# HOPE IN A BOTTLE - salicylic acid lotion Philosophy, 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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#### **OTC DRUG FACTS**

SALICYLIC ACID 2%

water

ethylhexyl palmitate

cetyl alcohol butylene glycol glyceryl stearate allyl methacrylates crosspolymer ppg-12/smdi copolymer dimethicone cetearyl alcohol tocopheryl acetate lavandula angustifolia (lavender) oil PEG-100 stearate ceteareth-20 xanthan gum polyacrylamide c13-14 isoparaffin laureth-7 triethanolamine tetrasodium edta propylene glycol methylparaben propylparaben diazolidinyl urea

STOP USE AND ASK A DOCTOR IF EXCESSIVE SKIN IRRITATIONS DEVELOPS OR INCREASES

KEEP OUT OF REACH OF CHILDREN - IF SWALLOWED GET MEDICAL HELP OR CONTACT A POISON CONTROL CENTER RIGHT AWAY IF PREGNANT OR BREAST FEEDING ASK A HEALTH PROFESSIONAL BEFORE USE HELPS PREVENT THE DEVELOPMENT OF NEW ACNE BLEMISHES. PENETRATES PORES TO CLEAR MOST ACNE BLEMISHES.

CLEANSE THE SKIN THOROUGHLY BEFORE APPLYING.

COVER THE ENTIRE EFFECTED AREA 1 TO 3 TIMES DAILY

BECAUSE EXCESSIVE DRYING OF THE SKIN MAY OCCUR STATE WITH 1 APPLICATION DAILY THEN GRADUALLY INCREASE TO 2 OR 3 IF NEEDED OR AS DIRECTED BY YOUR DOCTOR

#### FOR EXTERNAL USE ONLY



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HOPE IN A BOTTLE salicylic acid lotion							
Product Information							
Product Type	HUMAN OTC DRUG	Item Code (Source) NDC:		NDC:50184-290	2:50 18 4 - 29 0 0		
Route of Administration	TOPICAL						
Active Ingredient/Active Moi	ety						
Ingre	dient Name		Basis of Streng	th Stre	ngth		
SALICYLIC ACID (UNII: O414PZ4LPZ)	(SALICYLIC ACID - UNII:O414F	Z4LPZ)	SALICYLIC ACID	1.184 mL ii	n 59.2 mL		
Inactive Ingredients							
	Ingredient Name			Str	ength		
WATER (UNII: 059QF0KO0R)							
ETHYLHEXYL PALMITATE (UNII: 28)							
CETYL ALCOHOL (UNII: 936JST6JCN)							
BUTYLENE GLYCOL (UNII: 3XUS85K	BUTYLENE GLYCOL (UNII: 3XUS85K0RA)						
GLYCERYL MONOSTEARATE (UNII:	230 O U9 XXE4)						
<b>DIMETHICO NE</b> (UNII: 92RU3N3Y1O)							
CETOSTEARYL ALCOHOL (UNII: 2D	MT128M1S)						
ALPHA-TOCOPHEROL ACETATE (U	NII: 9E8X80D2L0)						
LAVENDER OIL (UNII: ZBP1YXW0H8)							
PEG-100 STEARATE (UNII: YD01N199							
POLYOXYL 20 CETOSTEARYL ETH	ER (UNII: YRC528SWUY)						
XANTHAN GUM (UNII: TTV12P4NEE)							
C13-14 ISOPARAFFIN (UNII: E4F12RO	E70)						
LAURETH-7 (UNII: Z95S6G8201)							
TROLAMINE (UNII: 903K93S3TK)	T)						
EDETATE SODIUM (UNII: MP1J84201) PROPYLENE GLYCOL (UNII: 6DC9Q							
METHYLPARABEN (UNII: A2I8C7HI9T							
PROPYLPARABEN (UNII: Z8IX2SC10)							
DIAZOLIDINYL UREA (UNII: H5RIZ3M							
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Packaging								
# Item Code	Package Description	Marketing Start Date		Marketing End Date				
1 NDC:50184-2900-1	59.2 mL in 1 BOTTLE							
Marketing Information								
Marketing Category	Application Number or Monogra	ph Citation	Marketing Start	Date	Marketing End Date			
OTC monograph final	part333D		09/28/2011					

Labeler - Philosophy, Inc. (948102256)

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
Philosophy Inc for BioTech Research Labs		948102256	manufacture

Revised: 9/2011

Philosophy, Inc.