

SIPA FOAM HAND SANITIZER WITH MOISTURIZERS- instant hand sanitizer liquid

Tourel (Changsha)Hotel Supplies Co.,Ltd

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

Benzalkonium chloride 0.15 %

Purpose

For hand sanitizing to decrease bacteria on the skin

Use

For hand sanitizing to decrease bacteria on the skin

Warnings

For external use only

Do not use

in or near the eyes in case of contact, rinse eyes thoroughly with water

When Using

Pay attention to the method of use. do not touch eyes

Stop Use

if irritation or rash appears and lasts

Ask Doctor

if irritation or rash appears and lasts

Keep Out Of Reach Of Children

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

Directions

Pump a small amount of foam into palm of hand
Rub thoroughly over all surfaces of both hands
Rub hands together briskly until dry

Inactive ingredients

Water, Didecyldimonium Chloride, Glycerin, PropyleneGlycol, Peg-10 Dimethicone, Peg-17 Dimethicone

PRINCIPAL DISPLAY PANEL

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The principal display panel is a rectangular label with a height of 50mm and a width of 96mm. It features a cartoon panda holding two balloons (one pink, one blue) in a green field with bamboo. The text on the label includes: 'FOAMING HAND SANITIZER' in large orange letters, 'FRAGRANCE FREE ALCOHOL FREE KILLS 99.9% OF GERMS 1.69OZ (50ML)' in green, and a 'Drug Facts' table on the right. The table lists the active ingredient Benzalkonium chloride (0.15%) with an antimicrobial purpose, and provides usage, warnings, directions, and inactive ingredients. It also includes a barcode and contact information for Spacemasks USA, Inc.

Drug Facts	
Active ingredient	Purpose
Benzalkonium chloride 0.15 %	Antimicrobial
Uses	
For hand sanitizing to decrease bacteria on the skin	
Warnings	
For external use only	
Do not use in or near the eyes in case of contact, rinse eyes thoroughly with water	
Stop use and ask a doctor if irritation or rash appears and lasts	
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center	
Directions	
• Pump a small amount of foam into palm of hand • Rub thoroughly over all surfaces of both hands • Rub hands together briskly until dry	
Inactive ingredients	
Water, Didecyldimonium Chloride, Glycerin, Propylene Glycol, Peg-10 Dimethicone, Peg-17 Dimethicone	

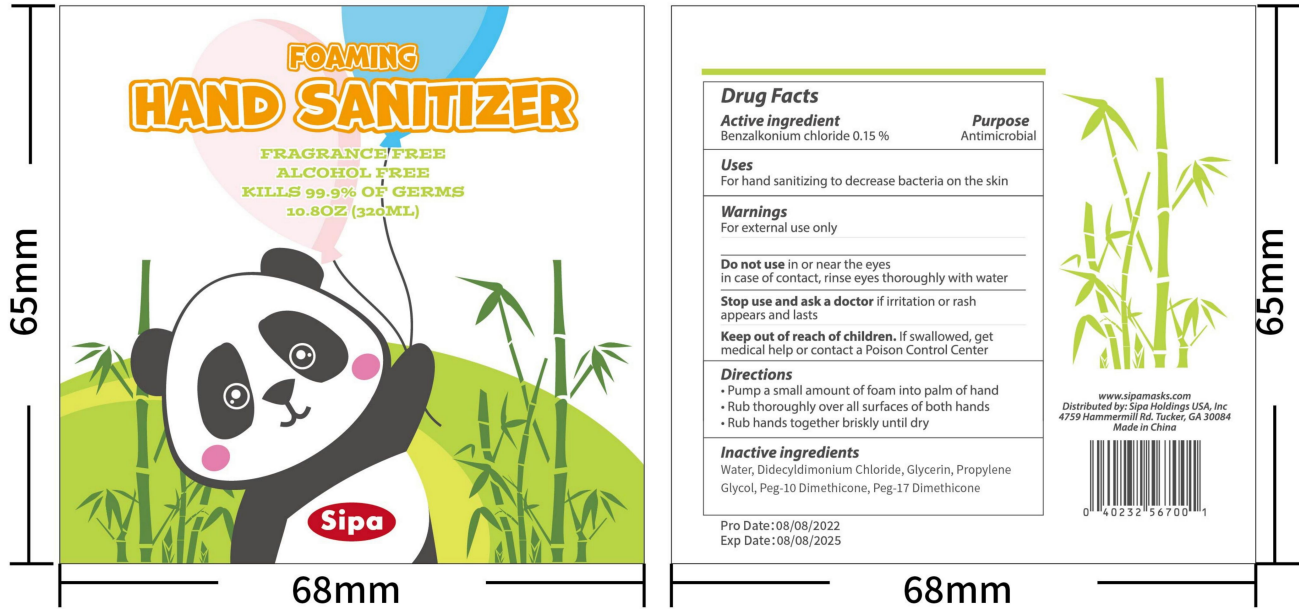
Pro Date: 08/08/2022
Exp Date: 08/08/2025
www.spamasks.com
Distributed by: Spacemasks USA, Inc
4759 Hammermill Rd. Tucker, GA 30084
Made in China

0 40252 56701 8

2022年7月15日10:16:19-LJ

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2022年7月15日10:15:09-LJ

SIPA FOAM HAND SANITIZER WITH MOISTURIZERS

instant hand sanitizer liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83502-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.15 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PEG-10 DIMETHICONE (220 CST) (UNII: 287GF3Y3WC)	
PEG-175 DISTEARATE (UNII: 96X9M8B71Y)	
DIDECYLDIMONIUM CHLORIDE (UNII: JXN4009Y9B)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83502-001-01	50 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2023	
2	NDC:83502-001-02	320 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/27/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	05/27/2023	

Labeler - Tourel (Changsha)Hotel Supplies Co.,Ltd (540791707)

Establishment

Name	Address	ID/FEI	Business Operations
Tourel (Changsha)Hotel Supplies Co.,Ltd		540791707	label(83502-001) , manufacture(83502-001)

Revised: 5/2023

Tourel (Changsha)Hotel Supplies Co.,Ltd