

**CALLICOS SAFE GOOD HAND GEL- alcohol gel
HEALKINBIO CO.**

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.

Active Ingredient(s)

alcohol

Purpose

Purpose: Antiseptic

Use

☐ Hand sanitizing to help reduce bacteria on the skin

Warnings

- ☐ For external use only.
- ☐ Flammable, keep away from fire or flame.
- ☐ When using this product, avoid contact with the eyes. In case of contact, rinse eyes thoroughly with water.
- ☐ Stop use and ask a doctor if irritation or redness appears and lasts.
- ☐ Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

Directions

☐ Take suitable amount of sanitizer in the hand. Wet thoroughly and rub hands together until dry
water glycerin carbome triethanolamine, tocopheryl acetate, Polysorbate 20, camellia sinensis leaf extract

Callicos Safe Good Hand gel

| Drug Facts | |
|--|--------------------|
| Active Ingredients | Purpose |
| Alcohol 70% ----- | Disinfecting Agent |
| Uses | |
| <ul style="list-style-type: none"> ■ instant healthcare personnel hand antiseptic to reduce bacteria that potentially can cause disease ■ instant hand antiseptic to decrease bacteria on the skin | |
| Warning | |
| <p>For external use only</p> <p>When using this product</p> <ul style="list-style-type: none"> ■ if following abnormal symptoms persist, discontinue use Irritation around the eyes, ears, mucous membranes, including the mouth, under the skin irritation and rashes ■ Stop immediately and consult a doctor if you experience <ol style="list-style-type: none"> 1) Hypersensitivity symptoms such as erythema, itching and dermatitis. 2) Skin Irritation 3) Following Instructions when using medication <ol style="list-style-type: none"> (1) For external use only (Do not use internally) (2) Avoid getting into the eyes (if contact occurs, wash well with clean water) ■ Be careful not to inhale or use excessively for a long time (ingesting ethanol repeatedly causes irritation to mucous membranes and headaches or other symptoms may appear. When used repeatedly in the same area, skin irritation may occur. ■ Do not use the product for a long time in the same area as swelling, inflammation or sickness may occur due to absorption through the skin. It is not recommended to use this one areas that have been medically treated with a cast or bandage. ■ Do not use in combination with soap or antibacterial cleansing agents. | |
| Directions | |
| <ul style="list-style-type: none"> ■ Pour a small amount into hands, spread evenly and rub into the skin | |
| Other Information | |
| <ul style="list-style-type: none"> - read the directions and warnings before use - avoid freezing and excessive heat above 40 degree C (104 degree F) | |
| Inactive Ingredients | |
| Water, glycerin, carbomer, triethanolamine, tocopherol acetate, polysorbate 20, camellia sinensis leaf extract | |
| Questions or Comments? | |

CALLICOS SAFE GOOD HAND GEL

alcohol gel

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76586-107 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 70 mL in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| TROLAMINE (UNII: 9O3K93S3TK) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| CARBOMER 940 (UNII: 4Q93RCW27E) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76586-107-01 | 500 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/04/2020 | |
| 2 | NDC:76586-107-02 | 100 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/04/2020 | |
| 3 | NDC:76586-107-03 | 30 mL in 1 POUCH; Type 0: Not a Combination Product | 06/04/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333A | 06/04/2020 | |

Labeler - HEALKINBIO CO. (694039685)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------|---------|-----------|------------------------|
| HEALKINBIO CO. | | 694039685 | manufacture(76586-107) |

Revised: 6/2020

HEALKINBIO CO.