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.

A.B.H.C. INSTANT HAND SANITIZER CITRUS SCENT (alcohol) gel [Safetec of America, Inc.]

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 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 and wrists thoroughly with product
- allow to dry without wiping
- children under 6 should be supervised while using this product

Inactive ingredients

aloe vera, carbomer, fragrance, purified water, triethanolamine

PRINCIPAL DISPLAY PANEL – 64 fl. oz. bottle

Safetec

NDC 61010-2111-7

ins tant

Hand

Sanitizer

Kills 99.9% of Germs

Enriched with Aloe Vera

Citrus

Manufactured by **SAFETEC OF AMERICA, Inc.**

Buffalo, NY 14215 800-456-7077 www.safetec.com

64 FL. OZ. (1.9 L) Reorder No. 18357

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INSTANT HAND SANITIZER

alcohol gel

Product Information

NDC:61010-2111 Product Type HUMAN OTC DRUG Item Code (Source)

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Basis of Strength Strength **Ingredient Name** alcohol (UNII: 3K9958 V90 M) (alcohol - UNII: 3K9958 V90 M) 540.26 g in 1 L alcohol

Inactive Ingredients

mactive ingredients			
Ingredient Name	Strength		
aloe vera leaf (UNII: ZY81Z83H0X)			
carbomer interpolymer type a (55000 mpa.s) (UNII: 59TL3WG5CO)			
water (UNII: 059QF0KO0R)			
trolamine (UNII: 9O3K93S3TK)			

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:61010-2111-7	1.9 L in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/10/2012	

Labeler - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(61010-2111)

Revised: 5/2013 Safetec of America, Inc.