

## **ACNE SPOT TREATMENT- salicylic acid cream**

### **Dime Beauty Co, LLC**

*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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### **Acne Spot Treatment**

**Active Ingredients:** Salicylic Acid 2%

**Purpose:** Acne medication

**Uses:** For the treatment of acne

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.

**Warning: For external use only**

### **Directions:**

- Clean the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer one to three times daily.
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily or as directed by a doctor
- If bothersome dryness or peeling occurs reduce application to once a day or every other day

**Inactive ingredients:** Water, Propanediol, Lactobacillus Ferment, Pentylene Glycol, Polyacrylate Crosspolymer-6, Octyldodecanol, Glycerin, 1,2-Hexanediol, Glycine Soja (Soybean) Oil, Laminaria Digitata Extract, Sodium Hydroxide, Artemisia Vulgaris Extract, Hydroxyacetophenone, Sea Water, Tetrasodium Glutamate Diacetate, Leptospermum Scoparium Branch/Leaf Oil, Magnolia Officinalis Bark Extract, Piper Nigrum (Pepper) Seed Extract, Chlorella Vulgaris Extract, Dicaprylyl Ether, Phragmites Kharka Extract, Poria Cocos Extract, Lauryl Alcohol, Magnolia Grandiflora Bark Extract, Saccharide Isomerate, Aloe Barbadensis Leaf Juice, Helichrysum Italicum Extract, Avena Sativa (Oat) Kernel Extract

### **Questions?**

(801) 996-8274

hello@dimebeautyco.com

DIME

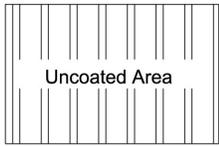
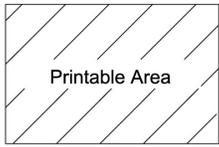
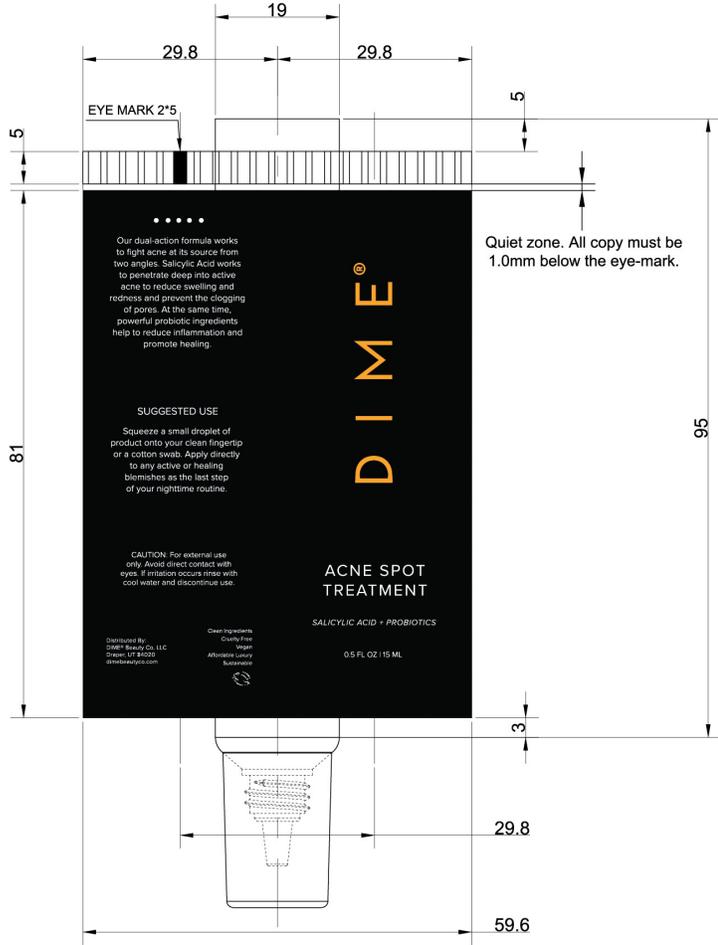
ACNE SPOT TREATMENT

SALICYLIC ACID + PROBIOTICS

0.5 FL OZ | 15 ML

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REV	DESCRIPTION	REV. BY	DATE

