HAND SANITIZER ANTICEPTIC- alcohol gel
Aztex Enterprises

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.

Hand Sanitizer

Uses

for handwashing to decrease bacteria on the skin.

Warnings for external use only.

When using this product; Do not use in eyes.

Discontinue use if irritation and redness develop

Directions

wet hand thoroughly with product

briskly rub hands together until dry

Inactive Ingredients

Deionized water

Glycerin

Propylen Glycol

Triethanolamine

Carbomer

Methyloaraben

Proplyparaben

Lemon Fragrance

Drug Fact 8ml/0.25 fl.oz. Made in Canada -> (L) 8295

Active ingredient Purpose

Ethyl alcohol 62% Antisepctic

8ml/0.25 fl. oz.

Flammable, keep away from fire or flames.

Keep out of reach of children

If swallowed contact a Poison Control Center right away

If pregnant or breast feeding, ask a health care professional before use

Not to Scale

Anticeptic Hand Sanitizer

AZX SPORT

Manufactured for

AZX SPORT

925 Century Drive

Burlington, ON L7L 5LB

HAND SANITIZER ANTICEPTIC

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:75887-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	5 mL in 8 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
CARBOMER 1342 (UNII: 809Y72KV36)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	LEMON (Lemon Fragrance)	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75887-001-01	30 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2011	
2	NDC:75887-001-02	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2011	
3	NDC:75887-001-03	8 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	01/13/2011	
4	NDC:75887-001-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2011	
5	NDC:75887-001-05	236 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/13/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	01/13/2011	

Labeler - Aztex Enterprises (253232326)

Registrant - Aztex Enterprises (253232326)

Establishment

Name	Address	ID/FEI	Business Operations
Aztex Enterprises		253232326	manufacture(75887-001)