

**ALOESAFE ANTISEPTIC HAND SANITIZER- ethyl alcohol liquid**  
**Medical Chemical Corporation**

*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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**AloeSafe**

**Indications for Use**

Indications for use: AloeSafe is intended to be used as a waterless hand sanitizer to reduce microorganisms that can cause disease. Recommended fo repeated use.

**Ingredients**

Ingredients: Ethyl alcohol 62% (active ingredient), purified water, carbomer, aloe vera gel, diisopropylamine, vitamin E, and lavender oil.

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**Warnings**

Warnings: Flammable, keep away from fire or flames. For external use on hands only. Avoid contact with face, eyes and broken skin. If this occurs, flush thoroughly with water. Discontinue use if irritation or redness develops. Keep out of reach of children. In case of ingestion contact Poison Control Center immediately.

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**Directions**

Directions: Wet hands thoroughly with AloeSafe and rub briskly until dry without wiping.

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## AloeSafe Label



The image shows the front and back of an AloeSafe hand sanitizer bottle. The front panel features the AloeSafe logo, which consists of a teal circle containing a white aloe vera plant, with a purple laurel wreath below it. The text 'AloeSafe™' is in large teal letters, followed by 'Antiseptic Hand Sanitizer with Aloe Vera, Lavender Oil, and Vitamin E' in purple. At the bottom, it says '16 Fl. Oz. (473ml)'. The Hardy Diagnostics logo is at the bottom center. The back panel contains detailed text: 'Your hands deserve only the best! Hardy's AloeSafe™ contains no dyes, parabens, or propylene glycol. Moisturizers and conditioners leave hands smooth, soft, and silky. Kills 99.99% of bacteria on contact.' It lists ingredients, directions, indications for use, and warnings. It also provides manufacturing information and the Hardy Diagnostics logo and contact details.

### ALOESAFE ANTISEPTIC HAND SANITIZER

ethyl alcohol liquid

#### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:12745-180
<b>Route of Administration</b>	TOPICAL		

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII:3K9958 V90M)	ALCOHOL	60 g in 100 mL

#### Inactive Ingredients

Ingredient Name	Strength
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.02 g in 100 mL
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	0.04 g in 100 mL
WATER (UNII: 059QF0K00R)	28.03 g in 100 mL
POLYACRYLIC ACID (450000 MW) (UNII: KD3S7H73D3)	0.25 g in 100 mL
DIISOPROPYLAMINE (UNII: BR9JLI40NO)	0.2 mL in 100 mL

**ALOE VERA LEAF (UNII: ZY81Z83H0X)**

0.2 g in 100 mL

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12745-180-01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2019	
2	NDC:12745-180-02	120 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2010	
3	NDC:12745-180-03	480 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/01/2010	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/01/2010	

**Labeler** - Medical Chemical Corporation (008496861)

**Registrant** - Medical Chemical Corporation (008496861)

**Establishment**

Name	Address	ID/FEI	Business Operations
Medical Chemical Corporation		008496861	manufacture(12745-180)

Revised: 10/2019

Medical Chemical Corporation