ANTISEPTIC HAND GEL - ethyl alcohol gel H and P Industries, Inc. dba Triad Group

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% v/v

PURPOSE

Antiseptic

USES

For handwashing when water is not available to decrease bacteria on the skin

- after changing diapers
- after assisting ill persons
- before contact with a person under medical care or treatment
- recommended for repeated use

WARNINGS

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

Do not use

in the eyes.

Stop use and ask a doctor

- if irritation and redness develop.
- if condition 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 palmful of product in one hand
- Spread on both hands and rub into skin until dry (approx. 1-2 min.)
- Place a smaller amount into one hand
- Spread over hands to wrist and rub into skin until dry (approx. 30 sec.)

OTHER INFORMATION

Store at room temperature: 15°- 30° C (59° - 86° F)

INACTIVE INGREDIENTS

aloe vera gel, carbomer 940, denatonium benzoate, fragrance, PEG-1450, tert-butyl alcohol, triethanolamine, water

LABEL INFORMATION

Triad®

Cat. No. 10-8604 NDC 50730-8604-3

Antis eptic Hand Gel

Reduces the risk of bacterial contamination and infection Helps meet CDC, OSHA and APIC Guidelines for Hand Hygiene Contains Aloe Vera Gel

Triad Group, Inc.

700 West North Shore Drive Hartland, WI 53029 MADE IN USA www.triad-group.net

4 fl. oz. (118 ml)



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fl. oz. (118 mL) o print area

Drug Facts

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and redness develop Ask a doctor if condition
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Inactive Ingredients aloe vera gel, carbomer 940,

denatonium benzoate, fragrance, PEG-1450, tert-butyl alcohol, triethanolamine, water VENDOR: PLEASE PLACE UPN (UCC-EAN/128) (01) 00350730860437 (01) 00350730860437

ANTISEPTIC HAND GEL

ethyl alcohol gel

Product Information

Route of Administration

Product Type HUMAN OTC DRUG

TOPICAL

Item Code (Source)

NDC:50730-8604

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

Strength

alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	.70 mL in 1 mL
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Inactive Ingredients	
Ingredient Name	Strength
aloe vera leaf (UNII: ZY8 1Z8 3H0 X)	
carbomer homopolymer type c (UNII: 4Q93RCW27E)	
denatonium benzoate (UNII: 4YK5Z54AT2)	
polyethylene glycol 1450 (UNII: OJ4Z5Z32L4)	
tert-butyl alcohol (UNII: MD83SFE959)	
trolamine (UNII: 9O3K93S3TK)	
water (UNII: 059QF0KO0R)	

ı	Packaging			
l	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:50730-8604-3	118 mL in 1 BOTTLE, PLASTIC		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333	11/17/1997	

Labeler - H and P Industries, Inc. dba Triad Group (050259597)

$\pmb{Registrant - \text{H and P Industries, Inc. dba Triad Group (050259597)}}$

Establishment				
Name	Address	ID/FEI	Business Operations	
Hand P Industries, Inc. dba Triad Group		050259597	manufacture	

Revised: 11/2009 Hand P Industries, Inc. dba Triad Group