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. 10-8628 NDC 50730-8628-7

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

128 fl. oz. (3.79L)



Helps meet CDC, OSHA and APIC Guidelines for Hand Hygiene

Reduces the risk of bacterial contamination and infection

Contains Aloe Vera gel

128 1. oz.

Drug Facts Active Ingredient Purpose Ethyl Alcohol, 70% v/v. Colors

For handwashing to decrease bacteria on the skin

After changing diapers

After statisting it 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 if irritation and redness develop-Ask a doctor if condition persists 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 paintful 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 also vera gel, carboner 940, denatorium benzoate, fragrance, PEG-1450, tert-butyl alcohol, riethanolamine, water

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

5



ANTISEPTIC HAND GEL

ethyl alcohol gel

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:50730-8628

Route of Administration TOPICAL

Active Ingredient/Active Moiety

l	Ingredient Name	Basis of Strength	Strength
l	alcohol (UNII: 3K9958V90M) (alcohol - UNII:3K9958V90M)	alcohol	.70 L in 1 L

Inactive Ingredients		
Ingredient Name	Strength	
aloe vera leaf (UNII: ZY81Z83H0X)		
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				
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
ı	1 NDC:50730-8628-7	3.79 L 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)

Registrant - 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