Ambix First Aid Antiseptic & Pain Relieving Cream

Active Ingredients
Phenol 0.5%
Dyclonine Hydrochloride 0.5%

Purpose
First Aid Antiseptic
Topical Anesthetic

Uses
- first aid to help protect against infection and for the temporary relief of pain and itching associated with minor burns, minor cuts, scrapes, insect bites, or minor skin irritations.

Warnings
- For external use only ■ Do not bandage ■ Do not use in the eyes or apply over large areas of the body ■ Do not use longer than 1 week unless directed by a doctor
- Do not use in eyes, do not apply over large areas of the body. In case of deep puncture wounds or serious burns, consult a doctor.

Ask a doctor before use if you have
a deep or puncture wound, an animal bite, serious burn, or before using on a child aged 2 or under.

Stop use and ask a doctor if
redness, irritation, swelling, or pain persists or increases.

Keep out of reach of children
If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- Clean the affected area ■ Apply a small amount of this product on the area 1 to 3 times daily

Other Information
- Store at controlled room temperature 15°C to 30°C (59°F to 86°F).
- You may report serious side effects to the phone number provided under “Questions?” below.
Inactive Ingredients
Allantoin, Benzyl Alcohol, Disodium EDTA, Glyceryl Stearate, Mineral Oil, Methyl Paraben, Petrolatum, Propyl Paraben, Sodium Lauryl Sulfate, Stearic Acid, Stearyl Alcohol, Triethanolamine, Water

Ambix
FIRST AID
Antiseptic & Pain Relieving Cream
Net Wt. 7/8 oz. (25 grams)
Dist. by Ambix Laboratories, Totowa, NJ 07512 ■ Made in USA ■ © 2013

Ambix
FIRST AID
Antiseptic & Pain Relieving Cream
Net Wt. 1-1/2 oz. (42.5 grams)
Dist. by Ambix Laboratories, Totowa, NJ 07512 ■ Made in USA ■ © 2013
AMBIX FIRST AID

Antiseptic & Pain Relieving Cream

Net Wt. 1-1/2 oz. (42.5 grams)

**Drug Facts**

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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</thead>
<tbody>
<tr>
<td><strong>DYCLONINE HYDROCHLORIDE</strong></td>
<td>DYCLONINE</td>
<td>0.005 g</td>
</tr>
<tr>
<td>(UNII: ZEC193879Q) (DYCLONINE - UNII:078A24Q30O)</td>
<td>HYDROCHLORIDE</td>
<td>in 1 g</td>
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<tr>
<td><strong>PHENOL</strong></td>
<td>PHENOL</td>
<td>0.005 g</td>
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<tr>
<td>(UNII: 339NCG44TV) (PHENOL - UNII:339NCG44TV)</td>
<td></td>
<td>in 1 g</td>
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</table>

**Inactive Ingredients**

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
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<tbody>
<tr>
<td><strong>ALLANTOIN</strong></td>
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<tr>
<td>(UNII: 344S277G0Z)</td>
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<tr>
<td><strong>BENZYL ALCOHOL</strong></td>
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<tr>
<td>(UNII: LKG8494WBH)</td>
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<tr>
<td><strong>EDETATE DISODIUM</strong></td>
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<td>(UNII: 7FLD9JIC86K)</td>
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<tr>
<td><strong>GLYCERYL MONOSTEARATE</strong></td>
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<tr>
<td>(UNII: 230U9XXE4)</td>
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<tr>
<td><strong>MINERAL OIL</strong></td>
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<td>(UNII: T5L8T28FGP)</td>
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<tr>
<td><strong>METHYL PARABEN</strong></td>
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<td>(UNII: A2BC7HBDT)</td>
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<tr>
<td><strong>PETROLATUM</strong></td>
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<tr>
<td>(UNII: 4T6H12BN9U)</td>
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<tr>
<td><strong>PROPYL PARABEN</strong></td>
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<tr>
<td>(UNII: Z8IX2SCI0H)</td>
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## SODIUM LAURYL SULFATE (UNII: 368GB5141J)

## STEARIC ACID (UNII: 4ELV7Z65AP)

## STEARYL ALCOHOL (UNII: 2KR894HIY)

## TROLAMINE (UNII: 9O3K93S3TK)

## WATER (UNII: 059QF0KO0R)

### Packaging

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<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
<th>Marketing Start Date</th>
<th>Marketing End Date</th>
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<td>1</td>
<td>NDC:10038-250-25</td>
<td>1 in 1 BOX</td>
<td>08/22/2013</td>
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<tr>
<td>1</td>
<td></td>
<td>25 g in 1 TUBE; Type 0: Not a Combination Product</td>
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<td></td>
<td>42.5 g in 1 TUBE; Type 0: Not a Combination Product</td>
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### Marketing Information

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<td>OTC monograph not final</td>
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### Labeler - Organics Corporation of America dba Ambix Laboratories (061061164)

### Registrant - Organics Corporation of America dba Ambix Laboratories (061061164)

### Establishment

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
<th>Business Operations</th>
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<tr>
<td>Suite K Value Added Services LLC</td>
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<td>036822144</td>
<td>manufacture(10038-250)</td>
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Revised: 11/2019

Organics Corporation of America dba Ambix Laboratories