

## **PIPERWAIHANDSANITIZERMINTY- alcohol solution**

### **Piperwai, 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.*

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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) (62%, 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.

### **Active Ingredient(s)**

Alcohol 62%. Purpose: Antiseptic

### **Purpose**

Antiseptic, Hand Rub

### **Use**

Reduces the amount of bacteria on hands. Recommended for repeated use.

### **Warnings**

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

### **Do not use**

avoid contact with eyes.

In case of contact, flush thoroughly with water.

When using this product avoid contact with eyes. In case of contact, flush thoroughly with water.

Stop use and ask a doctor if irritation occurs.

Stop use and ask a doctor if irritation or rash occurs.

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

## Directions

Pump onto dry hands as needed coating evenly.  
Allow to dry without wiping  
Supervise children under 6 years old  
Not recommended for infants.

## Other information

Do not store above 105F

## Inactive ingredients

Water, Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Mentha Piperita (Peppermint) Oil, Aminomethyl Propanol

## Package Label - Principal Display Panel

<p><b>PIPERWAI</b> Our moisturizing rinse-free cleansing hand sanitizer gel is formulated with 62% alcohol sourced from non-GMO sugar cane, soothing Aloe and an invigorating blend of Rosemary and Peppermint giving it a fresh, clean and herbaceous scent.</p> <p>Distributed by PiperWai, LLC Brooklyn, NY 11201 Made in the USA piperwai.com @piperwai</p>   	 <p><b>HAND SANITIZER GEL</b> Minty Fresh Blend   Aloe 62% Non-GMO Alcohol, Vegan, Cruelty-Free 1.7 fl oz / 50 ml</p>	<table border="1"><tr><td colspan="2"><b>Drug Facts</b></td></tr><tr><td><b>Active Ingredient</b></td><td><b>Purpose</b></td></tr><tr><td>Ethyl Alcohol 62%.....</td><td>Antiseptic</td></tr><tr><td colspan="2"><b>Use</b> • Reduces the amount of bacteria on hands. Recommended for repeated use.</td></tr><tr><td colspan="2"><b>Warnings</b> • For external use only. <b>Flammable. Keep away from heat or flame.</b></td></tr><tr><td colspan="2"><b>When using this product</b> • Avoid contact with eyes. In case of contact, flush thoroughly with water.</td></tr><tr><td colspan="2"><b>Stop use and ask doctor if</b> • Irritation occurs.</td></tr><tr><td colspan="2"><b>Keep out of reach of children</b> • If swallowed, get medical help or contact Poison Control Center right away.</td></tr><tr><td colspan="2"><b>Directions</b> • Pump onto dry hands as needed coating evenly • Allow to dry without wiping • Supervise children under 6 years old • Not recommended for infants.</td></tr><tr><td colspan="2"><b>Other information</b> • Do not store above 105°F • May discolor some fabrics.</td></tr><tr><td colspan="2"><b>Inactive ingredients</b> • Water, Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Mentha Piperita (Peppermint) Oil, Aminomethyl Propanol</td></tr></table>	<b>Drug Facts</b>		<b>Active Ingredient</b>	<b>Purpose</b>	Ethyl Alcohol 62%.....	Antiseptic	<b>Use</b> • Reduces the amount of bacteria on hands. Recommended for repeated use.		<b>Warnings</b> • For external use only. <b>Flammable. Keep away from heat or flame.</b>		<b>When using this product</b> • Avoid contact with eyes. In case of contact, flush thoroughly with water.		<b>Stop use and ask doctor if</b> • Irritation occurs.		<b>Keep out of reach of children</b> • If swallowed, get medical help or contact Poison Control Center right away.		<b>Directions</b> • Pump onto dry hands as needed coating evenly • Allow to dry without wiping • Supervise children under 6 years old • Not recommended for infants.		<b>Other information</b> • Do not store above 105°F • May discolor some fabrics.		<b>Inactive ingredients</b> • Water, Glycerin, Aloe Barbadensis Leaf Juice, Carbomer, Rosmarinus Officinalis (Rosemary) Leaf Oil, Mentha Piperita (Peppermint) Oil, Aminomethyl Propanol	
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## PIPERWAIHANDSANITIZERMINTY

alcohol solution

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:81741-111	
<b>Route of Administration</b>	TOPICAL			
<b>Active Ingredient/Active Moiety</b>				
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)		ALCOHOL	62 mL in 100 mL	
<b>Inactive Ingredients</b>				
<b>Ingredient Name</b>			<b>Strength</b>	
ROSEMARY (UNII: IJ67X351P9)				
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)				
PEPPERMINT OIL (UNII: AV092KU4JH)				
GLYCERIN (UNII: PDC6A3C0OX)				
ALOE (UNII: V5VD430YW9)				
WATER (UNII: 059QF0KO0R)				
<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:81741-111-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/31/2021	
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
OTC monograph not final	part333A	03/31/2021		

**Labeler** - Piperwai, LLC (047558690)

**Registrant** - Cospro Development Corp (785638821)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Cospro Development Corp		785638821	manufacture(81741-111) , pack(81741-111) , label(81741-111)