HAND SANITIZER- alcohol gel 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.

BthCncpts Trget Red Hnd Sntzr

Active Ingredient

Alcohol 62%

Purpose

Antiseptic

Use

■ For handwashing to decrease bacteria on the skin ■ Recommended for repeated use

Warnings

- For external use only
- Flammable, keep away from fire & flame
- Does not contain grain alcohol;do not drink. If taken internally will produce serious gastric disturbances

When using this product

- Avoid the eyes and mucous membranes
- In the case of eyes or mucous membranes contact, rinse area thoroughly with water

Stop use and ask a doctor if

- Condition worsens
- Redness or irritation develops
- If condition persists for more than 3 days

Keep out of reach of children

■ If swallowed contact a doctor or Poison Control Center immediately.

Directions

- Rub dime sized amount between hands until dry
- Supervise children in the use of this product
- In the case of eye contact, rinse eyes thoroughly with water

Other information

■ Store below 105°F ■ May discolor some fabrics

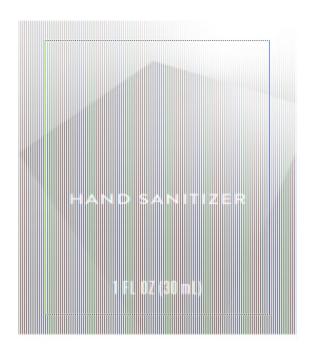
Inactive Ingredients

Water, Glycerin, Fragrance, Carbomer, Aminomethyl Propanol, Denatonium Benzoate, Red 40, Yellow 5

Questions?

■ 1-800-278-9218

Package Label Red





Drug Facts (continued)

IIII In the case of eyes or mucous membranes contact, rinse area thoroughly with water

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Drug Facts (continued)

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HAND SANITIZER

alcohol gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61805-403	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ALCOHOL (UNII: 3K9958 V90M) (ALCOHOL - UNII: 3K9958 V90M)	ALCOHOL	62 mL in 100 mL	

Inactive Ingredients		
Ingredient Name	Strength	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)		
GLYCERIN (UNII: PDC6A3C0OX)		
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0 A5MM307FC)		
WATER (UNII: 059QF0KO0R)		
DENATO NIUM BENZO ATE (UNII: 4YK5Z54AT2)		
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

ı	Packaging				
	# Item Code Package Description		Marketing Start Date	Marketing End Date	
	1 NDC:6180	5-403- 30 mL in 1 BOT Product	TLE, PLASTIC; Type 0: Not a Combination	07/01/2020	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333A	07/01/2020		

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Bath Concept Cosmetics (Dongguan) Co., Ltd		529623933	manufacture(61805-403)	

Revised: 7/2020 Bath Concept Cosmetics (Dongguan) Co., Ltd