BLUE DEVIL HAND SANITIZER- alcohol solution Blue Cross 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.

Blue Devil Hand Sanitizer

Active Ingredient(s)

Ethyl Alcohol 62% Purpose: Antiseptic

Purpose

Uses

- to decrease bacteria on the skin
- recommended for repeated use

Warnings

For external use only-hands. Flammable. Keep away from heat or flame

Do not use

- not recommended for infants
- avoid contact with broken skin
- do not inhale or ingest

When using this product

• keep out of eyes. In case of contact with eyes, flush thoroughly with water.

Stop use and ask a doctor if

• skin irritation develops

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.
- for children under 6, use only under adult supervision
- not recommended for infants

Inactive ingredients

water, glycerin, propylene glycol, carbomer

Package Label - Principal Display Panel

Blue Devil

Hand Sanitizer
Fights 99.99% of germs and bacteria
Helps stop the spread of illness
Great for travel, home, & workplace

8oz. 237ml part #00245



HAND SANITIZER

FIGHTS 99.99% OF GERMS & BACTERIA

HELPS STOP THE SPREAD OF ILLNESS

GREAT FOR TRAVEL, HOME & WORKPLACE

80z. • (237ml) • PART #00245

Drug Facts

Active Ingredient
Ethyl alcohol 62% ...

Purpose Antiseptic

Uses • to decrease bacteria on the skin that could cause disease • recommended for repeated use

Warnings

For external use only - hands

Flammable. Keep away from heat and flame.

When using this product \bullet Keep out of eyes. In case of contact with eyes, flush thoroughly with water. \bullet avoid contact with broken skin \bullet do not inhale or ingest

Stop use and ask a doctor if • skin irritation develops.

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 • for children under 6, use only under adult supervision • not recommended for infants

Other information • do not store above 105°F • may discolor some fabrics • harmful to wood finishes and plastics

Inactive ingredients water, glycerin, propylene glycol, carbomer

Questions Call 1-888-863-0426 (Mon-Fri 8am-5pm EST)

Distributed by: BlueDevil Products 854 Lowcountry Blvd. Suite 101 | Mt. Pleas<u>ant, SC 29464</u>

Made in China



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BLUE DEVIL HAND SANITIZER

alcohol solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:22431-222

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)
ALCOHOL (DRIE 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

ALCOHOL (DRIE 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)

Inactive Ingredients				
Ingredient Name	Strength			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)				
GLYCERIN (UNII: PDC6A3C0OX)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				

	Packaging						
ı	#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
ı	1 N	NDC:22431-222-01	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2020			

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph not final	part333A	05/13/2020				

Labeler - Blue Cross Laboratories (008298879)

Establishment						
Name	Address	ID/FEI	Business Operations			
Ningbo Liyuan Daily Chemical Products Co., Ltd		530766098	manufacture(22431-222)			

Revised: 5/2020 Blue Cross Laboratories