

INSTANT HAND SANITIZER- alcohol gel

Safetec of America

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.

Safetec Instant Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 66.5%

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on skin without soap and water
- recommended for repeated use

Warnings

For external use only

Flammable, keep away from fire or flame

Do not use in the eyes. If this happens, rinse thoroughly with water

Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours

Keep out of reach of children

If ingested get medical help or contact a Poison Control Center right away

Directions

- wet hands & wrists thoroughly with product and allow to dry without wiping
- children under 6 years of age should be supervised while using this product

Inactive ingredients

aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

Manufactured by

SAFETEC OF AMERICA, Inc.

Buffalo, NY 14215 · 800-456-7077

www.safetec.com

PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL – 0.9g Pouch Label

Safetec

Instant

Hand

Sanitizer

0.9 g (1/32 oz.)

Safetec of America, Inc.

Buffalo, NY 14215

800-456-7077



The image shows a box label for Safetec Instant Hand Sanitizer. The label is primarily green and white. At the top left is the Safetec logo. To the right is a circular seal with the text 'A.B.H.C.™ MEETS CDC HANDWASHING RECOMMENDATIONS' around a graphic of hands being washed. The product name 'Instant Hand Sanitizer' is prominently displayed in large, bold, black letters. Below the name, the quantity '0.9 g (1/32 oz.)' and the manufacturer information 'Safetec of America, Inc. Buffalo, NY 14215 800-456-7077' are listed. The bottom half of the label is enclosed in a black border and contains three sections: 'Drug Facts', 'Active ingredient Purpose', and 'Warnings'. The 'Drug Facts' section includes 'Ethyl Alcohol 66.5%... Antiseptic'. The 'Active ingredient Purpose' section lists 'Ethyl Alcohol 66.5%... Antiseptic'. The 'Use' section states 'For handwashing to decrease bacteria on skin without soap and water.' The 'Warnings' section says 'For external use only' with a right-pointing arrow.

Safetec

Instant Hand Sanitizer

0.9 g (1/32 oz.)

Safetec of America, Inc.
Buffalo, NY 14215
800-456-7077

Drug Facts

Active ingredient Purpose

Ethyl Alcohol 66.5%... Antiseptic

Use For handwashing to decrease bacteria on skin without soap and water.

Warnings
For external use only ▶

Drug Facts (continued)

Flammable, keep away from fire or flame. Keep out of reach of children.

Do not use in eyes, if this happens, rinse thoroughly with water. **Stop use, ask a doctor if** irritation develops and persists for 72 hours. If ingested, get medical help or contact a Poison Control Center right away.

