

MI- benzalkonium chloride hs solution
Infinity Manufacturing of America, 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.

SPL Unclassified Section

This is hand sanitizer manufactured according to OTC Monograph part 333a

Purpose

Antiseptic, Hand Sanitizer

- FOR EXTERNAL USE ONLY
- DO NOT USE ON CHILDREN UNDER 2 MONTHS OF AGE

WHEN USING THIS PRODUCT

- KEEP OUT OF EYES, EARS AND MOUTH
- IN CASE OF CONTACT WITH EYES, RINSE EYES THOROUGHLY WITH WATER
- STOP USE AND CONTACT A PHYSICIAN IF IRRITATION OR

RASH OCCUR

KEEP OUT OF REACH OF CHILDREN

IF SWALLOWED, CALL POISON CONTROL IMMEDIATELY

Do Not Use-OTC

on children less than 2 mos in age on open skin wounds.

When Using Section

When using this product keep out of eyes, ears, and mouth. in case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

Stop Use Section

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep Out of Reach of Children

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

PLACE PRODUCT IN HANDS TO COVER ALL SURFACES, RUB TOGETHER UNTIL DRY

CHILDREN UNDER 6 YEARS OF AGE SHOULD BE SUPERVISED WHILE USING PRODUCT

INACTIVE INGREDIENTS IONIZED WATER, CARBAMIDE

Storage and Handling

Store between 15-30C (59-86F)

Avoid freezing and excessive heat above 40C(104F)

Inactive Ingredients

Ionized Water, Carbamide

When using this product keep out of eyes, ears, and mouth. in case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

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

BENZALKONIUM CHLORIDE 0.13% v/v.....ANTIBACTERIAL

Active Ingredients

BENZALKONIUM CHLORIDE 0.13% v/v.....ANTIBACTERIAL

Uses

HAND SANITIZER TO DECREASE BACTERIA ON THE SKIN

RECOMMENDED FOR REPEATED USE

473ml NDC:81563-013-16



 220 Plasticraft Drive Albertville, AL 35951 Toll Free: 888.673.0707	PAPER	COLOR LIST				RUN DIRECTION		Print is 100% Size Not a Color Contract Proof! PLEASE REVIEW, SIGN AND RETURN. Please review this artwork for accuracy and completeness, carefully examine the overall appearance including color breaks, copy changes, spelling and/or punctuation. The colors on this approval are only a representation of the finished product color. Check colors listed with your PANTONE color book for accurate color representation. Your signature of approval states that the art, art position, type, size, and colors are correct, therefore releasing Alliant Label from liability of cost for art, negatives, plates, and printed product. Check the appropriate box below, sign and return to Alliant Label. Your cooperation in this will be greatly appreciated.
	White 60/40	PANTONE 198 C	PANTONE 576 C	PANTONE 2196 C	BLACK	1	2	
Job Information: Date: 02/05/2021 Project Number: nV50833 Project Description: MI Hand Sanitizer - 16oz Label Size: 6" x 4" Number of Colors: 4 UPC Code:	Revision History: Date: 02/05/21 Artist: Chris Revision: Initial proof/sep				3	4		
Signature of Approval _____ Date _____						<input type="checkbox"/> Approved. Proceed with production. <input type="checkbox"/> Make changes as noted. Another proof required.		

946ml NDC:81563-013-32



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	White 60/40	PANTONE 198 C PANTONE 576 C PANTONE 2196 C BLACK	1 2 3 4	<input type="checkbox"/> Approved. Proceed with production.	
Job Information: Date: 02/05/2021 Project Number: nV50833 Project Description: MI Hand Sanitizer - 32oz Label Size: 6" x 4" Number of Colors: 4 UPC Code:	Revision History: Date: 02/05/21 Artist: Chris Revision: Initial proof set up		Signature of Approval _____ Date _____		

3785 ml NDC: 81563-013-00



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	White 60/40	PANTONE 198 C	PANTONE 576 C	PANTONE 2196 C	BLACK	1 FEEL WAY A	
Job Information:	Revision History:						
Date: 02/05/2021	Date: 02/05/21	Artist: Chris	Revision: Initial proof set up				
Project Number: nV50833							
Project Description: MI Hand Sanitizer - 128oz							
Label Size: 6" x 4"							
Number of Colors: 4							
UPC Code:							
Signature of Approval _____ Date _____				<input type="checkbox"/> Approved. Proceed with production.		<input type="checkbox"/> Make changes as noted. Another proof required.	

236ml NDC: 81563-013-08



PAPER	COLOR LIST	RUN DIRECTION	Print to 100% Size
			<p>PLEASE REVIEW SIZE AND METRIC. Missions require the correct fit for your application. Carefully compare the overall dimensions including all embossing to your application. If you are unsure of the fit, please contact your representative for assistance. The fit of the label is critical to the success of the application. If you are unsure of the fit, please contact your representative for assistance.</p>
<p>Signature of Operator: _____ Date: _____</p>		<p><input type="checkbox"/> Approved <input type="checkbox"/> Priced with production <input type="checkbox"/> Miss change needed. <input type="checkbox"/> Clarify proof required.</p>	

MI
benzalkonium chloride hs solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81563-013(NDC:78003-120)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.0013 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
UREA (UNII: 8W8T17847W)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81563-013-08	236 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021	
2	NDC:81563-013-16	473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021	
3	NDC:81563-013-32	946 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021	
4	NDC:81563-013-00	3785 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	02/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	02/23/2021	

Labeler - Infinity Manufacturing of America, LLC (117711498)

Registrant - Bama-Bio Tech Corporation (117525750)

Establishment

Name	Address	ID/FEI	Business Operations
Infinity Manufacturing of America		117711498	relabel(81563-013)

Revised: 2/2021

Infinity Manufacturing of America, LLC