

CERTUS RECENS A- alcohol aerosol, foam
Certus Medical, Inc.

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.

Certus Recens Foam A 4802 Drug Facts and Label

Drug Facts Box OTC-Active Ingredients Section

Ethyl Alcohol 62%

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications and Usage Section

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

Drug Facts Box OTC-Warnings Section

Flammable, keep away from fire and flames

For external use only

Drug Facts Box OTC-When Using Section

do not get into eyes

if contact occurs, rinse eyes thoroughly with water

Drug Facts Box OTC-Stop Use Section

irritation and redness develop

Drug Facts Box OTC-Keep Out of Reach of Children Section

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

Drug Facts Box OTC-Dosage & Administration Section

press valve once to deliver one squirt (about a quarter size) of foaming product onto the palm of your hand

rub hands together and allow to dry without wiping

Drug Facts Box OTC-Inactive Ingredients Section

water, DEA-C8-18 perfluoroalkylethyl phosphate, cetearyl alcohol, polysorbate 60, polysorbate 65, dimethicone PEG-8 meadowfoamate, meadowfoamamidopropyl betaine, stearth 20, PEG 40 hydrogenated castor oil, butane, propane

Certus Recens Foam A 4802 Label and Drug Facts

WARNING: FLAMMABLE
CONTENTS UNDER PRESSURE
KEEP OUT OF REACH OF CHILDREN

Do not puncture or incinerate. Do not store near fire or flame.
Do not expose to temperatures above 125°F.
Avoid contact with eyes. Use only according to label directions.
Call Regional Poison Control Center for further assistance if necessary.

Drug Facts

| Active Ingredient | Purpose |
|-------------------|------------|
| Ethyl Alcohol 62% | Antiseptic |

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

Warnings

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

When using this product

- do not get into eyes
- if contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor 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 ■ press valve once to deliver one squirt (about a quarter size) of foaming product onto the palm of your hand ■ rub hands together and allow to dry without wiping

Inactive Ingredients water, DEA-C8-18 perfluoroalkylethyl phosphate, cetearyl alcohol, polysorbate 65, dimethicone PEG-8 meadowfoamate, meadowfoamidopropyl betaine, butane, propane

CERTUS
MEDICAL

Recens Foam A

Foaming Hand Sanitizer

NET WT. 7oz
(199 grams)

480207FM.032718

Reorder No.: 480207FM

Manufactured for
Certus Medical, Inc.
P. O. Box 16247
Atlanta, GA 30321-0247
www.certusmedikal.com



480207FM.032718

Certus Recens Foam A

CERTUS RECENS A

alcohol aerosol, foam

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:75990-774 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 620 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| | |
|---|--|
| PROPANE (UNII: T75W9911L6) | |
| BUTANE (UNII: 6LV4FOR43R) | |
| WATER (UNII: 059QF0K00R) | |
| DIETHANOLAMINE BIS(C8-C18 PERFLUOROALKYLETHYL)PHOSPHATE (UNII: 4J55VM509S) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| POLYSORBATE 65 (UNII: 14BGY2Y3MJ) | |
| DIMETHICONE PEG-8 BENZOATE (UNII: 18KOO18SJP) | |
| MEADOWFOAMAMIDOPROPYL BETAINE (UNII: HNV0L650LG) | |
| PEG-40 CASTOR OIL (UNII: 4ERD2076EF) | |
| STEARETH-20 (UNII: L0Q8IK9E08) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:75990-774-25 | 199 g in 1 CAN; Type 0: Not a Combination Product | 04/25/2011 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| OTC mono graph not final | part333E | 04/25/2011 | |

Labeler - Certus Medical, Inc. (966433653)

Registrant - ABC Compounding Co., Inc. (003284353)

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|------------------------|
| ABC Compounding Company of Texas, Inc. | | 026219253 | manufacture(75990-774) |

Revised: 11/2018

Certus Medical, Inc.