HAND SANITIZER- ethyl alcohol gel Landy International

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.

51706-911 Hand Sanitizer Ethyl Alcohol(62%)

Active Ingredient(s)

Ethyl Alcohol 62%

Purpose

Antiseptic

Use

decreases bacteria on the skin that could cause disease I 1 recommended for repeated use

Warnings

For external use only: hands

Flammable, keep away from fire or flame.

When using this product

■keep out of eyes. In case of contact with

eyes flush thoroughly with water . \blacksquare avoid contact with broken skin \blacksquare do not inhale or ingest

Stop use and ask doctor if irritation and redness develop 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

Wet hands thoroughly with product and allow to dry without wiping **I** for children under 6, use only under adult supervision not recommended for infants

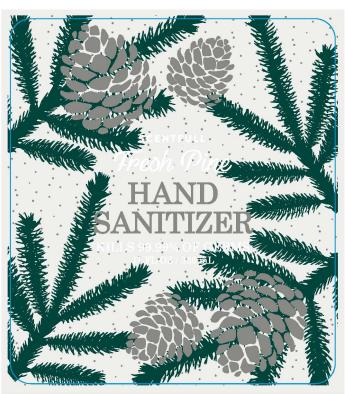
Inactive ingredients

Inactive Ingredients Water(aqua),fragrance (parfum), Acrylates/C10-30 alkyl acrylate crosspolymer, Glycerin, Triethanolamine, Tocopheryl acetate, Aloe barbadensis leaf extract,

Package Label - Principal Display Panel







*GRAY SHOWN FOR VISIBILITY ONLY. DO NOT PRINT. BACKGROUND IS TRANSLUCENT



*Effective at eliminating 99.99% of many common harmful germs



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m not recommended for infants

Other Information m do not store above 105° F m may discolor some fabrics m harmful to wood finishes and plastics

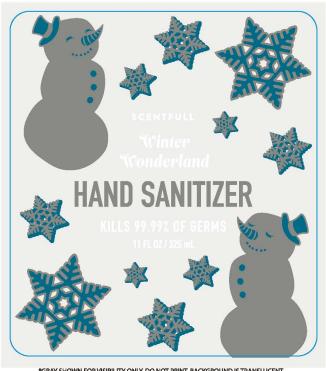
Inactive ingredients Water (Aqua), Fragrance (Parfum), Acrylates/C10-30 alkyl acrylate crosspolymer, Glycerin, Triethanolamine, Tocopheryl acetate, Aloe barbadensis leaf extract, Denatonium benoate, Prienosyethanol, Ethylhexylglycerin, Red 33 (CI 17200), Red 4 (CI 14700).

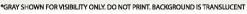
*Effective at eliminating 99.99% of many common harmful germs and bacteria in as little as 15 seconds 40038 218



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HAND SANITIZER

ethyl alcohol gel

Product Ir	nformation
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:51706-911

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name

Basis of Strength

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

62 mL in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
DENATONIUM BENZOATE (UNII: 4YK5Z54AT2)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C RED NO. 4 (UNII: X3W0AM1JLX)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		

FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
TROLAMINE (UNII: 903K93S3TK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER INTERPOLYMER TYPE A (55000 CPS) (UNII: 59TL3WG5CO)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:51706-911-	325 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/15/2020	

Labeler - Landy International (545291775)

Registrant - Landy International (545291775)

Establishment				
Name	Address	ID/FEI	Business Operations	
Landy International		545291775	manufacture(51706-911)	

Revised: 3/2022 Landy International