# ACORE BUBBLE GUM HAND SANITIZER GIRLS- alcohol denat. gel Gold Orient International Limited

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.

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### ACORE Bubble Gum(Girls)Hand Sanitizer

### Active ingredient

Alcohol Denat. 62%

#### **Purpose**

Antiseptic

#### Use

Use for hand-washing to decrease bacteria on the skin, only when water it not available.

#### **Warnings**

For external use only. Flammable, keep away from fire and flames.

### When using this product

Do not get into eyes.

If contact occurs, rinse eyes thoroughly with water.

#### Stop use and ask a doctor if

If irritation and redness develop.

#### Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

#### **Directions**

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

## Other information

Store at 68 to 77F (20-25C)

Do not store above 110F (43C)

You may report a serious adverse reaction to this product to Report Reaction, LLC, PO Box 22, Plainsboro, NJ 08536

## **Inactive ingredient**

Water,

Glycerin,

Acrylates/C10-30 Alkyl Acrylate Crosspolymer,
Fragrance,
Polysorbate 20,
Sodium Hydroxide,
Red 33,
Blue 1

# Label



# ACORE BUBBLE GUM HAND SANITIZER GIRLS

alcohol denat. gel

Product	<b>Information</b>
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:51522-046

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	62 mL in 100 mL

# **Inactive Ingredients**

Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
POLYSORBATE 20 (UNII: 7T1F30 V5YH)		
GLYCERIN (UNII: PDC6A3C0OX)		
D&C RED NO. 33 (UNII: 9DBA0SBB0L)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
SO DIUM HYDRO XIDE (UNII: 55X0 4QC32I)		
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)		

# **Packaging**

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7	# Item Code	Package Description	Marketing Start Date	Marketing End Date
:	NDC:51522-046- 01	1 in 1 CASE	08/03/2020	
:	L	30 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

# **Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	08/03/2020	

# Labeler - Gold Orient International Limited (679905914)

Establishment					
Name	Address	ID/FEI	Business Operations		
Cold Orient International Limited		670005014	manufacture (51522-0.46)		

Revised: 8/2020 Gold Orient International Limited