INSTANT HAND SANITIZER- alcohol gel Sanear Corporation

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.

Instant Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 66.5%

Purpose

Antiseptic

Use

For handwashing to decrease bacteria on skin without soap and water.

Warnings

For external use only.

Flammable, keep away from fire or flame.

Keep out of reach of children.

Do not use in eyes, if this happens, rinse thoroughly with water.

Stop use, ask a doctor If irritation develops and persists for 72 hours. If ingested, get medical help or contact a Poison Control Center right away.

Directions

• wet hands & wrists thoroughly with product and allow to dry without wiping

Inactive ingredients

aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

PRINCIPAL DISPLAY PANEL – Sanear 0.057 fl. oz. Pouch SaniPortables[®] Instant Hand Sanitizer KILLS 99.9% of GERMS FRESH SCENT Enriched with Aloe Vera 0.057 fl. oz. (1.68 ML) Distributed by SANEAR Corporation Matthews, NC 28105



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Drug Facts (continued)

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PRINCIPAL DISPLAY PANEL – Sanear 25 count Box

Made in the U.S.A. NDC 23638-1111-1 SaniPortables[®] Instant Hand Sanitizer KILLS 99.9% of GERMS Fresh Scent Enriched with Aloe Vera

25 packets

Each Packet .057 fl. oz. (1.68 ML)



alcohol gel

Product Information				
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:23638-1111	
Route of Administration	TOPICAL			
Active Ingradient/Activ	o Mojety			
Active Ingredient/Activ	•			
Ingredient Name		Basis of Str	ength Strength	
alcohol (UNII: 3K9958V90M)	(alcohol - UNII:3K9958V90M)	alcohol	665 mL in 1 L	
Inactive Ingredients				
Inactive Ingredients	Ingredient Name		Strength	
Inactive Ingredients aloe (UNII: V5VD430YW9)	Ingredient Name		Strength	
	Ingredient Name		Strength	

Packaging								
# Item Code	Package Description	Marketing	Start Date Ma	Marketing End Date				
1 NDC:23638-1111-1	25 in 1 BOX							
1	0.00168 L in 1 POUCH							
Marketing Information								
Marketing Category	Application Number or Monog	graph Citation	Marketing Start Date	Marketing End Date				
OTC monograph not fina	l part333E		11/21/2011					

Labeler - Sanear Corporation (831894980)

Registrant - Safetec of America, Inc. (874965262)

Establishment						
Name	Address	ID/FEI	Business Operations			
Safetec of America, Inc.		874965262	MANUFACTURE			

Revised: 11/2011

Sanear Corporation