and ask a doctor if irritation or rash appears and lasts.

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 appears and lasts.

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

Directions

- Put enough product in your palm to cover hands and rub hands together briskly until dry.
- Children under 6 years of age should be supervised when using this product.

Other information

• Store below 110F (43C)

Inactive ingredients

deionized water, gylcerin, polysorbate 20, aloe barbadensis leaf juice, orange peel oil, tocopheryl acetate, maltodextrin, fragrance

Package Label - Principal Display Panel

Dr. Jeannette Graf, M.D

Dermatologic Formula

SANITIZER HAND

70% Ethyl Alcohol

- Infused with Aloe Vera, Vitamin E & Glycerin
- Refreshing Scent

100 ml **e** 3.4 fl oz

Drug Facts

Active ingredient

Purpose

Use • Hand sanitizer to help reduce bacteria on the skin

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Other Information • Store Below 110°F (43°C)

Polysorbate 20, Aloe Barbadensis Leaf Juice, Citrus Aurantium Dulcis (Orange) Peel Oil, Tocopheryl Acetate, Maltodextrin, Parfum Inactive Ingredients Aqua (Deionized Water), Glycerin,

Questions? 610-376-4006

Dr. Jeannette Graf, MD Hand Sanitizer

with Aloe Vera, Vitamin E and Glycerin to keep with our plant-based hand sanitizers. Infused Never be without personal protection! Shield your hands from germs naturally

your hands while leaving them feeling Now you can cleanse and protect your hands feeling silky smooth. hydrated & healthy. CRUELTY FREE - No Animal Testing, No Animal Ingredients



Made In USA for Dr. Jeannette Graf M.D. by Cospro Development, Reading, PA. 19601

alcohol solution

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:46607-119	
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		
GLYCERIN (UNII: PDC6A3C0OX)			
POLYSORBATE 20 (UNII: 7T1F30 V5YH)			
WATER (UNII: 059QF0KO0R)			
ALOE (UNII: V5VD430 YW9)			
MALTO DEXTRIN (UNII: 7CVR7L4A2D)			
ORANGE PEEL (UNII: TI9 T76 XD44)			

l	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:46607-119-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/10/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	06/10/2020	

Labeler - Cospro Development Corp (785638821)

Registrant - Cospro Development Corp (785638821)

Establishment				
Name	Address	ID/FEI	Business Operations	
Cospro Development Corp		785638821	manufacture(46607-119), label(46607-119), pack(46607-119)	

Revised: 6/2020 Cospro Development Corp