

ALCARE OR FOAMED ANTISEPTIC HANDRUB- alcohol aerosol, foam
STERIS Corporation

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.

Alcare OR[®] Foamed Antiseptic Handrub

Drug Facts

Active ingredient

62% v/v Ethyl Alcohol

Purposes

Antiseptic

Uses

- **Surgical Scrub** significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care.
- **Healthcare Personnel Handwash** to decrease transient bacteria on the skin before contact with patients under medical care or treatment.

Warnings

Flammable, keep away from fire or flame. **For external use only.** Avoid contact with eyes. Eye irritant. If splashed in eyes, rinse promptly and thoroughly with water.

Discontinue use if irritation and redness develop.

If irritation persists for more than 3 days, consult a physician.

Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

Contents under pressure. Do not puncture or incinerate. Do not store above 120°F (49°C). For best foam density store and use at 55 - 85°F (13 - 29°C).

Directions

Surgical Scrub

Clean under nails with a pick. Nails should be maintained with a 1 mm free edge. Dispense 5 grams (tennis ball) onto one hand. Spread on both hands, paying particular attention to the nails, cuticles, and interdigital spaces and forearms. Rub into skin until dry. Dispense 2.5 grams (golf ball) onto one hand and spread over both hands to the wrists and rub into the skin until dry.

Healthcare Personnel Handwash

Apply product to hands and rub until thoroughly dry.

Inactive ingredients

Water, Hydrofluorocarbon 152A, Isobutane, Emulsifying Wax, Polyquaternium-6, Sodium Benzoate,

Propane, Sodium Sesquicarbonate

Questions or comments?

800-548-4873

PRINCIPAL DISPLAY PANEL - 482 g Can Label

Foamed
Antiseptic
Handrub

Alcare OR[®]

NDC 0519-6396-80

Hand Sanitizer

Excellent
Moisturization

Surgical Scrub

CHG Compatible

Manufactured for:
STERIS Corporation
7501 Page Avenue
St. Louis, MO 63133 ■ USA
800-548-4873 www.steris.com

For Hospital and Professional Use Only.

Net Weight: 482g (17 oz)

REORDER #

6396-80

STERIS[®]

6396-71F(1113)

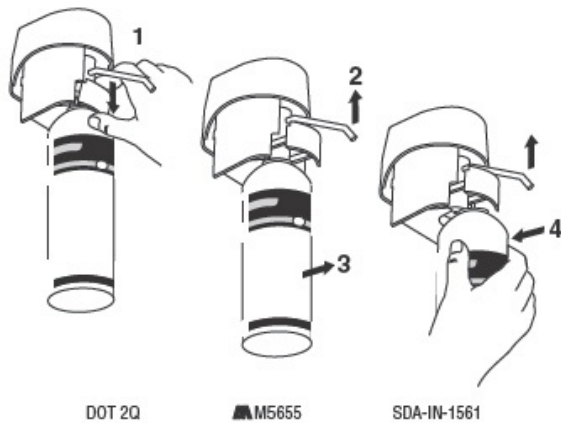
52374

Product Made in U.S.A.

| | |
|---|-------------------------------|
| Drug Facts | |
| Active ingredient 62% w/v Ethyl Alcohol | Purposes Antiseptic |
| Uses | |
| <ul style="list-style-type: none"> • Surgical Scrub significantly reduces the number of micro-organisms on the hands and forearms prior to surgery or patient care. • Healthcare Personnel Handwash to decrease transient bacteria on the skin before contact with patients under medical care or treatment. | |
| Warnings | |
| Flammable, keep away from fire or flame. For external use only. Avoid contact with eyes. Eye irritant. If splashed in eyes, rinse promptly and thoroughly with water. Discontinue use if irritation and redness develop. If irritation persists for more than 3 days, consult a physician. Keep this and all drugs out of the reach of children. In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately. Contents under pressure. Do not puncture or incinerate. Do not store above 120°F (49°C). For best foam density store and use at 55 - 85°F (13 - 29°C). | |
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| Healthcare Personnel Handwash Apply product to hands and rub until thoroughly dry. | |
| Inactive ingredients Water, Hydrofluorocarbon 152A, Isobutane, Emulsifying Wax, Polyquaternium-6, Sodium Benzoate, Propane, Sodium Sesquicarbonate | |
| Questions or comments? 800-548-4873 | |

For use with the T164-Q0 Aerosol Dispenser.

- (1) To replace can, snap can retainer downward to release.
 - (2) Raise nozzle to clear can.
 - (3) Pull can retainer straight out, then pull can straight out.
 - (4) Keep nozzle in up position to prevent can activation.
- Insert new can and push in retainer.



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| ALCARE OR FOAMED ANTISEPTIC HANDRUB | | | |
|-------------------------------------|----------------------|---------------------------|---------------|
| alcohol aerosol, foam | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG LABEL | Item Code (Source) | NDC:0519-6396 |
| Route of Administration | TOPICAL | DEA Schedule | |
| Active Ingredient/Active Moiety | | | |

| Ingredient Name | Basis of Strength | Strength |
|-------------------|-------------------|---------------|
| ALCOHOL (ALCOHOL) | ALCOHOL | 62 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------------------|----------|
| WATER | |
| 1,1-DIFLUOROETHANE | |
| ISOBUTANE | |
| CETOSTEARYL ALCOHOL | |
| POLYSORBATE 60 | |
| POLYQUATERNIUM-6 (15000 MW) | |
| SODIUM BENZOATE | |
| PROPANE | |
| SODIUM SESQUICARBONATE | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:0519-6396-90 | 12 in 1 CASE | | |
| 1 | NDC:0519-6396-80 | 482 g in 1 CAN | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part333E | 02/08/2005 | |

Labeler - STERIS Corporation (139424188)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|------------------------|
| Accra Pac, Inc. | | 024213616 | MANUFACTURE(0519-6396) |