Directions

■ wet hands & wrists thoroughly with product and allow to dry without wiping

Inactive ingredients

aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

PRINCIPAL DISPLAY PANEL – Box Label

NDC 61010-1112-2

Safetec

Infection Control

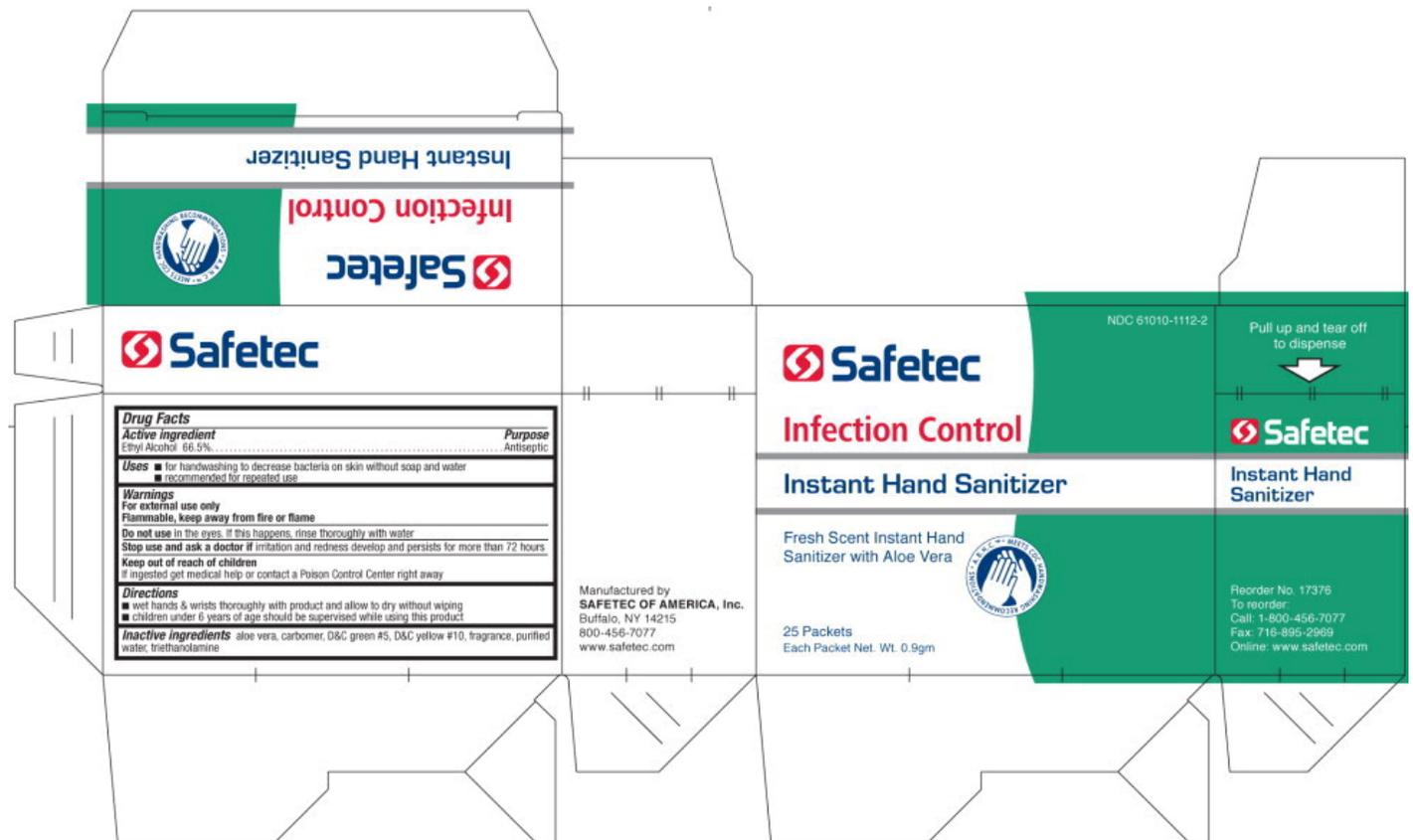
Instant Hand Sanitizer

Fresh Scent Instant Hand

Sanitizer with Aloe Vera

25 Packets

Each Packet Net. Wt. 0.9gm



PRINCIPAL DISPLAY PANEL – 10 Packet Box Label

Safetec®

**INSTANT
Hand Sanitizer**

*Fresh scent instant hand sanitizer
with moisturizing Aloe Vera*

10 Packets

Each Packet Net. Wt. 0.9g

Made in USA

Reorder No. 17395

10 packets
Each Packet Net. Wt. 0.9gm



INSTANT Hand Sanitizer

Drug Facts

Active ingredient

Ethyl Alcohol 66.5%..... Antiseptic

Purpose

Uses ■ for handwashing to decrease bacteria on skin without soap and water
■ recommended for repeated use

Warnings

For external use only

Flammable, keep away from fire or flame

Do not use in the eyes. If this happens, rinse thoroughly with water

Stop use and ask a doctor if irritation and redness develop and persists for more than 72 hours

Keep out of reach of children

If ingested get medical help or contact a Poison Control Center right away

Directions

- wet hands & wrists thoroughly with product and allow to dry without wiping
- children under 6 years of age should be supervised while using this product

Inactive ingredients aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

Manufactured by **SAFETEC OF AMERICA, Inc.**
Buffalo NY, 14215 1-800-456-7077 www.safetec.com

INSTANT
Hand Sanitizer



INSTANT Hand Sanitizer

*Fresh scent instant hand sanitizer
with moisturizing Aloe Vera*

10 Packets
Each Packet Net. Wt. 0.9g

Made in USA

Reorder No. 17395

INSTANT
Hand Sanitizer

INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:6 10 10 -1112
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	665 mL in 1 L

Inactive Ingredients

Ingredient Name	Strength
aloe (UNII: V5VD430 YW9)	
water (UNII: 059QF0 KO0R)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:6 10 10 -1112-2	25 in 1 BOX	12/15/20 10	
1	NDC:6 10 10 -1112-1	0.034 L in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:6 10 10 -1112-3	144 in 1 BOX	12/15/20 10	
2	NDC:6 10 10 -1112-1	0.034 L in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:6 10 10 -1112-8	10 in 1 BOX	04/0 1/2020	
3	NDC:6 10 10 -1112-1	0.034 L in 1 POUCH; 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	12/15/20 10	

Labeler - Safetec of America (874965262)**Establishment**

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(6 10 10 -1112)