# PLAN 36.5 HAND SANITIZER- alcohol gel 2bko

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.

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#### ACTIVE INGREDIENT

Active ingredient: ALCOHOL 70% w/w

#### INACTIVE INGREDIENT

Inactive ingredients:

Water, Carbomer, Tetrahydroxypropyl Ethylenediamine, Tocopheryl Acetate, Lavandula Angustifolia (Lavender) Oil, Fragaria Ananassa (Strawberry) Fruit Extract, Sophora Angustifolia Root Extract, Morus Alba Bark Extract, Glycyrrhiza Uralensis (Licorice) Root Extract, Citrus Paradisi (Grapefruit) Fruit Extract, Camellia Sinensis Leaf Extract, Aloe Barbadensis Extract, Salvia Officinalis (Sage) Extract

#### **PURPOSE**

Purpose: ANTISEPTIC

#### **WARNINGS**

Warnings:

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

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Do not use

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

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

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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

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

#### Uses

Uses:

Hand sanitizer to help reduce bacteria that potentially can cause disease.

#### **Directions**

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

Other information:

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

#### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL





### PLAN 36.5 HAND SANITIZER

alcohol gel

Product Type HUMAN OTC DRUG Item Code (Source) NDC:73264-011

Route of Administration TOPICAL

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII: 3K9958V90M)	ALCOHOL	350 mL in 500 mL

ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)

ALCOHOL

350 mL in 500 mL

### **Inactive Ingredients**

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
EDETOL (UNII: Q4R969U9FR)	
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)	
LAVENDER OIL (UNII: ZBP1YXW0H8)	
SOPHORA FLAVESCENS ROOT (UNII: IYR6K8KQ5K)	
MORUS ALBA BARK (UNII: 7071A48 NDP)	
GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K)	
GRAPEFRUIT (UNII: O82C39RR8C)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	
SALVIA OFFICINALIS ROOT (UNII: 236 QY0 A1BL)	

ı	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:73264-011- 01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	0 4/0 1/20 20		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	04/01/2020		

## **Labeler -** 2bko (695063277)

## **Registrant -** 2bko (695063277)

Establishment					
Name	Address	ID/FEI	Business Operations		
DongbangCosmetics Co., ltd.		694452564	manufacture(73264-011)		

Revised: 5/2020 2bko