HAND SANITIZER- alcohol aerosol, spray LMA Services Limited

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.

LMA KAND Hand Sanitiser

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.45% v/v).
- c. Hydrogen peroxide (0.125% v/v).
- d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 80% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

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

Do not use

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

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel



Multi-purpose





KAND hand & surface sanitiser is a strong bactericidal and viricidal alcohol based formula that works against many different bacteria and viruses. KAND hand & surface sanitiser is fully tested to BS EN 1276 (Cert: 15725) for biocidal efficacy.

How to use: Spray onto one hand and rub together with the other hand in a washing action until the alcohol has evaporated. To use on surfaces simply spray on and leave to evaporate or wipe an excess liquid off after 5 minutes to leave the active ingredients on the surface.

Please note: The product is an active solution with a high alcohol content, soothing emollients and bactericide. Avoid applying to broken skin. May cause dry skin or irritate sensitive skin. If you are irritated by this product discontinue use.

DANGER: Extremely flammable aerosol. Pressurised container: May burst if heated. Causes serious eye irritation. May cause drowsiness or dizziness. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.

CONTAINS: Aqua, Ethyl Alcohol, Iso-propyl Alcohol, Dimethicone, Paraffinum Liquidium, Methyl Alcohol, Didecyldimonium Chloride.

UFI: MJ71-40JY-G002-E723

CPNP: 3304171











LMA House, Halifax way, Pocklington, YO42 1NR. Tel: 01759 304676 www.aerosol.uk.com

HAND SANITIZER

alcohol aerosol, spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:79402-150
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	55.29 g in 155 g		
DIDECYLDIMONIUM CHLORIDE (UNII: JXN40O9Y9B) (DIDECYLDIMONIUM - UNII:Z7F472XQPA)	DIDECYLDIMONIUM CHLORIDE	0.45 g in 155 g		
1,3-BIS((1-METHYLETHYL)AMINO)PROPAN-2-OL (UNII: W10T5DVF8Q) (1,3-BIS((1-METHYLETHYL)AMINO)PROPAN-2-OL - UNII:W10T5DVF8Q)	1,3-BIS((1- METHYLETHYL)AMINO)PROPAN- 2-OL	0.25 g in 155 g		

Inactive Ingredients		
Ingredient Name	Strength	
BENZOTRIAZOLE (UNII: 86110 UXM5Y)	0.71 g in 155 g	
LIQUEFIED PETROLEUM GAS (UNII: 5K6 16 HU99 V)	45.9 g in 155 g	
ALLYL ALCOHOL (UNII: 3W678R12M0)	0.1 g in 155 g	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.45 g in 155 g	
BORIC ACID (H3BO3), COMPD. WITH 2,2',2''-NITRILOTRIS(ETHANOL) (1:3) (UNII: 43O5OP619T)	0.89 g in 155 g	
METHYL ALCOHOL (UNII: Y4S76JWI15)	0.5 g in 155 g	
WATER (UNII: 059QF0KO0R)	12.1 g in 155 g	
METHYLAL (UNII: 7H1M4G2NUE)	0.1 g in 155 g	
PEG-5 PROPYLHEPTYL ETHER (UNII: B14N5T2HEY)	0.45 g in 155 g	
ACETONE (UNII: 1364PS73AF)	32.84 g in 155 g	

Product Characteristics			
Color	Score		
Shape	Size	200 mm	
Flavor	Imprint Code		
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:79402-150-01	155 g in 1 CAN; Type 0: Not a Combination Product	03/30/2020	



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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - LMA Services Limited (736891396)

Registrant - LMA Services Limited (736891396)

Establishment				
Name	Address	ID/FEI	Business Operations	
LMA Services Limited		736891396	manufacture(79402-150)	

Revised: 12/2020 LMA Services Limited