

**FIORE RX CORAL SORBET ANTIFUNGAL NAIL POLISH- undecylenic acid film  
Cosco International, 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.*

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**Drug Facts**

| <b>Active Ingredient</b> | <b>Purpose</b> |
|--------------------------|----------------|
| Undecylenic Acid 3%..... | Anti-fungal    |

**Anti-fungal**

**Warnings For external use only.**

**Do not use** on children under 2 years of age unless directed by a doctor.

**KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.**

In case of accidental ingestion, contact a physician, emergency medical care facility or poison control center immediately for advice.

**When using this product** avoid contact with eyes.

**Stop use and ask a doctor if** irritation occurs.

**Directions**

Clean nails and dry thoroughly.

Remove any nail polish with nail polish remover. Allow to dry thoroughly. Roll your bottle of Fioré Rx Antifungal Nail Lacquer in between your hands to mix the lacquer thoroughly. Do not shake the bottle, as this can introduce air bubbles that will affect the quality of the lacquer. Using only the brush provided in the Fioré Rx bottle, apply a strip of lacquer down the middle of your nail from cuticle to tip before following it with lacquer on either side. Allow lacquer to dry for at least 2 minutes. For best results, apply a second coat and allow to dry for 30 minutes.

**Inactive ingredients**

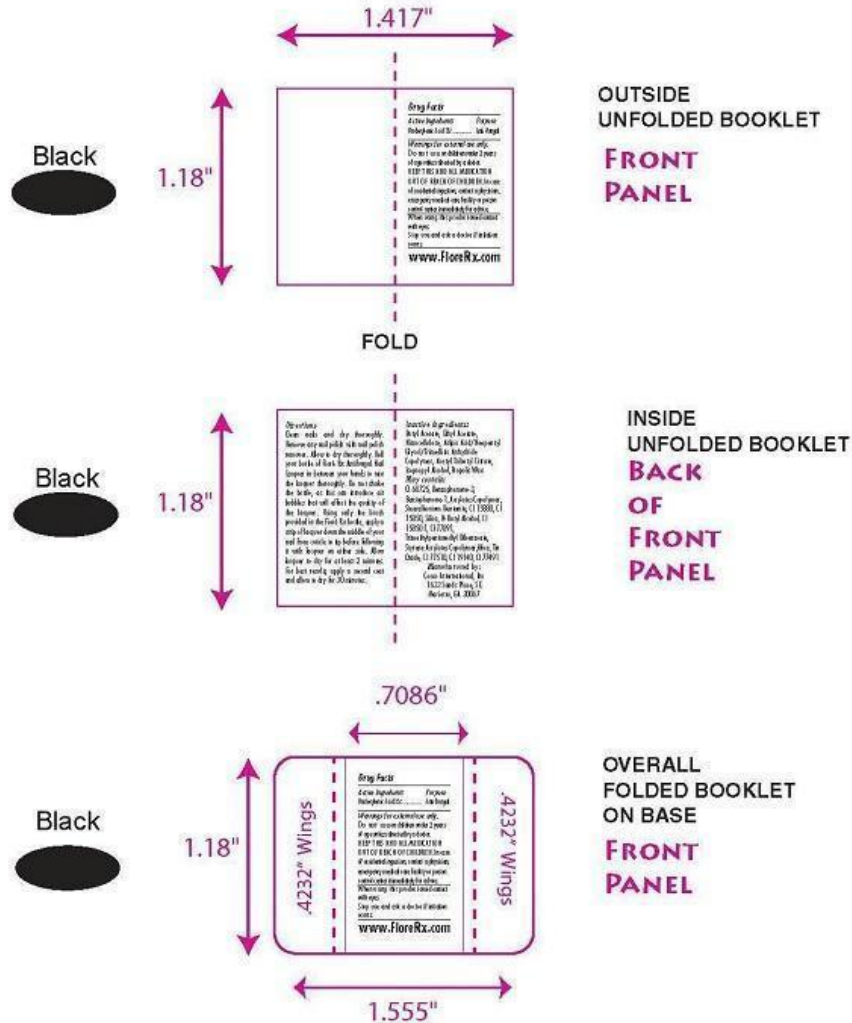
Butyl acetate, ethyl acetate, nitrocellulose, adipic acid/neopentyl glycol/trimellitic copolymer, acetyl tributyl citrate, isopropyl alcohol, propolis wax