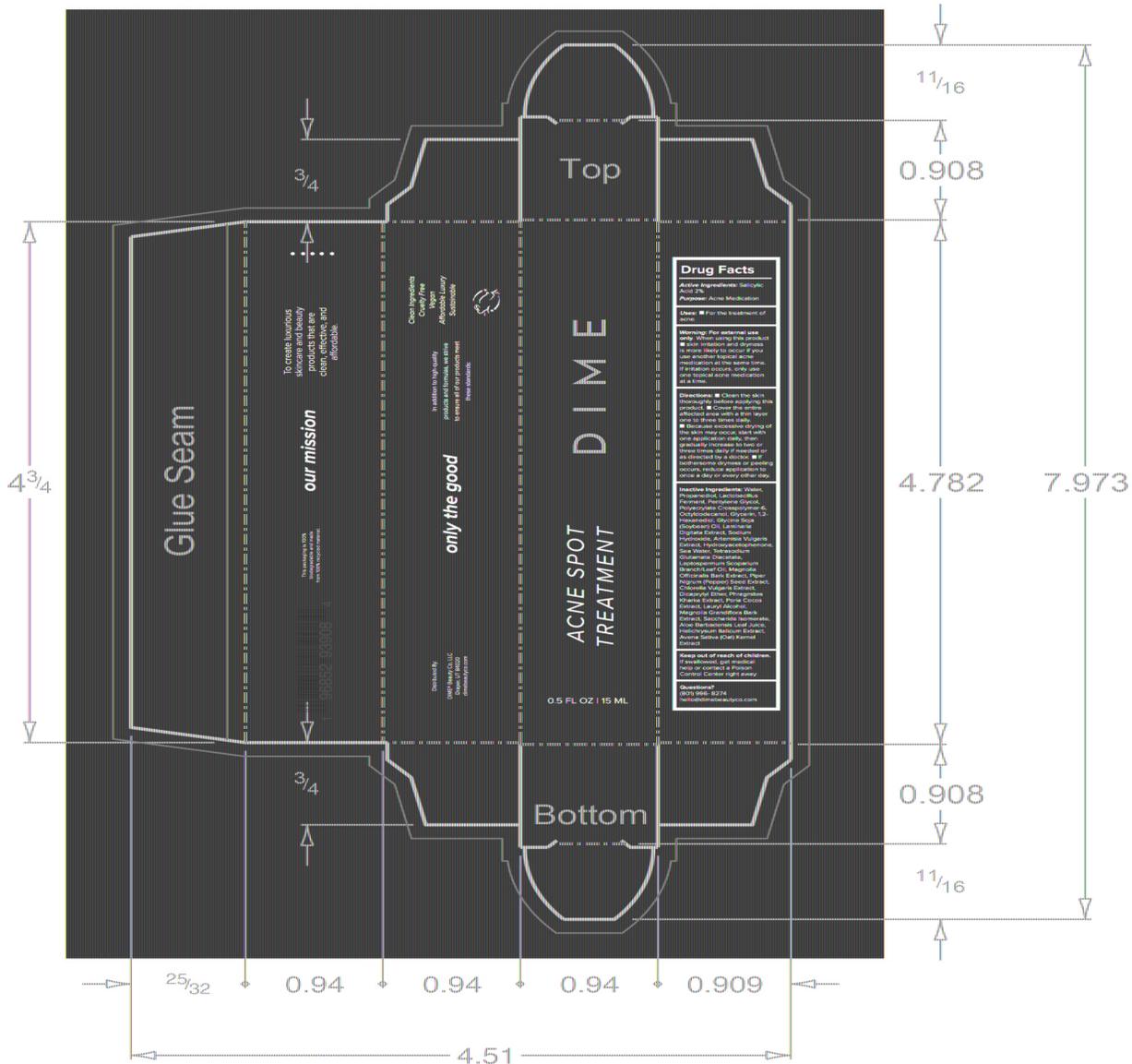






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PART NAME			DWG SIZE	
<b>TE19-004 15mL</b>			<b>A4</b>	
DES. ENG	CHK.	APP.	DATE	
<b>YOUNG</b>	<b>YOUNG</b>	<b>QI</b>	<b>2022/07/18</b>	
PROJECT NO.		REV.	UNIT	SCALE
			<b>mm</b>	<b>1:1</b>
Please include a PDF, list of colors, and convert text to outlines when submitting.				



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ACNE SPOT TREATMENT			
salicylic acid cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:82870-006
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SALICYLIC ACID (UNII: 0414PZ4LPZ) (SALICYLIC ACID - UNII:0414PZ4LPZ)	SALICYLIC ACID	2 g in 100 mL	

## Inactive Ingredients

Ingredient Name	Strength
ARTEMISIA VULGARIS ROOT (UNII: 32MP823R8S)	
MANUKA OIL (UNII: M6QU9ZUH2X)	
MAGNOLIA OFFICINALIS BARK (UNII: 5M609NV974)	
MAGNOLIA GRANDIFLORA BARK (UNII: J4XF5T6418)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
FU LING (UNII: XH37TWY5O4)	
PROPANEDIOL (UNII: 5965N8W85T)	
CHLORELLA VULGARIS (UNII: RYQ4R60M02)	
HELICHRYSUM ITALICUM FLOWER (UNII: P62Y550X24)	
WHITE PEPPER (UNII: M29DW54Q9E)	
LIMOSILACTOBACILLUS FERMENTUM (UNII: 2C1F12C6AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
AMMONIUM ACRYLOYLDIMETHYLTAURATE, DIMETHYLACRYLAMIDE, LAURYL METHACRYLATE AND LAURETH-4 METHACRYLATE COPOLYMER, TRIMETHYLOLPROPANE TRIACRYLATE CROSSLINKED (45000 MPA.S) (UNII: Q7UI015FF9)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
DICAPRYLYL ETHER (UNII: 77JZM5516Z)	
WATER (UNII: 059QF0KO0R)	
OAT (UNII: Z6J799EAJK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SACCHARIDE ISOMERATE (UNII: W8K377W98I)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
SOYBEAN OIL (UNII: 241ATL177A)	
LAMINARIA DIGITATA (UNII: 15E7C67EE8)	
LAURYL ALCOHOL (UNII: 178A96NLP2)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
GLYCERIN (UNII: PDC6A3C0OX)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82870-006-01	15 mL in 1 CARTON; Type 0: Not a Combination Product	03/27/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	03/27/2023	

**Labeler** - Dime Beauty Co, LLC (058459261)