

HAND SANITIZER - alcohol liquid
Rochester Midland 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.

Hand Sanitizer 6585 Drug Facts and Label

Drug Facts Box OTC-Active Ingredient Section

Ethyl Alcohol 62% v/v

Drug Facts Box OTC-Purpose Section

Antiseptic

Drug Facts Box OTC-Indications & 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 pump twice to deliver two squirts (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 Ingredient Section

water, DEA-C8-18 perfluoroalkylethyl phosphate, propylene glycol, fragrance

Hand Sanitizer 6585 650 ml bag

6585B6P5488.jpg Hand Sanitizer 650 ml bag

HAND sanitizer

less waste - less storage space - better for the environment

Drug Facts

Active Ingredients

Ethyl Alcohol 62% v/v.....

Purpose

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 pump twice to deliver two squirts (about a quarter size) of foaming product onto the palm of your hand
- rub hands together and allow to dry without wiping

Inactive Inredients water. DEA-C8-18 perfluoro-

alkylethyl phosphate, propylene glycol, fragrance



Manufactured for:
Rochester Midland Corporation
155 Paragon Drive
Rochester, NY 14624
1.800.388.4762
www.rochestermidland.com

11928687

8036-lbl

Volume NET: 650ml (21.98 fluid oz.)

made in the USA

HAND SANITIZER

alcohol liquid

Product Information

| | | | |
|-------------------------|----------------|--------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59503-6585 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M) | ALCOHOL | 0.62 mL in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DIETHANOLAMINE BIS(C8-C18 PERFLUOROALKYLETHYL)PHOSPHATE (UNII: 4J55VM509S) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:59503-6585-9 | 650 mL in 1 BAG | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part333E | 09/23/2011 | |

Labeler - Rochester Midland Corporation (002207041)

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|---------------------|
| ABC Compounding Co., Inc. | | 003284353 | manufacture |

Revised: 9/2011

Rochester Midland Corporation