FIERA HAND SANITIZER- alcohol gel DONGBANGCOSMETICS 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.

ACTIVE INGREDIENT

Active ingredients: ALCOHOL 68.0%

INACTIVE INGREDIENT

Inactive Ingredients:

Water, Carbomer, Triethanolamine, PEG-60 Hydrogenated Castor Oil, Lavandula Angustifolia (Lavender) Oil, Methylparaben, Butylene Glycol, Fragaria Chiloensis (Strawberry) Fruit Extract, Pyrus Malus (Apple) Fruit Extract, Punica Granatum Fruit Extract, Citrullus Vulgaris (Watermelon) Fruit Extract, Solanum Lycopersicum (Tomato) Fruit Extract, Capsicum Annuum Fruit Extract, 1,2-Hexanediol, Glycosaminoglycans

PURPOSE

Purpose: SANITIZER

WARNINGS

Warnings:

1.Do not use the product on the following body parts:

Around the eyes and ears, in the mouth, large body parts and damaged skin(Irritation may occur)

- 2.If you experience any of the following symptoms, discontinue use of the product immediately and consult a physician or pharmacist.
- 1) Hypersensitivity symptoms, e.g. rash, erythema, itchiness, and edema
- 2)Skin irritation symptoms
- 3.Other precautions
- 1) For external use only (do not swallow).
- 2) Avoid contact with eyes. If contact occurs, wash with clean water and consult a doctor or pharmacist.
- 3)Be careful not to inhale vapors in cases of extended or prolonged use. (Repeating inhaling of large amounts of ethanol vapor may cause irritation of the mucous membranes and headaches).
- (Limited to ethanol-containing products)
- 4) If used repeatedly in the same area, care should be provided as the skin may become rough due to excessive oil removal.
- 5) Do not use sealed bandages, cast bandages, or packs as they may cause irritation.
- 6) Do not use this drug on the anal or vagina areas, or with hot packs, as it may cause irritation or chemical burns.
- 7) Use only for the intended purposes.
- 4. Precautions for storage
- 1) Keep away from direct sunlight and do not expose the product to heating devices or flame.
- 2) Keep out of reach of children and go to the hospital immediately if swallowed.
- 3) After use, close the lid completely to prevent the product from drying or foreign objects from getting inside the container.

4) Storing the product in a different container may cause accidents or deterioration of quality. Therefore, keep the product in its original container.

Dust or foreign substances may get on the product while using it.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children and go to the hospital immediately if swallowed.

Uses

Uses:

It contains 68% ethanol and sterilizes 99.9% virus while also being mild and soft on your hands.

Directions

Directions:

Take an appropriate amount on your hands and rub thoroughly to dry

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL



FIERA HAND SANITIZER

alcohol gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:74002-5020
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	340 g in 500 mL		

Inactive Ingredients	
Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	

CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)	
TROLAMINE (UNII: 9O3K93S3TK)	
PEG-60 Hydrogenated Castor Oil (UNII: 02NG325BQG)	
LAVENDER O IL (UNII: ZBP1YXW0 H8)	
Methylparaben (UNII: A2I8 C7HI9T)	
Butylene Glycol (UNII: 3XUS85K0RA)	

l	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date
	1	NDC:74002-5020-	500 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	03/01/2020		

Labeler - DONGBANGCOSMETICS CO.,LTD (694452564)

Registrant - DongbangCosmetics Co.,LTD (694452564)

Establishment				
Name	Address	ID/FEI	Business Operations	
DONGBANGCOSMETICS CO.,LTD		694452564	manufacture(74002-5020)	

Revised: 4/2020 DONGBANGCOSMETICS CO.,LTD