O2 CLEAN HAND SANITIZER- alcohol gel O2 Clean

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.

ACTIVE INGREDIENT

Alcohol 70% v/v

INACTIVE INGREDIENTS

Acorus Calamus Root Extract, Camellia Sinensis Leaf Extract, Carbomer, Citrus Paradisi (Grapefruit) Fruit Extract, Cnidium Officinale Rhizome Extract, Fragaria Chiloensis (Strawberry) Fruit Extract, Glycyrrhiza Uralensis (Licorice) Root Extract, Lavandula Angustifolia (Lavender) Oil, Morus Alba Bark Extract, Sophora Angustifolia Root Extract, Tetrahydroxypropyl Ethylenediamine, Tocopheryl Acetate, Water

PURPOSE

Hand Sanitizer

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.

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

Can be used anytime and has effective Sterilization

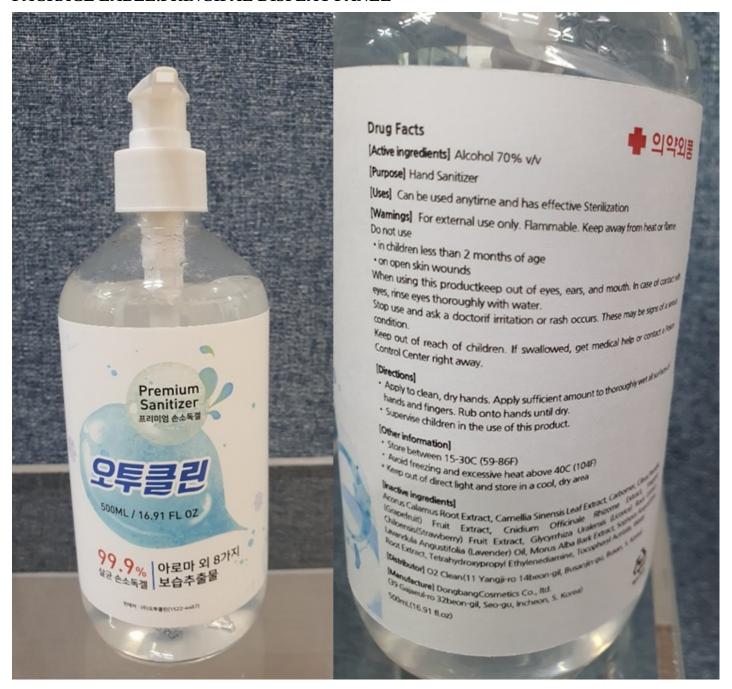
Directions

- Apply to clean, dry hands. Apply sufficient amount to thoroughly wet all surfaces of hands and fingers. Rub onto hands until dry.
- Supervise children in the use of this product.

Other Information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)
- * Keep out of direct light and store in a cool, dry area

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



O2 CLEAN HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:80453-010	
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		

Inactive Ingredients			
Ingredient Name	Strength		
ACORUS CALAMUS ROOT (UNII: XY1K7KIQ0F)			
GREEN TEA LEAF (UNII: W2ZU1RY8B0)			
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)			
GRAPEFRUIT (UNII: O82C39RR8C)			
CNIDIUM OFFICINALE ROOT (UNII: 8S3OZD358J)			
BEACH STRAWBERRY (UNII: 98542F2TQS)			
GLYCYRRHIZA URALENSIS ROOT (UNII: 42B5YD8F0K)			
LAVENDER OIL (UNII: ZBP1YXW0H8)			
MORUS ALBA BARK (UNII: 7071A48 NDP)			
SOPHORA FLAVESCENS ROOT (UNII: IYR6 K8 KQ5K)			
EDETOL (UNII: Q4R969U9FR)			
.ALPHATO COPHEROL ACETATE (UNII: 9E8X80D2L0)			
Water (UNII: 059QF0KO0R)			

ı	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:80453-010- 01	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	09/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	09/01/2020		

Labeler - O2 Clean (694888055)

Registrant - O2 Clean (694888055)

Establishment					
Name	Address	ID/FEI	Business Operations		
DongbangCosmetics Co., ltd.		694452564	manufacture(80453-010)		

Revised: 9/2020 O2 Clean