PROBLEND HAND SANITIZER GEL- ethanol gel Seatex, 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.

Formula 27139 Problend

Drug Facts

Active Ingredient Purpose

Ethanol 70% v/v...... Antiseptic

When using this product

Avoid contact with eyes. In case of eye contact, flush eyes with water.

Keep out of reach of children

If swallowed, get medical help or cantact a Poison Control Center right away.

Inactive Ingredients

Water, Glycerin, Polyacrylidc Acid, Fragrance, Dye.

Purpose Section

Antiseptic

Stop Use Section

Stop use and ask a doctor if irritation or redness develops and conditions persist for more than 72 hours.

Indications & Usage Section

Uses: For hand sanitizing to decrease bacteria on the skin.

Dosage and Administation Section

Directions

Place enough product in your palm to thoroughly cover hands. Rub thoroughly over all surfaces of both hands. Rub hands together briskly until dry.

Warnings

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

Label

Muy eficaz en la eliminación de bacterias peligrosas de la piel. Suave con la piel, dejándola limpia y tersa. Sin fragancia. Aroma de primavera de montaña.





PROBLEND 4



Highly effective at removing dangerous bacteria from skin. Gentle on skin, leaving skin clean and smooth. Mountain spring scent.





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In Case of Emergency, Contact Infotrac 800-535-5053

REV:110122

Problend Hand Sanitizer Gel Label-Front







INFOTRAC# 27139

NET CONTENTS/CONTENIDO NETO:

1.25 LITERS/42 OZ

Problend Hand Sanitizer Gel Label-Back

Hand Sanitizer

mountain spring scent

Highly effective at removing dangerous bacteria from skin. Gentle on skin, leaving skin clean and smooth. REV:103122

Drug Facts

Active Ingredient

Purpose

Ethanol 70% v/v.....Antiseptic

Uses

For hand sanitizing to decrease bacteria on the skin.

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

When using this product • Avoid contact with eyes. In

case of eye contact, flush eyes with water.

Stop use and ask a doctor if irritation or redness develops and conditions persist for more than 72 hours.

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LOT#

Seatex, LLC. 445 TX Hwy 36 Rosenberg, TX 77471

866.389.9430

ProBlendSolutions.com

EXP. DATE



PROBLEND HAND SANITIZER GEL

ethanol gel

Duadicat	Information
Product	Intormation

Product Type HUMAN OTC DRUG Item Code (Source) NDC:76250-140

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 70 mL

Inactive I	ngredients
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Ingredient Name	Strength
METHACRYLIC ACID-ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (LINII- NX76LV5T8L)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
FRAGRANCE CLEAN ORC0600327 (UNII: 329LCV5BTF)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	

P	Packaging				
#	Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:76250- 140-01	1249000 mL in 1 CONTAINER; Type 0: Not a Combination Product	01/25/2023		
2	NDC:76250- 140-02	125000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product	01/25/2023		
3	NDC:76250- 140-03	18900 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/25/2023		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/25/2023	

Labeler - Seatex, LLC (026647404)

Registrant - Seatex, LLC (026647404)

Establishment			
Name	Address	ID/FEI	Business Operations
Seatex, LLC		026647404	label(76250-140), manufacture(76250-140), pack(76250-140)

Revised: 1/2023 Seatex, LLC