HAND SANITIZER- ethanol gel Just Play, LLC

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

Drug Facts

Active Ingredient

Ethyl alcohol 60%

Purpose

Antimicrobial

Uses

for hand sanitizing to decrease bacteria on the skin when soap and water are not available.

Warnings

For external use only-hands.

When using this product

avoid contact with eyes. In case of eye contact, rinse eyes with water.

Stop use and ask a doctor if

irritation or redness develops.

Keep out of reach of children.

If swallowed, drink plenty of water & consult a physician or Poison Control Center immediately.

Other information

- do not store above 105°F.
- may discolor some fabrics.
- harmful to wood finishes and plastics.

Directions

- pour a small amount of gel onto palm of hand. Rub briskly over all surfaces of both hands until dry.
- children under 6 should be supervised while using this product. Not recommended for infants.

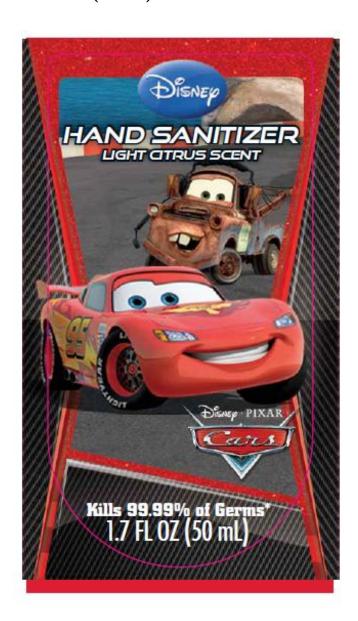
Inactive Ingredients

carbomer, fragrance, glycerin, propylene glycol, tocopheryl acetate, triethanolamine, water/aqua *Effective at eliminating over 99.99% of many common household germs & bacteria in as little as 15 seconds.

Distributed by: Just Play Deerfield Beach, FL 1-800-317-3245

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Principal Display Panel – Bottle Label
HAND SANITIZER
LIGHT CITRUS SCENT
Kills 99.99% of Germs*
1.7 FL OZ (50 mL)



HAND SANITIZER

ethanol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76308-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	600 mL in 1000 mL

Inactive Ingredients			
Ingredient Name	Strength		
CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E)			
GLYCERIN (UNII: PDC6A3C0OX)			
PROPYLENE GLYCOL (UNII: 6 DC9Q167V3)			
.ALPHATO COPHEROL ACETATE, D- (UNII: A7E6112E4N)			
TROLAMINE (UNII: 9O3K93S3TK)			
WATER (UNII: 059QF0KO0R)			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
NDC:76308-001-01	50 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	09/05/2011	

Labeler - Just Play, LLC (961720922)

Establishment				
Name	Address	ID/FEI	Business Operations	
Kingkey Daily Chemical Co., Ltd.		545349263	MANUFACTURE	

Revised: 9/2011 Just Play, LLC