

**ALCOHOL FREE HAND SANITIZER- benzalkonium chloride solution
Hybrisan 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.

Hybrisan Alcohol Free Aloe Vera & Cucumber Hand Sanitizer

Drug Facts

Benzalkonium Chloride 0.13% Purpose Antiseptic

Drug Facts

Antiseptic

Drug Facts

For personal hand sanitizing and to reduce bacteria on the skin. Recommended for repeated use

Avoid contact with eyes. In the case of eye contact flush eyes with water.

Warnings

When using this product avoid contact with eyes. In case of eye contact flush eyes with water.

Ask Doctor

Stop use and ask a doctor if irritation and redness develop

Inactive ingredients

Fragrances, water

Directions

Apply liberally to the hands and gently rub until dry

Questions?

Telephone: 44-1639-898150 Monday through Friday 8:00am til 4:30pm UK time

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Package quantity





**Alcohol Free
Hand Sanitiser**

Liquid with
Cucumber and Aloe Vera Fragrance

Made with  technology

A spray on alcohol free sanitiser providing ongoing protection to treated hands. Kills up to 99.999% of pathogenic organisms

100ml (3.38fl oz)^e

www.gwaliahealthcare.com

100ml (3.38 Floz) NDC 81685-321-10

Drug Facts		Drug Facts (Continued)	
Active Ingredient Benzalkonium Chloride 0.13%..Antiseptic	Purpose	If swallowed, get medical help or contact a Poison Control Center right away.	
Uses For personal hand sanitizing and to reduce bacteria on the skin. Recommended for repeated use.		Directions Apply liberally to the hands and gently rub until dry.	
Warnings for external use only. Do not use in the eyes		Inactive ingredients Fragrances, Water	
When using this product avoid contact with eyes. In case of eye contact flush eyes with water.		Questions? Telephone: +44 1639 898150 Monday through Friday 8:00am till 4:00pm GMT	
Stop use and ask a doctor if irritation and redness develops.			

Effective against up to 99.999% of pathogenic organisms according to BS EN1276:2019 and BS EN14476:2013 + A2:2019. Provides ongoing protection between uses.

Manufactured by:
Hybrisan Ltd.
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SA13 1RU
www.hybrisan.com

Distributed by:
Gwalia Healthcare Ltd.
Taffs Mead Road,
Treforest Ind. Est.
Pontypridd,
RCT. UK
CF37 5TF
www.gwaliahealthcare.com



ALCOHOL FREE HAND SANITIZER

benzalkonium chloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:81685-321
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII: 7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
PHENYLETHYL ALCOHOL (UNII: ML9LGA7468)	
3A,4,5,6,7,7A-HEXAHYDRO-1H-4,7-METHANOINDEN-6-YL ACETATE (UNII: 5232EN3X2F)	
ISOMETHYL-.ALPHA.-IONONE (UNII: 9XP4LC555B)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
.ALPHA.-HEXYLCINNAMALDEHYDE (UNII: 7X6O37OK2I)	
.ALPHA.-TERPINEOL (UNII: 21334LVV8W)	

LINALOOL, (+/-)- (UNII: D81QY6I88E)

METHYL HEPTINE CARBONATE (UNII: 0TTP6YT2T3)

Product Characteristics

Color	yellow (Clear liquid)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81685-321-10	100 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	03/23/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/23/2021	

Labeler - Hybrisan Ltd (219599200)

Establishment

Name	Address	ID/FEI	Business Operations
Hybrisan Ltd		219599200	manufacture(81685-321)

Establishment

Name	Address	ID/FEI	Business Operations
Gwalia Healthcare Limited		220632253	pack(81685-321)

Revised: 3/2021

Hybrisan Ltd