ANTI-BACTER HAND SANITIZER 70 ETHYL ALCOHOL PINEAPPLE- alcohol gel ADEX COSMETICS & PHARMA LESZEK SIERDZINSKI

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.

Anti-Bacter Hand Sanitizer 70% Ethyl Alcohol Pineapple

Drug Facts

Active Ingredient

Ethyl alcohol 70% v/v

Purpose

Antiseptic

Uses

- for travel, shopping, school, work and home use
- to help reduce bacteria on the skin
- for use when water and soap are not available
- recommended for repeated uses

Warnings:

For external use only: hands

flammable, keep away from sources of heat or fire

do not use

on broken, cut or irritated skin

When using this product

keep out of reach of children.

• avoid contact with eyes. if contact occurs, rinse thoroughly with water,

stop using and ak a doctor

if irritation or redness develops or lasts

• if swallowed, get medical help or contact a Poison Control Center immediately

Directions

• place enough gel in your palms to thoroughly cover hand, rub hands together brikly until dry

- children under 6 years of age should be supervised when using Anti-Bacter Hand Sanitizer
- not recommended for infants

Other information

- store at a temperature below 104°F (40°C)
- may discolor certain fabrics and surfaces

Inactive Ingredients:

AQUA (WATER), GLYCERIN, ALOE BARBADENSIS LEAF JUICE, ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER / CARBOMER*, MANNITOL, MICROCRYSTALLINE CELLULOSE, HYDROXYPROPYL METHYLCELLULOSE, ALOE BARBADENSIS LEAF JUICE POWDER, TOCOPHERYL ACETATE, ALGIN, PARFUM (FRAGRANCE), AMINOMETHYL PROPANOL, BENZOPHENONE-3, POTASSIUM SORBATE, SODIUM BENZOATE, LIMONENE, CITRAL, CI 74260, CI 77492 (IRON OXIDES), CI 19140 (FD&C YELLOW 5), CI 17200 (D&C RED 33).

*The letter next to the batch number means: A-ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER B-CARBOMER

Package Labeling:



HAND SANITIZER

70% Ethyl Alcohol



no water needed 3.38 FL OZ (100mL)

Hand Sanitizer Pineapple Scented

With Aloe Vera and Vitamin E. Contains glycerin.

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When using this product ■ keep out of reach of children ■ avoid contact with eyes, if contact occurs, rinse thoroughly with water, stop using and ask a doctor if irritation or redness develops or lasts ■ if swallowed, get medical help or contact a Poison Control Center immediately

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A - ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER B - CARBOMER



Made in the European Union

Distributed by
ADEX COSMETICS & PHARMA USA LLC
Miami, FL 33132
1-800-558-1763
www.adexcosmeticsusa.com
Produced by
ADEX COSMETICS & PHARMA, Poland

3.38 FL 0Z (100mL)

ANTI-BACTER HAND SANITIZER 70 ETHYL ALCOHOL PINEAPPLE

alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:80457-007

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	70 mL in 100 mL

Inactive Ingredients

GLYCERIN (UNII: PDC6A3C0OX) ALOE VERA LEAF (UNII: ZY81Z83H0X) MANNITOL (UNII: 30WL53L36A) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) SODIUM ALGINATE (UNII: C269C4G2ZQ) AMINOMETHYLPROPANOL (UNII: LU49E6626Q) OXYBENZONE (UNII: 950OS7VE0Y) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) SODIUM BENZOATE (UNII: 0J245FE5EU) LIMONENE, (+)- (UNII: GFD7C86Q1W) CITRAL (UNII: T7EU009VPP)	Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X) MANNITOL (UNII: 30WL53L36A) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) SODIUM ALGINATE (UNII: C269C4G2ZQ) AMINOMETHYLPROPANOL (UNII: LU49E6626Q) OXYBENZONE (UNII: 950OS7VE0Y) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) SODIUM BENZOATE (UNII: 0J245FE5EU) LIMONENE, (+)- (UNII: GFD7C86Q1W) CITRAL (UNII: T7EU009VPP)	WATER (UNII: 059QF0KO0R)	
MANNITOL (UNII: 30WL53L36A) MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0) SODIUM ALGINATE (UNII: C269C4G2ZQ) AMINOMETHYLPROPANOL (UNII: LU49E6626Q) OXYBENZONE (UNII: 950OS7VE0Y) POTASSIUM SORBATE (UNII: 1VPU26JZZ4) SODIUM BENZOATE (UNII: OJ245FE5EU) LIMONENE, (+)- (UNII: GFD7C86Q1W) CITRAL (UNII: T7EU0O9VPP)	GLYCERIN (UNII: PDC6A3C0OX)	
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LIMONENE, (+)- (UNII: GFD7C86Q1W) CITRAL (UNII: T7EU0O9VPP)	POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
CITRAL (UNII: T7EU0O9VPP)	SODIUM BENZOATE (UNII: OJ245FE5EU)	
	LIMONENE, (+)- (UNII: GFD7C86Q1W)	
FERRIC OXIDE YELLOW (UNII: EX43802MRT)	CITRAL (UNII: T7EU0O9VPP)	
	FERRIC OXIDE YELLOW (UNII: EX43802MRT)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:80457-007- 01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021		

Marketing In	Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333E	03/01/2021			

Labeler - ADEX COSMETICS & PHARMA LESZEK SIERDZINSKI (366050458)

Revised: 3/2021 ADEX COSMETICS & PHARMA LESZEK SIERDZINSKI