

BACTAKLEEN HAND SANITIZER- benzalkonium chloride liquid
Excelsia Technologies Sdn Bhd

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.

BACTAKLEEN HAND SANITIZER

Active Ingredients

Benzalkonium chloride (0.1%)

Purpose

Antibacterial

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Uses

Hand Sanitizer to help reduce bacteria on skin

Warnings

For external use only

Do not use if you are allergic to any of the ingredients

When using this product avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.
avoid contact with broken skin

Stop use and ask a doctor if irritation or redness develops and condition persists for more than 72 hours

If pregnant or breast-feeding, ask a health professional before use.

Place enough product in your palm to thoroughly spread on both hands and rub into the skin until dry.

Inactive Ingredients

Water. Aloe Barbadosensis Leaf Juice, Lime (Citrus Aurantifolia) Juice, Tea Tree (Melaleuca Alternifolia) Leaf Oil.

BACTAKLEEN HAND SANITIZER

Why use harsh chemicals when you can do the job with non-toxic, environment-friendly BACTAKLEEN?

Drug Facts	
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Inactive Ingredients	
Water, Aloe Barbadensis Leaf Juice, Lime (Citrus Aurantifolia) Juice, Tea Tree (Melaleuca Alternifolia) Leaf Oil	
Manufactured by: company name (address)	
Distributed by: company name (address)	

BACTAKLEEN HAND SANITIZER

benzalkonium chloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73215-101
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.5 g in 500 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Product Characteristics

Color	Score
Shape	Size
Flavor	Imprint Code
Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73215-101-01	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	07/24/2019	

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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	07/24/2019	

Labeler - Excelsia Technologies Sdn Bhd (659311797)

Registrant - Excelsia Technologies Sdn Bhd (659311797)

Establishment

Name	Address	ID/FEI	Business Operations
MBH Cosmeceutical Sdh Bhd		659311739	manufacture(73215-101)

Revised: 7/2019

Excelsia Technologies Sdn Bhd