

SMARTCARE SHOPKINS- ethyl alcohol gel
Shenzhen Lantern Science Co., Ltd.

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.

Active Ingredient

Ethyl Alcohol 62%

Purpose

Antiseptic

Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center right away.

Uses

To help reduce bacteria and germs on the skin.

Directions

- Place enough product in palm to cover hands and rub hands briskly together until dry.
- Children under 6, use only under adult supervision.
- Not recommended for infants.

Warning

Flammable. Keep away from fire or flame. For external use only.

Stop use and ask a doctor if irritation or redness develops and persists.

Inactive ingredients

aloe barbadensis gel, carbomer, fragrance, glycerin, isopropyl myristate, propylene glycol, tocopheryl acetate, triethanolamine, water



HAND SANITIZER - Alcohol



PMS: RHODAMINE RED (MAGENTA)
 C: 0
 M: 100
 Y: 0
 K: 0



Spanish
 INSIDE LEFT

Hechos de droga
Propósito de ingrediente activo Propósito Antiséptico
 Ethyl Alcohol 62%
Uso para ayudar a reducir las bacterias y los gérmenes en la piel.
ADVERTENCIA es inflamable. Aléjese de fuego o la llama. Para uso externo solamente. Evite el agua para evitar la irritación o resquebrajamiento de la piel y la vista. - Mantenga fuera del alcance de los niños. En caso de digestión accidental, lavar su sistema gastrointestinal con agua inmediatamente con un centro de control de toxinas.
Indicaciones - Colocar suficiente producto en la palma para cubrir las manos y frotar las manos vigorosamente hasta que se seque. - Usar sólo cuando se sienta o se cree que se está sucio. - No se recomienda para los bebés.
Otras informaciones - no almacenar por encima de 100 °F (38 °C). - Evitar el contacto con algunas superficies. - No usarse en superficies de madera y plásticos.
Ingredientes inactivos Water, Aloe Barbadensis Leaf Juice, Carbomer, Fragrance, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Triethanolamine.
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 Form # 00591-24
 8 52538 00591 6
 Smart Care®

French
 INSIDE RIGHT

Drug Facts
But de l'ingrédient actif But Antiseptique
 Ethyl Alcohol 62%
Utilisation pour aider à réduire les bactéries et germes sur la peau.
AVERTISSEMENT inflammable. Tenez à l'écart des flammes. Pour usage externe seulement. Évitez l'eau pour éviter l'irritation ou la décoloration de la peau et des yeux. - Maintenez hors de la portée des enfants. En cas de digestion accidentelle, rincez votre système digestif avec de l'eau immédiatement avec un centre de contrôle de toxines.
Directions - placez suffisamment de produit dans la paume pour couvrir les mains et frottez les mains vigoureusement jusqu'à ce qu'elles soient sèches. - Utilisez uniquement lorsque vous vous sentez ou pensez être sale. - Ne recommander pas pour les bébés.
Autres informations - ne stockez pas au-dessus de 100 °F (38 °C). Pour se débarrasser certaines surfaces. - Ne pas utiliser sur le bois et en plastique.
Les ingrédients inactifs Water, Aloe Barbadensis Leaf Juice, Carbomer, Fragrance, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Triethanolamine.
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English
 OUTSIDE/BACK

Drug Facts **PEEL HERE**
Active Ingredient Purpose Antiseptic
 Ethyl Alcohol 62%
Use To help reduce bacteria and germs on the skin.
Warning Flammable. Keep away from fire or flame. For external use only. - Stop use and ask a doctor if irritation or redness develops and persists. - Keep out of reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.
Directions - Place enough product in palm to cover hands and rub hands together until dry. - Cleanse only when you feel or think you are dirty. - Not recommended for infants.
Other Information - Do not store above 100°F (38°C). - May irritate some fabrics. - Harmful to wood finishes and plastics.
Inactive Ingredients Water, Aloe Barbadensis Leaf Juice, Carbomer, Fragrance, Glycerin, Isopropyl Myristate, Propylene Glycol, Tocopheryl Acetate, Triethanolamine.
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SMARTCARE SHOPKINS

ethyl alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54860-019
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54860-019-01	59 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/27/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	10/27/2017	

Labeler - Shenzhen Lantern Science Co., Ltd. (421222423)

Establishment

Name	Address	ID/FEI	Business Operations
Shenzhen Lantern Science Co., Ltd.		421222423	manufacture(54860-019)