HYDRATING HAND SAINTIZER- ethyl alcohol gel Monfitello 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.

Hydrating Hand Sanitizer:Gel

Ethyl Alcohol 70%

Purpose -Antiseptic Skin cleanser

Use

• Antiseptic Skin cleanser

Warnings

Keep away from open flame & sources of heat.

For extenal use only.

Keep out of children

If accidently swallowed, call a posion control center or get medical help right away.

Do not get into eyes

If contact occurs, rinse thoroughly with water

- Children, adolescents and adults 2 years and over.
- for occasional and personal domestic use
- supervise children when they use this product.
- Place enough product on your plam to thoroughly cover your hands.
- rub thoroughly into hands for at least 30 seconds
- Allow to dry.

Other Information

- May discolor certain fabrics or surfaces
- do not store above 110 F (43 C)

Distilled Water, Vegetable Glycerin, Carbomer Polymer, Triethanolamine, Grapefruit essential oil blend, Aloe Barbadensis Leaf Juice, Vitamin E Extract, Denatonium Benzoate

DRUG FACTS

Active Ingredients.....Purpose
Ethyl Alcohol 70% w/w.....Antiseptic

Use

Helps reduce bacteria on the skin.

Warnings

Flammable. Keep away from fire or flame.

For external use only.

When using this product do not use in or near eyes. In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or redness develops.

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

Directions ■Apply palmful to hands. ■ Rub hands together viorously until dry. ■ Supervise children in the use of this product.

Other information

■ Store below 110°F (43°). ■ May discolour certain fabrics or surfaces.

Inactive ingredients:

Water, Vegetable Glycerin, Carbomer Polymer, Aloe Barbensis Leaf Juice, Citrus Paradisi (Grapefruit) Oil, Triethanolamine, Vit E Extract



hydrating HAND

Désinfectant hydratant pour les mains



plant-based + essential oils à base végétale + huiles essentielles

70% ALCOHOL ALCOOL 70% ALOES

PINK GRAPEFRUIT | PAMPLEMOUSSE

GEL NPN 80099915 60 mL | 2 fl oz



HYDRATING HAND SAINTIZER

ethyl alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81170-001
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	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)		
TROLAMINE (UNII: 9O3K93S3TK)		
.ALPHATO CO PHERO L ACETATE (UNII: 9E8X80D2L0)		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)		
GLYCERIN (UNII: PDC6 A3C0 OX)		
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)		
WATER (UNII: 059QF0KO0R)		
GRAPEFRUIT OIL (UNII: YR377U58W9)		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:81170-001-60	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2020	
2 NDC:81170-001-12	125 mL in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/20/2020		

Labeler - Monfitello Inc (243794851)

Revised: 11/2020 Monfitello Inc