WET WIPES- disinfectant wipes cloth Anhui Hanbon Daily Chemical 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.

Hanbon Wet Wipes

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.

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.

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)

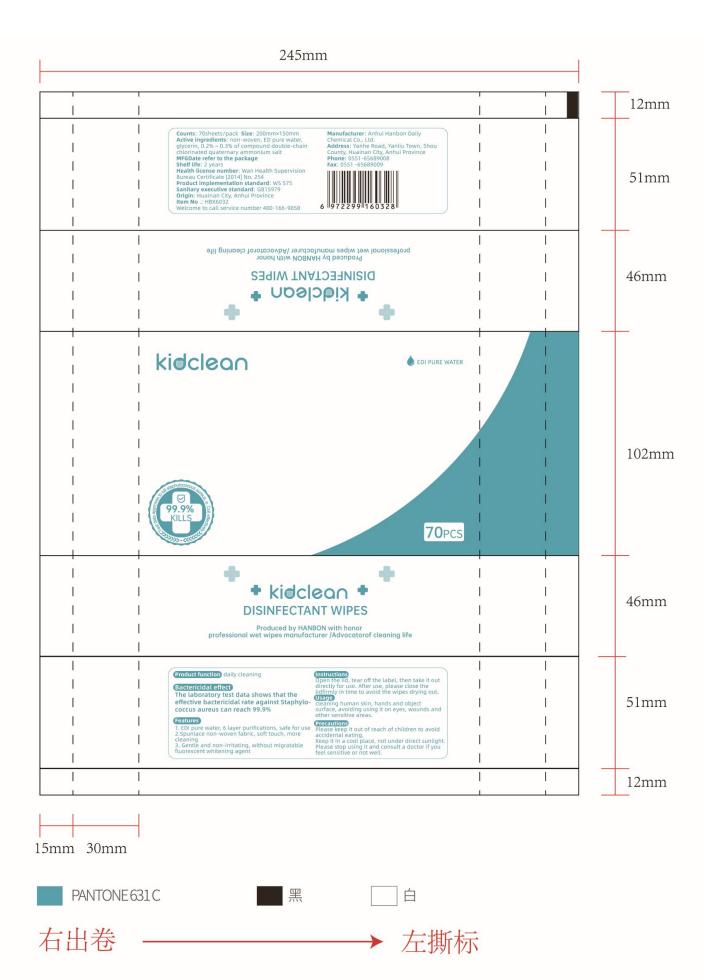
Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

40 PATCH in 1 PACKET NDC: 40562-008-03





WET WIPES

disinfectant wipes cloth

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:40562-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
TEA TREE OIL (UNII: VIF565UC2G) (TEA TREE OIL - UNII:VIF565UC2G)	TEA TREE OIL	0.03 mg in 100 mL		
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.1 mg in 100 mL		
CHAMO MILE (UNII: FGL3685T2X) (CHAMOMILE - UNII:FGL3685T2X)	CHAMOMILE	0.05 mg in 100 mL		
DIDECYLDIMO NIUM CHLO RIDE (UNII: JXN40 O9 Y9 B) (DIDECYLDIMO NIUM - UNII: Z7F472 XQ PA)	DIDECYLDIMONIUM CHLORIDE	0.05 mg in 100 mL		
N-ALKYL ETHYLBENZYL DIMETHYL AMMONIUM CHLORIDE (C12-C14) (UNII: G258 TFN6 1X) (N-ALKYL ETHYLBENZYL DIMETHYL AMMONIUM (C12-C14) - UNII:85440 928 RV)	N-ALKYL ETHYLBENZYL DIMETHYL AMMONIUM CHLORIDE (C12-C14)	0.05 mg in 100 mL		

Inactive Ingredients			
Ingredient Name	Strength		
GLYCERIN (UNII: PDC6A3C0OX)	0.3 mL in 100 mL		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.2 mL in 100 mL		
WATER (UNII: 059QF0KO0R)	99.065 mL in 100 mL		
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	0.1 mL in 100 mL		
ANHYDRO US CITRIC ACID (UNII: XF417D3PSL)	0.005 mL in 100 mL		
CETYLPYRIDINIUM CHLO RIDE ANHYDRO US (UNII: 6BR7T22E2S)	0.05 mL in 100 mL		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:40562-008-01	10 in 1 PACKET	06/16/2020	
1		4 mL in 1 PATCH; Type 0: Not a Combination Product		
2	NDC:40562-008-02	20 in 1 PACKET	06/16/2020	
2		4 mL in 1 PATCH; Type 0: Not a Combination Product		
3	NDC:40562-008-03	40 in 1 PACKET	06/16/2020	
3		4 mL in 1 PATCH; Type 0: Not a Combination Product		
4	NDC:40562-008-04	50 in 1 PACKET	06/16/2020	
4		4 mL in 1 PATCH; Type 0: Not a Combination Product		
5	NDC:40562-008-05	70 in 1 PACKET	06/16/2020	
5		4 mL in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	06/16/2020	

Labeler - Anhui Hanbon Daily Chemical Co., Ltd. (405624856)

Establishment				
Name	Address	ID/FEI	Business Operations	
Anhui Hanbon Daily Chemical Co., Ltd.		405624856	manufacture(40562-008)	

Revised: 6/2020 Anhui Hanbon Daily Chemical Co., Ltd.