

INSTANT HAND SANITIZER - ethyl alcohol gel
BJWC

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 65 PERCENT

PURPOSE

ANTISEPTIC

USES

TO HELP REDUCE BACTERIA ON THE SKIN.

WARNINGS

FOR EXTERNAL USE ONLY. FLAMMABLE, KEEP AWAY FROM FIRE OR FLAME.

WHEN USING THIS PRODUCT

AVOID CONTACT WITH EYES. IF CONTACT OCCURS, RINSE WITH WATER. DO NOT INHALE OR INGEST.

STOP USING THIS PRODUCT AND ASK DOCTOR IF

IRRITATION OR REDNESS DEVELOPS AND LASTS.

KEEP OUT OF REACH OF CHILDREN

IN CASE OF ACCIDENTAL INGESTION, GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER IMMEDIATELY.

DIRECTIONS

WET HANDS THOROUGHLY AND RUB TOGETHER UNTIL DRY. FOR CHILDREN UNDER 6, USE ONLY UNDER ADULT SUPERVISION. NOT RECOMMENDED FOR INFANTS.

OTHER INFORMATION

STORE BELOW 110⁰F (43⁰C). MAY DISCOLOR CERTAIN FABRICS.

QUESTIONS OR COMMENTS

1-800-934-1204

INACTIVE INGREDIENTS

WATER, ISOPROPYL ALCOHOL, GLYCERIN, CARBOMER, AMINOMETHYL PROPANOL,

FRAGRANCE, PROPYLENE GLYCOL, ISOPROPYL MYRISTATE, TOCOPHERYL ACETATE.



Drug Facts	
Active ingredient Ethyl Alcohol 65%.....	Purpose Antiseptic
Uses ■ To help reduce bacteria on the skin.	
Warnings	
■ For external use only. ■ Flammable, keep away from fire or flame.	
When using this product ■ Avoid contact with eyes. If contact occurs, rinse with water. ■ Do not inhale or ingest	
Stop using this product and ask doctor if ■ Irritation or redness develops and lasts.	
Keep out of reach of children ■ In case of accidental ingestion, get medical help or contact a Poison Control Center immediately.	
Directions ■ Wet hands thoroughly and rub together until dry. ■ For children under 6, use only under adult supervision. ■ Not recommended for infants	
Other Information: Store below 110°F (43°C) ■ May discolor certain fabrics	
Questions/Comments? 1-800-934-1204	
Inactive ingredients: Water (Aqua), Isopropyl Alcohol, Glycerin, Carbomer, Aminomethyl Propanol, Fragrance (Parfum), Propylene Glycol, Isopropyl Myristate, Tocopheryl Acetate.	

Distributed by BJWC - 1 Mercer Road, Natick, MA 01760
1-800-934-1204 Product of Canada
06-15882

INSTANT HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68391-267
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	65 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 934 (UNII: Z135WT9208)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
.ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68391-267-12	354 mL in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	01/06/2011	

Labeler - BJWC (159082692)**Registrant** - APOLLO HEALTH AND BEAUTY CARE (201901209)**Establishment**

Name	Address	ID/FEI	Business Operations
APOLLO HEALTH AND BEAUTY CARE		201901209	manufacture

Revised: 1/2011

BJWC