HYDRATING INSTANT HAND SANITIZER- alcohol gel Micrylium Laboratories

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.

Drug Facts

Active Ingredient

Ethyl Alcohol 70 percent

Purpose

Antimicrobial

Uses

Cleansing gel for hands that need frequent care.

Decrease bacteria on skin.

Warnings

For external use only.

Flammable, keep away from fire or flame.

Do not use in or near the eyes, in case of exposure rinse eyes throughly with water.

Do not use if you have preexisting rash condition.

Stop use and ask a doctor if irritation, redness or rash appear.

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

Directions

Apply approximately 3ml on palm and rub hands for 30 seconds.

Rinsing is not required.

Inactive Ingredients

aloe barbadensis, aroma, blue 1 (CI 42090), carbomer, cetyl alcohol, glycerin, panthenol, tocopherol acetate, triethanolamine, water, yellow 5 (CI 19140)

Drug Facts





Hydrating Instant Hand Sanitizer

Cleansing gel for hands that need frequent care. Decreases bacteria on skin.

With Vitamin B & Aloe. Leaves hands feeling smooth and silky.

Order No. H6500

Net Contents: 15.2 fl. oz. / 450 mL

Distributed By



PN H6143-LF Rev. A

Drug Facts

Active Ingredient

Purpose

Ethyl Alcohol 70%

Antimicrobial

Uses

- Cleansing gel for hands that need frequent care.
- Decreases bacteria on skin.

Warnings

For external use only.

Flammable, keep away from fire or flame.

Do not use in or near the eyes, in case of exposure rinse eyes thoroughly with water.

Do not use if you have preexisting rash condition.

Stop use and ask doctor if irritation, redness or rash appear.

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

Directions

- Wet hands thoroughly with Gel. Rub into skin covering all surfaces of hands until dry, about 30 seconds.
- No rinsing required.

Inactive Ingredients

aloe barbadensis, aroma, blue 1 (Cl 42090), carbomer, cetyl alcohol, glycerin, panthenol, tocopherol acetate, triethanolamine, water, yellow 5 (Cl 19140)







www.airtechniques.com 1295 Walt Whitman Road Melville, NY 11747-3062

PN H6143-L Rev. B

HYDRATING INSTANT HAND SANITIZER

alcohol gel

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:59371-6500

Route of Administration TOPICAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	315 mL in 450 mL		

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA FLOWER (UNII: 575DY8C1ER)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
GLYCERIN (UNII: PDC6A3C0OX)				
PANTHENOL (UNII: WV9CM0O67Z)				
.ALPHATO COPHERO L ACETATE (UNII: 9E8X80D2L0)				
TROLAMINE (UNII: 9O3K93S3TK)				
WATER (UNII: 059QF0KO0R)				
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)				

Packaging					
#	Item Code Package Description		Marketing Start Date	Marketing End Date	
1 NDC:59371-6500-0		450 mL in 1 BOTTLE, PLASTIC			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	0 2/0 1/20 13			

Labeler - Micrylium Laboratories (252529185)

Registrant - Micrylium Laboratories (252529185)

Establishment						
Name	Address	ID/FEI	Business Operations			
Micrylium Laboratories		252529185	pack(59371-6500), label(59371-6500), manufacture(59371-6500)			

Revised: 2/2013 Micrylium Laboratories