

INSTANT HAND SANITIZER- alcohol gel
Safetec of America, Inc.

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.

Drug Facts

Active Ingredient

Ethyl Alcohol 70%

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on skin whenever soap and water handwashing is not readily available
- helps prevent the risk of cross-contamination of bacteria that potentially can cause disease or infection
- recommended for repeated use

Warnings

For external use only. Flammable, keep away from fire or flame

When using this product

- do not get into eyes. If contact occurs, rinse eyes thoroughly with water

Stop use and ask doctor if

- irritation and redness develop and persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away

Directions

- place a small amount into one hand
- spread over both hands and wrist
- rub into the skin until dry
- do not wipe off; no rinsing required

Inactive ingredients

Aloe vera, carbomer, purified water, triethanolamine

Manufactured by **SAFETEC OF AMERICA, Inc.** Buffalo, NY 14215 800-456-7077
www.safetec.com

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL – 34,688 fl. oz. Container Label

NDC 61010-7111-0

Safetec

instant

Hand

Sanitizer

Kills 99.9% of Germs

Enriched with

Aloe Vera

Unscented

34,688 fl.oz. (1,026 L) Reorder No. 17393



instant Hand Sanitizer

Kills 99.9% of Germs

Enriched with
Aloe Vera

Unscented

34,688 fl.oz. (1,026 L) Reorder No. 17393

Drug Facts	
Active ingredient Ethyl Alcohol 70%.....	Purpose Antiseptic
Uses <ul style="list-style-type: none"> ■ for handwashing to decrease bacteria on skin whenever soap and water handwashing is not readily available ■ helps prevent the risk of cross-contamination of bacteria that potentially can cause disease or infection ■ recommended for repeated use 	
Warnings For external use only. Flammable, keep away from fire or flame When using this product <ul style="list-style-type: none"> ■ do not get into eyes. If contact occurs, rinse eyes thoroughly with water Stop use and ask doctor if <ul style="list-style-type: none"> ■ irritation and redness develop and persists for more than 72 hours Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away	
Directions <ul style="list-style-type: none"> ■ place a small amount into one hand ■ spread over both hands and wrist ■ rub into the skin until dry ■ do not wipe off; no rinsing required 	
Inactive ingredients aloe vera, carbomer, purified water, triethanolamine	

Manufactured by **SAFETEC OF AMERICA, Inc.** Buffalo, NY 14215 800-456-7077 www.safetec.com

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 10 10-7111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958 V90 M) (alcohol - UNII:3K9958 V90 M)	alcohol	700 mg in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z83H0 X)	
carbomer interpolymer type a (55000 mpa.s) (UNII: 59TL3WG5CO)	
water (UNII: 059 QF0 KO 0 R)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 10 10-7111-0	1026 L in 1 CONTAINER		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	11/06/2013	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(6 10 10-7111)

Revised: 11/2013

Safetec of America, Inc.