ORBEL- ethyl alcohol liquid Bath Concept Cosmetics (Dongguan) 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.

Orbel

Active Ingredient

Ethyl Alcohol-72%

Purpose

Antiseptic Hand Rub

Uses

Hand sanitizer to decrease bacteria on the skin that potentially can cause disease. Recommended for repeated use.

Warnings

For external use only

Avoid contact with eyes.

In case of eye contact, rinse eyes thoroughly with water. Discontinue use if irritation and redness develop.

Consult a doctor if condition persists for more than 72 hours.

Keep out of reach of children unless under adult supervision.

If swallowed, immediately call Poison Control Center or doctor.

Directions

• Apply small amount into your palm and thoroughly spread on both hands. Rub into skin until dry.

Questions or Comments ?:

Call +44 (0) 7970 443778

Hours M-F 9am-4pm (GMT)

Other Information

Store at 20-25°C

Inactive ingredients

DI water, Glycerin, Methylglucamine, Hydroxyethylcellulose, Fragrance

Principal Display Panel

Orbel Ethyl Alcohol 72%





ORBEL

ethyl alcohol liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61805-090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	72 mL in 100 mL	

Inactive Ingredients				
Ingredient Name	Strength			
WATER (UNII: 059QF0KO0R)				
GLYCERIN (UNII: PDC6A3C0OX)				
MEGLUMINE (UNII: 6 HG8 UB2MUY)				
HYDROXYETHYL CELLULOSE (4000 MPA.S AT 1%) (UNII: ZYD53NBL45)				
BUTYLPHENYL METHYLPROPIONAL (UNII: T7540GJV69)				
ISOMETHYLALPHAIONONE (UNII: 9XP4LC555B)				
.ALPHAAMYLCINNAMALDEHYDE (UNII: WC51CA3418)				
.ALPHAAMYLCINNAMYL ALCOHOL (UNII: DKB52S61GU)				
BENZYL ALCOHOL (UNII: LKG8494WBH)				
BENZYL BENZOATE (UNII: N863NB338G)				
CITRAL (UNII: T7EU0O9VPP)				
.BETACITRONELLOL, (+/-)- (UNII: 565OK72VNF)				
COUMARIN (UNII: A4VZ22K1WT)				
EUGENOL (UNII: 3T8H1794QW)				
GERANIOL (UNII: L837108USY)				
.ALPHAHEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)				
HYDRO XYISO HEXYL 3-CYCLO HEXENE CARBO XALDEHYDE (UNII: QUE 43B9 Z2Q)				
HYDRO XYCITRO NELLAL (UNII: 8SQ0 VA4YUR)				
LIMO NENE, (+)- (UNII: GFD7C86Q1W)				
LINALOOL, (+/-)- (UNII: D81QY6I88E)				
EVERNIA PRUNASTRI (UNII: O3034Q5AHK)				
PSEUDEVERNIA FURFURACEA (UNII: 49 ZMN0 9 Q0 K)				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:61805-090- 01	60 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/08/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH NOT FINAL	part333A	05/08/2019		

Labeler - Bath Concept Cosmetics (Dongguan) Co., Ltd (529623933)

Registrant - Bath Concept Cosmetics (Dongguan) Co., Ltd (529623933)

Establishment				
Name	Address	ID/FEI	Business Operations	
Bath Concept Cosmetics (Dongguan) Co., Ltd		529623933	manufacture(61805-090)	

Revised: 5/2019

Bath Concept Cosmetics (Dongguan) Co., Ltd