INSTANT HAND SANITIZER- alcohol gel Aero Healthcare

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

Aero Healthcare

Drug Facts

Active Ingredients

Ethyl Alcohol 66.5%

Purpose

Antiseptic

Uses

- for handwashing to decrease bacteria on skin
- 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 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

Manufactured for Aero Healthcare

63 Seaton St, Armidale, NSW 2350, Email: <u>sales@aerohealthcare.com</u> Ramsey, NJ 07446 www.aerohealthcare.us.com

PRINCIPAL DISPLAY PANEL – 2 fl. oz. Bottle Label

AERO CLEANSE

INSTANT HAND SANITIZER

Moisturizing Base with

Aloe Vera

60ml

2.0 fl.oz.

WATER-FREE

SOAP-FREE

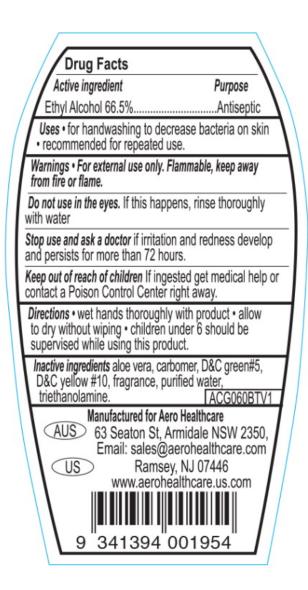
RINSE-FREE

Contains: Ethyl Alcohol 66.5% v/v

Code: ACG060

MADE IN USA





PRINCIPAL DISPLAY PANEL – 4 fl. oz. Bottle Label

AERO CLEANSE

INSTANT HAND SANITIZER

Moisturizing Base with

Aloe Vera

120ml

4.0 fl.oz.

WATER-FREE

SOAP-FREE

RINSE-FREE

Contains: Ethyl Alcohol 66.5% v/v

Code: ACG120



PRINCIPAL DISPLAY PANEL – 8 fl. oz. Bottle Label

AERO

CLEANSE

INSTANT HAND SANITIZER

Moisturizing Base with

Aloe Vera

240ml

8.0 fl.oz.

WATER-FREE

SOAP-FREE RINSE-FREE Contains: Ethyl Alcohol 66.5% v/v Code: ACG240



INSTANT HAND SANITIZER

alcohol gel

Product Information			
Product T ype	HUMAN OTC DRUG	Item Code (Source)	NDC:55305-111
Route of Administration	TOPICAL		

Ingredient Name			Basis of Strength	n Strength		
alcohol (UNII: 3K9958V9		alcohol	0.665g in $1mL$			
Inactive Ingredients	5					
	Strength					
aloe vera leaf (UNII: ZY81Z83H0X)						
carbomer interpolymer type a (55000 mpa.s) (UNII: 59TL3WG5CO)						
d&c green no. 5 (UNII: 8J6RDU8L9X)						
d&c yellow no. 10 (UNII: 35SW5USQ3G)						
water (UNII: 059QF0KO0)	P)					
water (Unit. 059QF0K00)	K)					
	,					
	,					
	,					
trolamine (UNII: 903K93	,					
trolamine (UNII: 903K93 Packaging	,	Marketii	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 Packaging # Item Code	S3TK)	Marketin	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 Packaging # Item Code 1 NDC:55305-111-10	S3TK) Package Description	Marketii	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 Packaging # Item Code 1 NDC:55305-111-10 2 NDC:55305-111-11	S3TK) Package Description 60 mL in 1 BOTTLE, PLASTIC	Marketii	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 Packaging	S3TK) Package Description 60 mL in 1 BOTTLE, PLASTIC 120 mL in 1 BOTTLE, PLASTIC	Marketii	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 Packaging # Item Code 1 NDC:55305-111-10 2 NDC:55305-111-11	S3TK) Package Description 60 mL in 1 BOTTLE, PLASTIC 120 mL in 1 BOTTLE, PLASTIC	Marketii	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 # Item Code 1 NDC:55305-111-10 2 NDC:55305-111-11 3 NDC:55305-111-12	S3TK) Package Description 60 mL in 1 BOTTLE, PLASTIC 120 mL in 1 BOTTLE, PLASTIC 240 mL in 1 BOTTLE, PUMP	Marketii	ng Start Date	Marketing End Date		
trolamine (UNII: 903K93 Fackaging Item Code NDC:55305-111-10 NDC:55305-111-11 NDC:55305-111-12 Marketing Infor	S3TK) Package Description 60 mL in 1 BOTTLE, PLASTIC 120 mL in 1 BOTTLE, PLASTIC 240 mL in 1 BOTTLE, PUMP mation					
trolamine (UNII: 903K93 Packaging # Item Code 1 NDC:55305-111-10 2 NDC:55305-111-11 3 NDC:55305-111-12	S3TK) Package Description 60 mL in 1 BOTTLE, PLASTIC 120 mL in 1 BOTTLE, PLASTIC 240 mL in 1 BOTTLE, PUMP		ng Start Date			
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Labeler - Aero Healthcare (008186174)

Registrant - Safetec of America, Inc. (874965262)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America, Inc.		874965262	MANUFACTURE(55305-111)

Revised: 12/2013

Aero Healthcare