BZK HAND SANITIZER- bzk hand sanitizer spray Tropical Enterprises International, Inc.

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.

BK-S/F-0312012-CRC BZK non-alcohol sanitizer

ACTIVE INGREDIENT

Active Ingredient

Benzalkonium Chloride 0.13%

Purpose.... Antiseptic

INDICATIONS AND USAGE

Use Hand Sanitizer to help reduce bacteria that potentially can cause disease.

For use when soap and water are not available.

DOSAGE AND ADMINISTRATION

Directions: Wet hands thoroughly with product and allow to dry without wiping.

INACTIVE INGREDIENT

Inactive Ingredients Water, Phenoxyethanol, Ethylhexylglycerin

WARNING

WARNINGS: For external use only.

When using this product avoid contact with eyes.

If contact with eyes occurs, flush with water.

Stop use and ask a doctor if irritation or redness develops and perists.

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develops and persists.

KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If swallowed, seek prompt medical attention.

Flammable. Keep away from open flames.

Avoid freezing and excessive heat above 40C (104F)

Questions: 1-800-535-5053

Other Information: Non-staining, may discolor certain fabrics.



BZK HAND SANITIZER

bzk hand sanitizer spray

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:58418-187

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient NameBasis of StrengthStrengthBENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)BENZALKONIUM CHLORIDE0.039 g in 30 mL

Inactive Ingredients Ingredient Name Strength ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) WATER (UNII: 059QF0K00R) PHENOXYETHANOL (UNII: HIE492ZZ3T)

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:58418- 187-05	15 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012				
2	NDC:58418- 187-10	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012				
3	NDC:58418- 187-01	30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012				
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4	187-02	60 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012
5	NDC:58418- 187-04	120 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	08/01/2012
6	NDC:58418- 187-08	240 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012
7	NDC:58418- 187-17	50.275 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	08/01/2012
8	NDC:58418- 187-70	211200 mL in 1 DRUM; Type 0: Not a Combination Product	02/02/2020
9	NDC:58418- 187-32	1228800 mL in 1 CONTAINER, FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	02/02/2020
10	NDC:58418- 187-25	$960000\ mL$ in $1\ CONTAINER,$ FLEXIBLE INTERMEDIATE BULK; Type 0: Not a Combination Product	04/24/2020

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC monograph not final	part333E	08/01/2012						

Labeler - Tropical Enterprises International, Inc. (091986179)

Registrant - Tropical Enterprises International, Inc. (091986179)

Revised: 4/2020 Tropical Enterprises International, Inc.