# B4 ANTISEPTIC HAND SANITIZER WITH ETHYL ALCOHOL- ethyl alcohol gel Midway Advanced Products, 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.

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# b4 Antiseptic Hand Sanitizer with ethyl alcohol gel

#### **DRUG FACTS**

## **Active ingredient**

Ethyl Alcohol 65% w/w

# **Purpose**

Antimicrobial

#### Uses

- to sanitize hands without water
- kills 99% of most common bacteria

## Warnings

FLAMMABLE. For external use only.

# When using this product:

- keep away from fire or flame
- do not use in eyes
- discontinue use if irritation or redness develop

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center immediately.

#### **Directions**

- tear open packet and apply entire amount of gel to unsoiled hands
- rub in thoroughly until hands are dry
- do not wipe or use water rinse

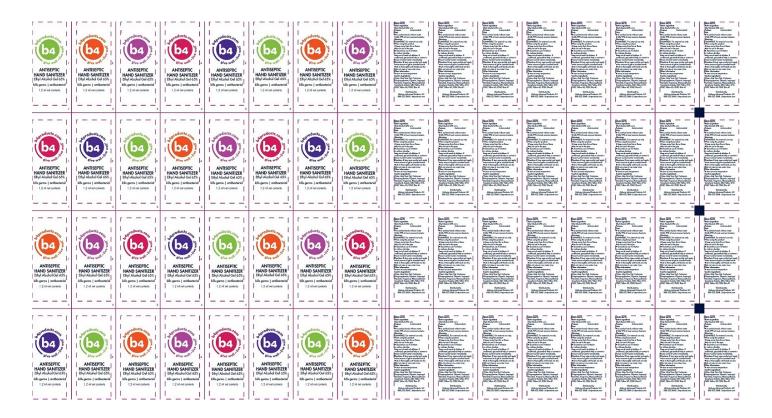
#### Other information

• store at room temperature

#### **Inactive ingredients**

Water, Aloe Vera Gel, Carbomer, Diisopropylamine, Glycerin, Isopropyl Myristate, Fragrance, Phenoxyethanol, Tocopheryl Acetate, D&C Yellow # 10, FD&C Yellow #5, FD&C Blue #1

# **Package Labeling**



# **B4 ANTISEPTIC HAND SANITIZER WITH ETHYL ALCOHOL**

ethyl alcohol gel

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:52490-201

Route of Administration TOPICAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) ALCOHOL (550 mg in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
CARBOXYPOLYMETHYLENE (UNII: 0 A5MM307FC)				
DIISOPROPYLAMINE (UNII: BR9JLI40NO)				
GLYCERIN (UNII: PDC6A3C0OX)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				
PHENO XYETHANO L (UNII: HIE49 2ZZ3T)				
ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)				
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)				
FD&C YELLOW NO. 5 (UNII: 1753WB2F1M)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				

Packaging							
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>			
1	NDC:52490-201-10	500 in 1 CARTON	02/01/2018				
1		1.2 mL in 1 CARTON; Type 0: Not a Combination Product					

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 18			

**Labeler -** Midway Advanced Products, LLC (962765009)

Revised: 2/2018 Midway Advanced Products, LLC