

**PRISTALL SANISHIELD ALCOHOL FREE ANTISEPTIC HAND SANITIZER -  
benzalkonium chloride spray  
Sani Home Products International 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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**Pristall SaniShield Alcohol Free Antiseptic Hand Sanitizer Spray**

Drug Facts

Active Ingredient	Purpose
Benzalkonium Chloride 0.13 percent	Antiseptic

Uses

For hand washing to decrease bacteria on the skin. Recommended for repeated use.

Warnings

For external use only.

Do not use in eyes.

Discontinue if irritation or redness develop. If condition persists for more than 72 hours, consult a doctor.

Keep out of reach of children.

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

Directions

Wet hands thoroughly with product and allow to dry without wiping.

Inactive Ingredients

Cocoamidopropyl Betaine, Edetate Sodium USP Dihydrate, Fragrance, Hydroxypropyl Cellulose, Propylene Glycol, Water

Lot No.    Expiration Date    Made in USA    Manufactured by: Sani Home Products International, LLC  
15 Frowein Road Buiding E Suite 2 Center Moriches, NY 11934

Pristall    SaniShield    It's not clean until it's SaniClean    Alcohol Free Antiseptic Hand Sanitizer  
Spray    Kills Germs Not Your Skin    8.45 fl oz (250 ml)

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UPC



**PRISTALL SANISHIELD ALCOHOL FREE ANTISEPTIC HAND SANITIZER**

benzalkonium chloride spray

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50757-250
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>BENZALKONIUM CHLORIDE</b> (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 mL in 100 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3011KX)	
<b>EDETATE SODIUM</b> (UNII: MP1J8420LU)	
<b>HYDROXYPROPYL CELLULOSE</b> (UNII: RFW2ET671P)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50757-250-08	250 mL in 1 BOTTLE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	03/23/2010	

**Labeler** - Sani Home Products International LLC (961615478)

**Registrant** - Sani Home Products International LLC (961615478)

**Establishment**

Name	Address	ID/FEI	Business Operations
Sani Home Products International LLC		961615478	manufacture

Revised: 3/2010

Sani Home Products International LLC