

ANTI-BACTER HAND SANITIZER 70 ETHYL ALCOHOL COCONUT- 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 Coconut

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 ask 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 briskly 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, BENZYL SALICYLATE, LINALOOL, ALPHA-ISOMETHYL IONONE, LIMONENE, CI 77492, CI 77492 (IRON OXIDES), CI 42090, 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:

ANTI-BACTER

HAND SANITIZER

70% Ethyl Alcohol



Coconut

● Vitamin E ● aloe vera

no water needed

3.38 FL OZ (100mL)

Hand Sanitizer Coconut Scented

With Aloe Vera and Vitamin E. Contains glycerin.

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*The letter next to the batch number means:
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 OZ (100mL)

ANTI-BACTER HAND SANITIZER 70 ETHYL ALCOHOL COCONUT

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80457-002
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

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
MANNITOL (UNII: 3OWL53L36A)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
SODIUM ALGINATE (UNII: C269C4G2ZQ)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
OXYBENZONE (UNII: 95OOS7VE0Y)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
BENZYL SALICYLATE (UNII: WAO5MKN9TU)	
LINALOOL, (+/-)- (UNII: D81QY6I88E)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80457-002-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021	

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

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