

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 thoroughly 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

Apple Scent 



Monarch™

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. H6510

Net Contents: 2 fl. oz. / 60 mL

Distributed By



PN H6147-LF Rev. A

Drug Facts

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Ethyl Alcohol 70%	Antimicrobial

Uses

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- Decreases bacteria on skin.

Warnings

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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 (CI 42090), carbomer, cetyl alcohol, glycerin, panthenol, tocopherol acetate, triethanolamine, water, yellow 5 (CI 19140)



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PN H6147-L Rev. B

HYDRATING INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59371-6510
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	42 mL in 60 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)	
.ALPHA.-TOCOPHEROL 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:59371-6510-0	60 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	02/01/2013	

Labeler - Micrylium Laboratories (252529185)

Registrant - Micrylium Laboratories (252529185)

Establishment			
Name	Address	ID/FEI	Business Operations
Micrylium Laboratories		252529185	manufacture(59371-6510) , pack(59371-6510) , label(59371-6510)

Revised: 2/2013

Micrylium Laboratories