ALPHA HANDRUB ANTISEPTIC HAND SANITIZER- ethyl alcohol gel Alpha Cleantech Labs Inc

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.

ALPHA HANDRUB ANTISEPTIC HAND SANITIZER GEL

Drug Facts

Active ingredient

Ethyl alcohol 75 %

Purpose

Antiseptic

Uses

- hand sanitizer to decrease bacteria on the skin
- recommended for repeated use
- for use when soap and water are not available

Warnings

Flammable, keep away from fire/flame For external use only

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product • do not get into eyes. In case of contact, rinse eyes thoroughly with water

Stop use and ask a 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
- supervise children under 6 years of age when using this product to avoid swallowing

Other information

- store between 15-30°C (59-86°F)
- avoid freezing and excessive heat above 40°C (104°F)
- sealed cap

Inactive ingredients

carbomer 940, glycerin, hydrogen peroxide, water

Questions?

+1-877-962-2636

You may also report serious side effects to this phone number.

Mon-Fri 9:00 AM - 5:00 PM

Manufactured for: Alpha Cleantech Labs Inc., Unit 111 – 20351 Duncan Way,

Langley, British Columbia, V3A 7N3

COUNTRY OF ORIGIN: CANADA

Website: www.alphacleantech.com

Packaging

ALPHA HANDRUB

ANTISEPTIC HAND SANITIZER GEL

8.45 fl oz (250 mL)

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Lot No:

Expiry:

ALPHA HANDRUB ANTISEPTIC HAND SANITIZER

ethyl alcohol gel

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:77959-202

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients	
Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
GLYCERIN (UNII: PDC6 A3C0 OX)	
HYDRO GEN PERO XIDE (UNII: BBX060AN9V)	
WATER (UNII: 059QF0KO0R)	

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:77959-202- 25	250 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2020		
2	NDC:77959-202- 50	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2020		
3	NDC:77959-202- 01	1000 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2020		
4	NDC:77959-202- 04	3785 mL in 1 BOTTLE; Type 0: Not a Combination Product	11/17/2020		
5	NDC:77959-202- 20	18927 mL in 1 CONTAINER; Type 0: Not a Combination Product	11/17/2020		
6	NDC:77959-202- 55	208198 mL in 1 CONTAINER; Type 0: Not a Combination Product	11/17/2020		

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC monograph not final	part333A	11/17/2020			

Labeler - Alpha Cleantech Labs Inc (204074603)

Establishment				
Name	Address	ID/FEI	Business Operations	
Alpha Cleantech Labs Inc		204074603	manufacture(77959-202)	

Revised: 11/2020 Alpha Cleantech Labs Inc