FIORE RX CRANAPPLE CRUSH 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.

Drug Facts

Active Ingredient ***Purpose***
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 anhydride copolymer, acetyl tributyl citrate, isopropyl alcohol, propolis wax

May contain:

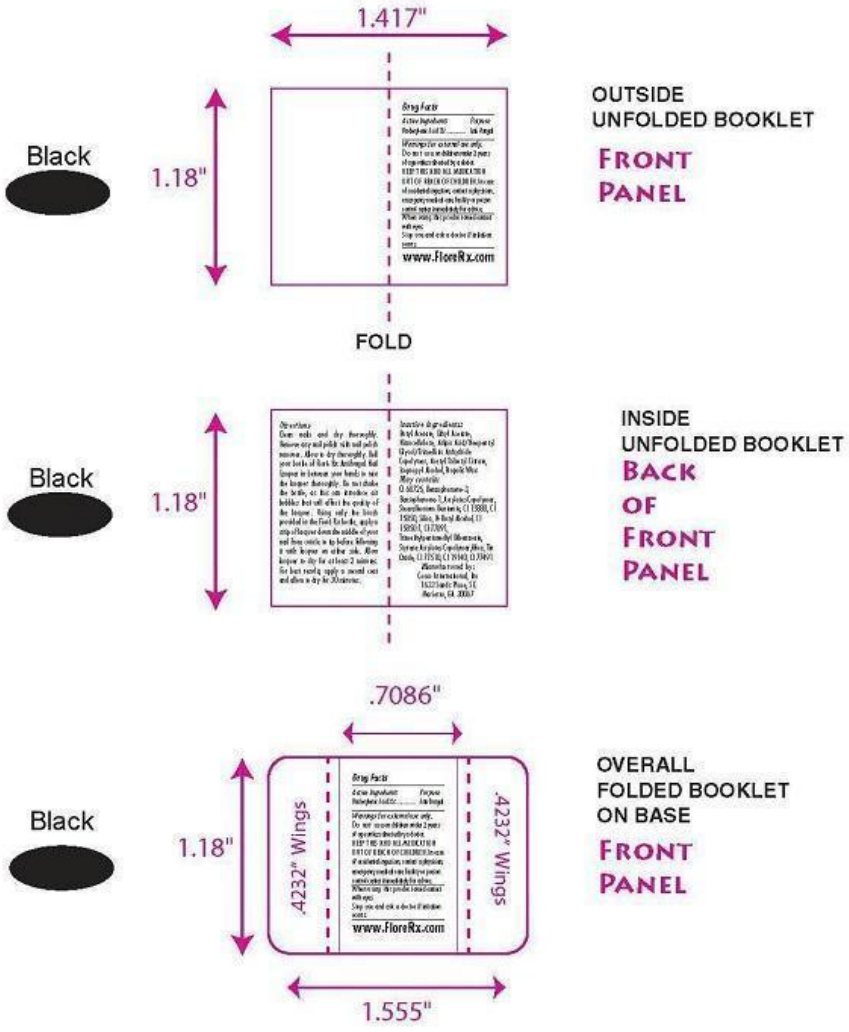
Stearalkonium Bentonite, Acrylates Copolymer, CI 77891, Styrene Acrylates Copolymer, CI 15850, Silica, Benzophenone-1, Trimethylpantanediyl Dibenzoate, Mica, Tin Oxide, CI 77510, CI 19140, CI 77491

NO.	REVISIONS	DATE	BY
1	ADDED TO INACTIVE INGREDIENTS: Mica, Tin Oxide, Silica, CI 77510, CI 19140	5/16/13	MARK
2	ADDED TO INACTIVE INGREDIENTS: Propolis Wax REMOVED FROM ACTIVE INGREDIENTS: Propolis Wax 0.1% Anti-fungal	8/29/13	MARK

LABEL SIZE: 1.417" x 1.18" FINISHED PRODUCT

PRINT COLORS: YES ☐ UV NO ☑

NOTES:
DIE LINE DOES NOT PRINT.



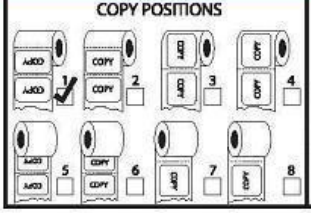
OUTSIDE
UNFOLDED BOOKLET
FRONT
PANEL

INSIDE
UNFOLDED BOOKLET
BACK
OF
FRONT
PANEL

OVERALL
FOLDED BOOKLET
ON BASE
FRONT
PANEL

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

COPY POSITIONS



CUSTOMER SIGN-OFF
Please notify your customer service representative if an error is found.
CUSTOMER APPROVAL: _____
DATE: ___/___/___

PLEASE CHECK THIS PROOF CAREFULLY.
YOUR LABEL IS PRODUCED DIRECTLY FROM THIS PROOF. IT IS NECESSARY THAT WE RECEIVE A SIGNED APPROVAL TO BEGIN PRODUCTION.

UNLESS NOTED OTHERWISE DIMENSIONS ARE IN INCHES

TOLERANCES UNLESS NOTED OTHERWISE +/- .030"

Gould Southern

	NAME	DATE
DRAWN BY	MJB.	3/1/13
APVD BY		
QUALITY		

DRAWING # STEG50-FIORE-BK
DESCRIPTION/PART # 1.417x1.18 2 Fiore Drug Facts Booklet
SCALE 100% SHEET 1 # OF SHTS 1

FIORE RX CRANAPPLE CRUSH ANTIFUNGAL NAIL POLISH

undecylenic acid film

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:52261-0206
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Undecylenic Acid (UNII: K3D86KJ24N) (Undecylenic Acid - UNII:K3D86KJ24N)	Undecylenic Acid	0.45 g in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Butyl Acetate (UNII: 464P5N1905)	6.314865 g in 15 mL
Ethyl Acetate (UNII: 76845O8NMZ)	2.504385 g in 15 mL
Pyroxylin (UNII: KYR8BR2X6O)	1.96203 g in 15 mL
POLYESTER-10 (UNII: 212N9O2MMZ)	1.40145 g in 15 mL
Acetyltributyl Citrate (UNII: 0ZBX0N59RZ)	0.981015 g in 15 mL
Isopropyl Alcohol (UNII: ND2M416302)	0.84087 mL in 15 mL
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER (UNII: 905HNO1SIH)	0.140145 g in 15 mL
Bentoquatam (UNII: 7F465U79Q1)	0.126135 g in 15 mL
D&C Red No. 7 (UNII: ECW0LZ41X8)	0.07128 g in 15 mL
Butyl Alcohol (UNII: 8PJ61P6TS3)	0.07008 mL in 15 mL
Silicon Dioxide (UNII: ETJ7Z6XBU4)	0.042045 g in 15 mL
D&C Red No. 6 (UNII: 481744AI4O)	0.0312 g in 15 mL
Benzoresorcinol (UNII: LJ54R4Z029)	0.028035 g in 15 mL
PROPOLIS WAX (UNII: 6Y8XYV2NOF)	0.015 g in 15 mL
Trimethylpentanediyl Dibenzoate (UNII: Y8PB83G67A)	0.01401 g in 15 mL
D&C Red No. 34 (UNII: BAN556989E)	0.007455 g in 15 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:52261-0206-0	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	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-0206) , label(52261-0206) , pack(52261-0206)

Revised: 9/2013 Cosco International, Inc.