# HANDTASTIC FOAMY MANGO ANTISEPTIC HAND AND BODY WASHchloroxylenol soap Momar Incorporated

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.

-----

# Handtastic Foamy Mango Antiseptic Hand and Body Wash 6876 Drug facts and Label

### **Drug Facts Box OTC-Active Ingredient Section**

Chloroxylenol 0.3%

#### **Drug Facts Box OTC-Purpose Section**

Antiseptic

#### **Drug Facts Box OTC-Indications & Usage Section**

for hand-washing to decrease bacteria on the skin

## **Drug Facts Box OTC-Warnings Section**

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**

- wet hands and forearms
- apply 5 milliliters (teaspoonful) or palmful to hands and forearms
- scrub thoroughly for 1 minute and rinse

#### **Drug Facts Box OTC-Inactive Ingredient Section**

water, decyl glucoside, sodium laureth sulfate, cocamide MIPA, propylene glycol, DMDM hydantoin, fragrance, methylchloroisothiazolinone, methylisothiazolinone, aloe barbadensis, acid red 1

#### Handtastic Foamy Mango Antiseptic Hand and Body Wash 6876 Label



# Hand & Body Wash

Net Contents: 18oz (532ml)



# Hand & Body Wash

Net Contents: 18oz (532ml)



Handtastic Foamy Mango Antiseptic Hand and Body Wash 6876 Label

Made in the U.S.A.

#### HANDTASTIC FOAMY MANGO ANTISEPTIC HAND AND BODY WASH

chloroxylenol soap

| Product Information      |
|--------------------------|
| F I VUUCT IIIVI IIIAUVII |

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63533-876

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

**DMDM HYDANTO IN** (UNII: BYR0 546 TO W) **ALOE VERA LEAF** (UNII: ZY8 1Z8 3H0 X)

| Ingredient Name |   | Basis of Strength | Strength     |
|-----------------|---|-------------------|--------------|
|                 | CHLOROXYLENOL (UNII: 0 F32U78 V2Q) (CHLOROXYLENOL - UNII: 0 F32U78 V2Q) | CHLOROXYLENOL     | 3 mg in 1 mL |

# Ingredient Name Strength WATER (UNII: 059QF0KO0R) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) SODIUM LAURETH SULFATE (UNII: BPV390UAP0) DECYL GLUCOSIDE (UNII: Z17H97EA6Y) ACID RED 1 (UNII: 3365R6427R) METHYLCHLORO ISOTHIAZOLINO NE (UNII: DEL7T5QRPN) METHYLISOTHIAZOLINO NE (UNII: 229D0E1QFA)

| Pa | Packaging            |  |                         |                       |
|----|----------------------|--|-------------------------|-----------------------|
| #  | Item Code            | Package Description                                | Marketing Start<br>Date | Marketing End<br>Date |
| 1  | NDC:63533-876-<br>06 | 1 in 1 BOX   | 0 1/20 /20 17           |                       |
| 1  |                      | 800 mL in 1 BAG; Type 0: Not a Combination Product |                         |                       |

| 2  | NDC:63533-876-<br>17 | 532 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 1/20 /20 17 |
|----|----------------------|---|---------------|
| 3  | NDC:63533-876-<br>24 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 1/20/20 17  |
| 4  | NDC:63533-876-<br>01 | 1200 mL in 1 CARTRIDGE; Type 0: Not a Combination Product       | 0 1/20 /20 17 |
| 5  | NDC:63533-876-<br>03 | 350 mL in 1 CARTRIDGE; Type 0: Not a Combination Product        | 0 1/20 /20 17 |
| 6  | NDC:63533-876-<br>05 | 540 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 1/20 /20 17 |
| 7  | NDC:63533-876-<br>07 | 700 mL in 1 BAG; Type 0: Not a Combination Product              | 0 1/20 /20 17 |
| 8  | NDC:63533-876-<br>09 | 2000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product       | 0 1/20 /20 17 |
| 9  | NDC:63533-876-<br>10 | 1000 mL in 1 CARTRIDGE; Type 0: Not a Combination Product       | 0 1/20 /20 17 |
| 10 | NDC:63533-876-<br>11 | 1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 1/20 /20 17 |
| 11 | NDC:63533-876-<br>12 | 1000 mL in 1 BAG; Type 0: Not a Combination Product             | 0 1/20 /20 17 |
| 12 | NDC:63533-876-<br>13 | 800 mL in 1 BAG; Type 0: Not a Combination Product              | 0 1/20 /20 17 |
| 13 | NDC:63533-876-<br>14 | 3785 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 0 1/20/20 17  |
| 14 | NDC:63533-876-<br>15 | 946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 1/20/20 17  |
| 15 | NDC:63533-876-<br>28 | 149 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 1/20/20 17  |
| 16 | NDC:63533-876-<br>27 | 800 mL in 1 CARTRIDGE; Type 0: Not a Combination Product        | 0 1/20/20 17  |
| 17 | NDC:63533-876-<br>55 | 208200 mL in 1 DRUM; Type 0: Not a Combination Product          | 0 1/20/20 17  |
| 18 | NDC:63533-876-<br>08 | 1 in 1 BOX  | 0 1/20/20 17  |
| 18 |                      | 1000 mL in 1 BAG; Type 0: Not a Combination Product             |               |
| 19 | NDC:63533-876-<br>16 | 236 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product  | 0 1/20/20 17  |
| 20 | NDC:63533-876-<br>18 | 50 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product   | 0 1/20/20 17  |
| 21 | NDC:63533-876-<br>19 | 18900 mL in 1 CONTAINER; Type 0: Not a Combination Product      | 0 1/20/20 17  |
| 22 | NDC:63533-876-<br>20 | 75600 mL in 1 DRUM; Type 0: Not a Combination Product           | 0 1/20/20 17  |
| 23 | NDC:63533-876-<br>35 | 132500 mL in 1 DRUM; Type 0: Not a Combination Product          | 0 1/20 /20 17 |

| Marketing Information   |  |                      |                    |
|-------------------------|--|----------------------|--------------------|
| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part333E                                 | 0 1/20/20 17         |                    |
|                         |  |                      |                    |

# Labeler - Momar Incorporated (003266616)

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

| Establishment             |         |           |                        |  |
|---------------------------|---------|-----------|------------------------|--|
| Name                      | Address | ID/FEI    | Business Operations    |  |
| ABC Compounding Co., Inc. |         | 003284353 | manufacture(63533-876) |  |

Revised: 12/2018 Momar Incorporated