*May contain:*

CI 60725, Benzophenone-3,  
Benzophenone-1, Acrylates Copolymer,  
Stearalkonium Bentonite, CI 15880, CI  
15850, Silica, N-Butyl Alcohol, CI  
15850:1, CI 77891,  
Trimethylpentanediyl Dibenzoate,  
Styrene Acrylates Copolymer, Mica, Tin  
Oxide, CI 77510, CI 19140, CI 77491

| NO. | REVISIONS   | DATE    | BY   | LABEL SIZE | 1.417" x 1.18"   | PRINT COLORS | YES <input type="checkbox"/> UV <input checked="" type="checkbox"/> NO <input type="checkbox"/> |
|-----|---|---------|------|------------|------------------|--------------|---|
| 1   | ADDED TO INACTIVE INGREDIENTS: Minig. Tin Oxide, Shing. CI 77550, CI 19140                                | 5/16/13 | MARK |            | FINISHED PRODUCT |              |   |
| 2   | ADDED TO INACTIVE INGREDIENTS: Propolis Wax REMOVED FROM ACTIVE INGREDIENTS: Propolis Wax 0.1% Anti-Taxol | 8/29/13 | MARK |            |                  |              |   |

**NOTES:**  
DIE LINE DOES NOT PRINT.



DATE: 8/30/13  
TIME: 3:45PM

|                              |  |   |  |                     |  |
|------------------------------|--|---|--|---------------------|--|
| <p><b>COPY POSITIONS</b></p> | <p><b>CUSTOMER SIGN-OFF</b></p> <p>Please notify your customer service representative if an error is found.</p> <p>CUSTOMER APPROVAL: _____</p> <p>DATE: / /</p> | <p><b>PLEASE CHECK THIS PROOF CAREFULLY.</b></p> <p>YOUR LABEL IS PRODUCED DIRECTLY FROM THIS PROOF. IT IS NECESSARY THAT WE RECEIVE A SIGNED APPROVAL TO BEGIN PRODUCTION.</p> <p>UNLESS NOTED OTHERWISE DIMENSIONS ARE IN INCHES</p> <p>TOLERANCES UNLESS NOTED OTHERWISE +/- .030"</p> |  |                     |  |
|                              |  |   | <p>DRAWN BY: <u>W.B.</u></p> <p>APVD BY: _____</p> <p>QUALITY: _____</p> | <p>DATE: 3/1/13</p> | <p>DRAWING # STEG50-FIORE-BK</p> <p>DESCRIPTION/PART # 1.417x1.18 2 Fiore Drug Facts Booklet</p> <p>SCALE 100%</p> <p>SHEET 1</p> <p># OF SHTS 1</p> |

undecylenic acid film

### Product Information

|                                |                      |                           |                |
|--------------------------------|----------------------|---------------------------|----------------|
| <b>Product Type</b>            | HUMAN OTC DRUG LABEL | <b>Item Code (Source)</b> | NDC:52261-0207 |
| <b>Route of Administration</b> | TOPICAL              | <b>DEA Schedule</b>       |                |

### Active Ingredient/Active Moiety

| <b>Ingredient Name</b>              | <b>Basis of Strength</b> | <b>Strength</b> |
|-------------------------------------|--------------------------|-----------------|
| Undecylenic Acid (Undecylenic Acid) | Undecylenic Acid         | 0.45 g in 15 mL |

### Inactive Ingredients

| <b>Ingredient Name</b>   | <b>Strength</b>     |
|--|---------------------|
| Butyl Acetate  | 5.483175 g in 15 mL |
| Ethyl Acetate  | 3.353295 g in 15 mL |
| Pyroxylin  | 2.081865 g in 15 mL |
| POLYESTER-10   | 1.059525 g in 15 mL |
| Acetyltributyl Citrate   | 1.040925 g in 15 mL |
| Isopropyl Alcohol  | 0.89223 mL in 15 mL |
| BENTOQUATAM  | 0.17844 g in 15 mL  |
| DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER | 0.167295 g in 15 mL |
| TITANIUM DIOXIDE   | 0.0939 g in 15 mL   |
| Polacrillin  | 0.074355 g in 15 mL |
| D&C RED NO. 6  | 0.03564 g in 15 mL  |
| Silicon Dioxide  | 0.029745 g in 15 mL |
| Benzoresorcinol  | 0.029745 g in 15 mL |
| PROPOLIS WAX   | 0.015 g in 15 mL    |
| Trimethylpentanediyil Dibenzoate   | 0.014865 g in 15 mL |

### Packaging

| # | Item Code        | Package Description                | Marketing Start Date | Marketing End Date |
|---|------------------|------------------------------------|----------------------|--------------------|
| 1 | NDC:52261-0207-0 | 15 mL in 1 BOTTLE, WITH APPLICATOR |                      |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part333C                                 | 05/22/2013           |                    |

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**Labeler** - Cosco International, Inc. (016433141)

**Registrant** - Cosco International, Inc. (016433141)

**Establishment**

| Name                      | Address | ID/FEI    | Business Operations  |
|---------------------------|---------|-----------|--|
| Cosco International, Inc. |         | 016433141 | manufacture(52261-0207), label(52261-0207), pack(52261-0207) |

Revised: 9/2013

Cosco International, Inc.