

GLYCARE ACNE - glycolic acid gel
MD Formulation

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.

Glycare Acne Gel

Salicylic Acid 1%

Acne Treatment

If swallowed, get medical help or contact a Poison Control Center right away.

Clears up acne blemishes and helps prevent new acne blemishes.

For external use only.

Directions Cleanse skin thoroughly before applying medication. Cover the entire affected area with a thin layer 1 to 3 times daily. Because excessive drying of the skin may occur, start with 1 application daily, then gradually increase to 2 to 3 times daily if needed or as directed by a physician. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

Water (aqua), sd alcohol 40-b, glycolic acid, ammonium glycolate, hydroxypropyl methylcellulose.

NDC 56078-035-25

Drug Facts	
Active Ingredient Salicylic Acid 1%	Purpose Acne Treatment
Uses Clears up acne blemishes and helps prevent new acne blemishes.	
Warnings For external use only.	
When using this product Avoid unnecessary sun exposure and use sunscreen. Keep away from eyes, lips and mouth. This product may cause irritation, characterized by redness, burning, itching, peeling or possible swelling. More frequent use or higher concentrations may aggravate such irritation.	
Stop use and ask a doctor if Condition worsens or does not improve after regular use.	
Keep out of reach of children If swallowed, get medical help or contact a Poison Control Center right away.	
See Carton for complete information	

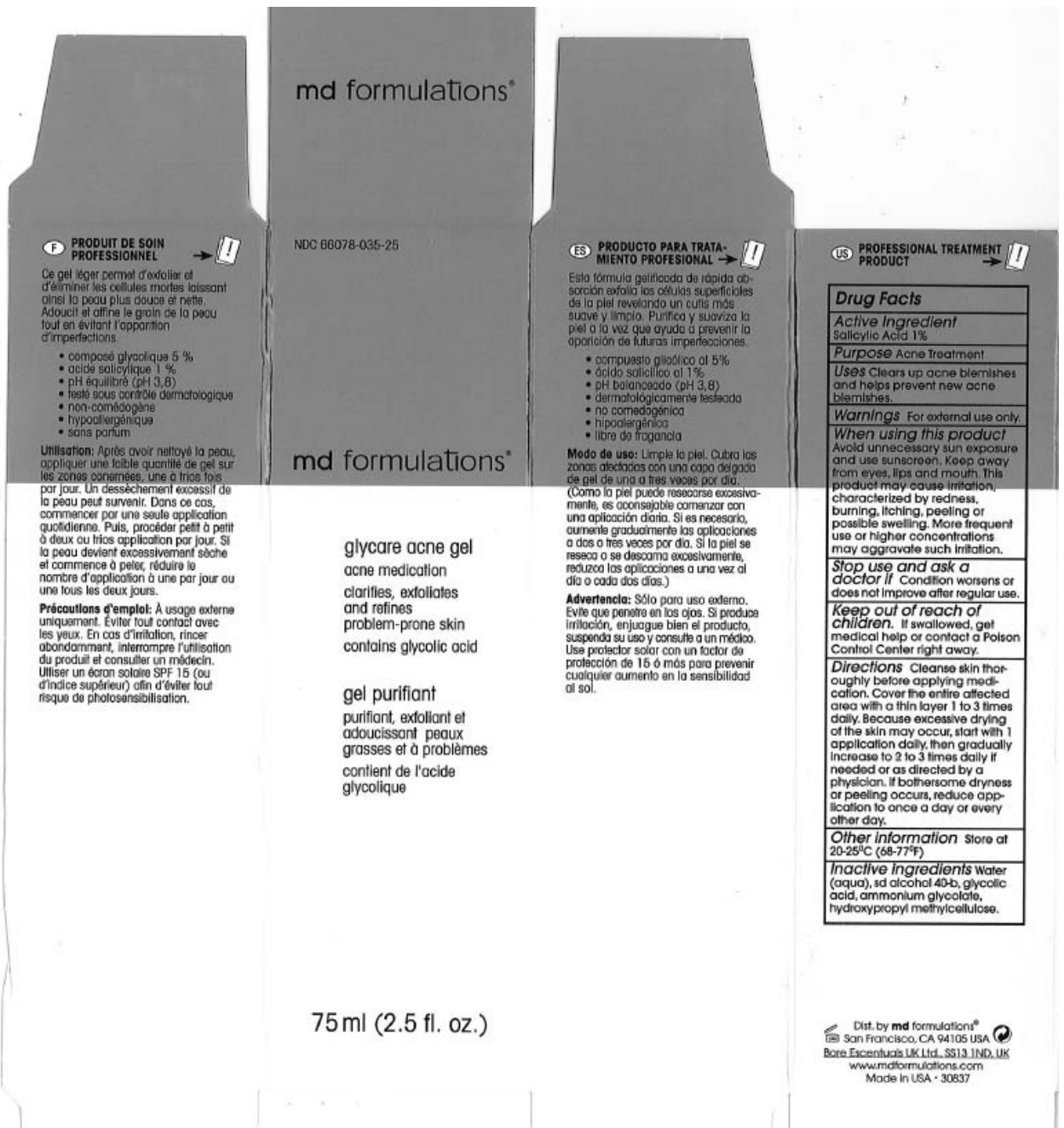
glycare acne gel
acne medication
clarifies, exfoliates and refines

gel purifiant
purifiant, exfoliant et
adouçissant

75 ml (2.5 fl. oz.)

md formulations®

Dist. by md formulations®
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GLYCARE ACNE

glycolic acid gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66078-035
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCOLIC ACID (UNII: 0WT12SX38S)	
HYPROMELLOSE 2208 (15000 MPA.S) (UNII: Z78RG6M2N2)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66078-035-25	54 in 1 CASE		
1		1 in 1 CARTON		
1		72 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/07/2001	

Labeler - MD Formulation (087008363)**Registrant** - Harmony Labs, Inc. (105803274)**Establishment**

Name	Address	ID/FEI	Business Operations
Harmony Labs, Inc.		105803274	manufacture, label, pack, relabel, repack

Revised: 7/2011

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