ADVANCED ALCOHOL FOAMING HAND SANITIZER- alcohol soap Betco Corporation, 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.

Advanced Alcohol Foaming Hand Sanitizer

Active Ingredient

Active Ingredient

Ethyl Alcohol 70%

Uses

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- Use hand sanitizer to reduce microorganisms on the skin.
- Use this product when soap and water are not available.

Warnings

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- For external use only. Do not ingest.
- FLAMMABLE. This product contains ethyl alcohol. Keep away from sources of ignition.
- Avoid contact with eyes. In case of eye contact, flush with large quantities of water, seek medical attention if irritation persists.
- If skin irritation develops, discontinue use. If irritation persists for more than 72 hours, seek medical attention.
- Keep out of reach of children.
- If swallowed, get medical help or contact a Poison Control Center right away

Directions

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Read the entire label before using this product.

Place enough product on your palm to thoroughly cover your hands.

Rub hands together briskly until dry.

Inactive Ingredients

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Water, PEG-10 Dimethicone, PEG-10 Acrylate/Perfluorohexylethyl Acrylate

Copolymer, Perfluorohexylethyl Alcohol, Propylene Glycol, Fragrance, D&C

Green #5.

Purpose

Purpose

Advanced Alcohol Foaming Hand Sanitizer

KEEP OUT OF REACH OF CHILDREN

Advanced Alcohol Foaming Hand Sanitizer



ADVANCED ALCOHOL FOAMING HAND SANITIZER

alcohol soap

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65601-795		
Route of Administration	TOPICAL				

l	Active Ingredient/Active Moiety		
l	Ingredient Name	Basis of Strength	Strength
l	ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.7 mL in 1 mL

Inactive Ingredients				
Ingredient Name	Strength			
2-(PERFLUOROHEXYL)ETHANOL (UNII: G2R5YO5N3V)				
WATER (UNII: 059QF0KO0R)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PEG-10 ACRYLATE (UNII: F4663X97LW)				
D&C GREEN NO. 5 (UNII: 8J6RDU8L9X)				
PEG-10 DIMETHICO NE (600 CST) (UNII: 8PR7V1SVM0)				

Product Characteristics				
Color	blue	Score		
Shape		Size		

Flavor	Imprint Code	
Contains		

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65601-795- 04	3780 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019			
2	NDC:65601-795- 53	50 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2019			
3	NDC:65601-795- 57	550 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2019			
4	NDC:65601-795- 29	1000 mL in 1 BAG; Type 0: Not a Combination Product	08/01/2019			
5	NDC:65601-795- 03	750 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2019			
6	NDC:65601-795- 05	1200 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/01/2019			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part333E	08/01/2019		

Labeler - Betco Corporation, Ltd. (024492831)

Registrant - Betco Corporation, Ltd. (024492831)

Establishment				
Name	Address	ID/FEI	Business Operations	
Betco Corporation, Ltd.		024492831	manufacture(65601-795), label(65601-795)	

Revised: 8/2019 Betco Corporation, Ltd.