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**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	650 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	02/01/2018	

Labeler - Midway Advanced Products, LLC (962765009)

Revised: 2/2018 Midway Advanced Products, LLC