

PPE BUDDY- ethyl alcohol gel
Tecnología en Sachets, S.A. de C.V.

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.

Active Ingredient

Ethyl alcohol 70%

Purpose

Antiseptic

Use

Hand sanitizer to help reduce bacteria on the skin.

Warnings

Flammable. Keep away from heat or flame

For external use only.

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

Stop use and ask a doctor if irritation or rash appears & last.

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

Directions

Place enough product on hands to cover all surfaces. Rub hands together until dry.
Supervise children under 6 years of age when using this product to avoid swallowing

Other information

Store between 15-30°C (59-86F)

Avoid freezing and excessive heat above 40°C (104F)

Inactive ingredients

Glycerin, water (Aqua), Triethanolamine, carbomer

Drug



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Model S001



PPEBuddy

Hand sanitizer.

.068 OZ (2 mL)

DESIGNED & DISTRIBUTED WITH ❤️ IN THE USA

PPE BUDDY

ethyl alcohol gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:80014-001

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	
WATER (UNII: 059QF0K00R)				
GLYCERIN (UNII: PDC6A3C0OX)				
TROLAMINE (UNII: 9O3K93S3TK)				
CARBOMER HOMO POLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80014-001-01	2 mL in 1 PACKET; Type 0: Not a Combination Product	08/14/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	08/14/2020		

Labeler - Tecnología en Sachets, S.A. de C.V. (951580550)

Establishment

Name	Address	ID/FEI	Business Operations
Gm Integraciones y Soluciones en Control, S.A. de C.V.		812758685	manufacture(80014-001)

Establishment

Name	Address	ID/FEI	Business Operations
Tecnología en Sachets, S.A. de C.V.		951580550	repack(80014-001)

Revised: 8/2020

Tecnología en Sachets, S.A. de C.V.