

ACORE BUBBLE GUM HAND SANITIZER BOYS- 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.

ACORE Bubble Gum Boys Hand Sanitizer

Active ingredient

Alcohol Denat. 62%

Purpose

Antiseptic

Use

Use for hand-washing to decrease bacteria on the skin, only when water is 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



HAND SANI COLOR:



PANTONE 193



PANTONE 369



PANTONE 291



PANTONE 727



WHITE



ACORE BUBBLE GUM HAND SANITIZER BOYS

alcohol denat. gel

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51522-043 |
| 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) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| D&C RED NO. 33 (UNII: 9DBA0SBB0L) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:51522-043-01 | 1 in 1 CASE | 07/30/2020 | |
| 1 | | 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 | 07/30/2020 | |

Labeler - Gold Orient International Limited (679905914)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|------------------------|
| Gold Orient International Limited | | 679905914 | manufacture(51522-043) |