FIORE RX PIXIE DUST PINK 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 copolymer, acetyl tributyl citrate, isopropyl alcohol, propolis wax

May contain:

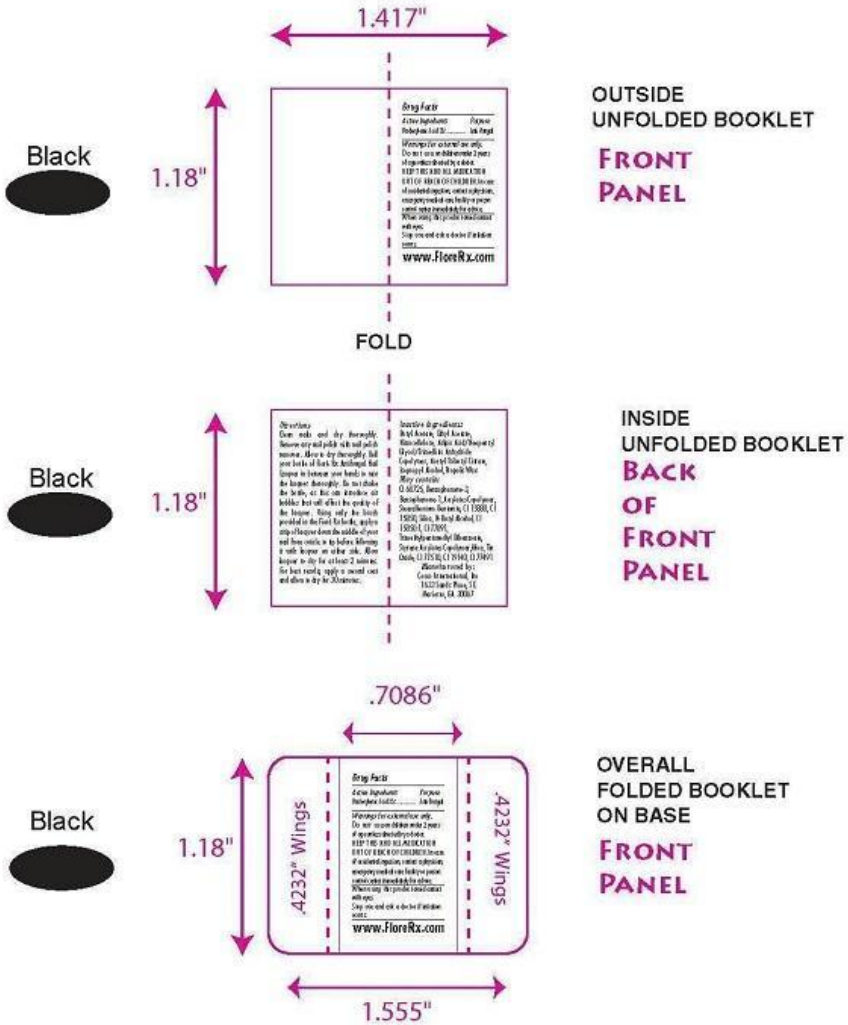
CI 60725, Benzophenone-3, Bensophenone-1, Acrylates Copolymer, Stearalkonium Bentonite, CI 15880, CI 15850, Silica, N-Butyl Alcohol, CI 15850:1, CI 77891, Trimethylpentanediyl Dibenzoate, Styrene Acrylates Copolymer,Mica, Tin Oxide, CI 77510, CI 19140, CI 77491

NO.	REVISIONS	DATE	BY
1	ADDED TO INACTIVE INGREDIENTS: Wax, 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

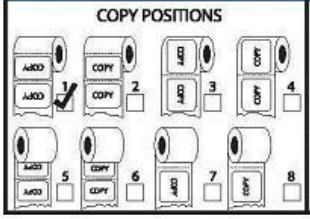
PRINT COLORS: YES UV ☐ NO ☑

NOTES:
DIE LINE DOES NOT PRINT.



DATE	TIME
8/30/13	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	MLB.	3/1/13
APVD BY		
QUALITY		

DRAWING # STEG50-FIORE-BK

DESCRIPTION/PART # 1.417x1.18 2 Fiore Drug Facts Booklet

SCALE	SHEET	# OF SHTS
100%	1	1

FIORE RX PIXIE DUST PINK ANTIFUNGAL NAIL POLISH

undecylenic acid film

Product Information

Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:52261-0204
Route of Administration	TOPICAL	**DEA Schedule**	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Undecylenic Acid (Undecylenic Acid)	Undecylenic Acid	0.45 g in 15 mL

Inactive Ingredients

Ingredient Name	Strength
Butyl Acetate	6.2260095 g in 15 mL
Ethyl Acetate	2.527011 g in 15 mL
Pyroxylin	1.979754 g in 15 mL
POLYESTER-10	1.41411015 g in 15 mL
Acetyltributyl Citrate	0.98987715 g in 15 mL
Isopropyl Alcohol	0.84846615 mL in 15 mL
DIMETHYLAMINOETHYL METHACRYLATE - BUTYL METHACRYLATE - METHYL METHACRYLATE COPOLYMER	0.141411 g in 15 mL
Bentoquatam	0.1272684 g in 15 mL
TITANIUM DIOXIDE	0.0973554 g in 15 mL
BUTYL ALCOHOL	0.07071285 g in 15 mL
Silicon Dioxide	0.04242765 g in 15 mL
Benzoresorcinol	0.02828505 g in 15 mL
MICA	0.0267153 g in 15 mL
PROPOLIS WAX	0.015 g in 15 mL
Trimethylpentanediyl Dibenzoate	0.0141426 g in 15 mL
D&C RED NO. 34	0.0007122 g in 15 mL
D&C RED NO. 6	0.00037785 g in 15 mL
STANNIC OXIDE	0.00036345 g in 15 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52261-0204-0	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	05/21/2013	

Labeler - Cosco International, Inc. (016433141)

Registrant - Cosco International, Inc. (016433141)

Establishment

Name	Address	ID/FEI	Business Operations
Cosco International, Inc.		016433141	manufacture(52261-0204), label(52261-0204), pack(52261-0204)

Revised: 9/2013 Cosco International, Inc.