PURELY SANITIZER- alcohol gel King Pharma

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.

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) (65%, weight/weight (w/w)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. Glycerol (1.5% w/w).
- c. Hydroxypropyl Cellulose (1.1% w/w).
- d. Lauryl Lactate (1.0% w/w)
- e. 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 65% w/w. 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, hydroxypropyl cellulose, lauryl lactate, purified water USP

Package Label - Principal Display Panel

KING PHARMA

120 mL NDC: 74858-200-04

PURELLY SANITIZER alcohol gel Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:74858-200 Route of Administration TOPICAL NDC:74858-200 NDC:74858-200 Active Ingredient/Active Moiety Active Ingredient/Active Moiety Ingredient Name Basis of Strength Strength ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNIE3K9958 V90M) ALCOHOL 65 mL in 100 mL Ingredient Name Basis of Strength ALCOHOL (UNII: 9K9958 V90M) (ALCOHOL - UNIE3K9958 V90M) ALCOHOL 65 mL in 100 mL Ingredient Name Strength GLYCERIN (UNII: PDC6A3C00X) 15 mL in 100 mL WATER (UNII: 959QF0K00R) 15 mL in 100 mL HydroXypropyl Cellulose, UNSPECIFIED (UNII: 9X28H6N6OH) 1.1 mL in 100 mL LAURY LACTATE (UNII: GSSU0BFK/// SSU0BFK/// SU0A/// SSU0A///								
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2 NDC:74858-200- 08	240 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/09/2020	
3 NDC:74858-200- 38	3780 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/09/2020	
Marketing In	formation		
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Labeler - King Pharma (104697470)

Establishment

Name	Address	ID/FEI	Business Operations
King Pharma		104697470	manufacture(74858-200)

Revised: 4/2020

King Pharma