

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.

INSTANT HAND SANITIZER – alcohol gel

Safetec of America, Inc.

Instant Hand Sanitizer

Drug Facts

Active Ingredient

Ethyl Alcohol 70%

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

Inactive ingredients

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

Supplied by

STATINA

HEALTHCARE AUSTRALIA

3/12 Yatala Rd.

Mt. Kuring-Gai, NSW, 2080

1300 365 404

www.statina.com.au

PRINCIPAL DISPLAY PANEL

NDC 61010-4111-0

Safetec

instant

Hand

Sanitizer

Kills 99.9% of Germs

Enriched with

Aloe Vera

Fresh

16 FL. OZ. (473 ML)

Reorder No. 17358

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INSTANT HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61010-4111
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	0.7 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
aloe (UNII: V5VD430YW9)	
water (UNII: 059QF0K00R)	
trolamine (UNII: 9O3K93S3TK)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61010-4111-0	473 mL in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/15/2010	

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

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE

Revised: 9/2010

Safetec of America