

**CREAM- salicylic acid lotion**  
**Oxygen Development 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 SERUM Medicated Treatment**

**Active Ingredient**

Salicylic Acid

**Purpose**

Acne Medication

**Uses**

Treats Acne and helps skin heal. Penetrates pores to eliminate most acne blemishes and blackheads. Helps prevent new acne blemishes and blackheads from forming

**Warnings**

For external use only

**When using use only**

Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.

**Keep out of reach of children**

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

**Directions**

Clean the skin thoroughly before applying this product.

Cover the entire affected area with a thin layer morning and night for best results.

If bothersome dryness or peeling occurs, reduce application to once a day or every other day.

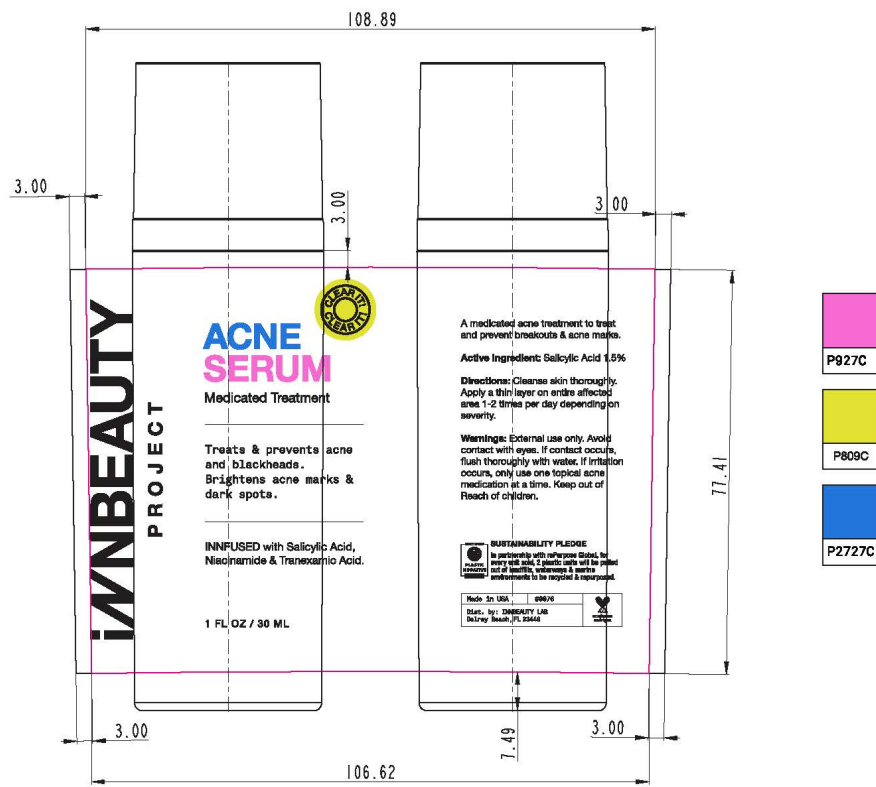
**Other information**

Store at 20 - 25C (68-77F)

### **Inactive Ingredient**

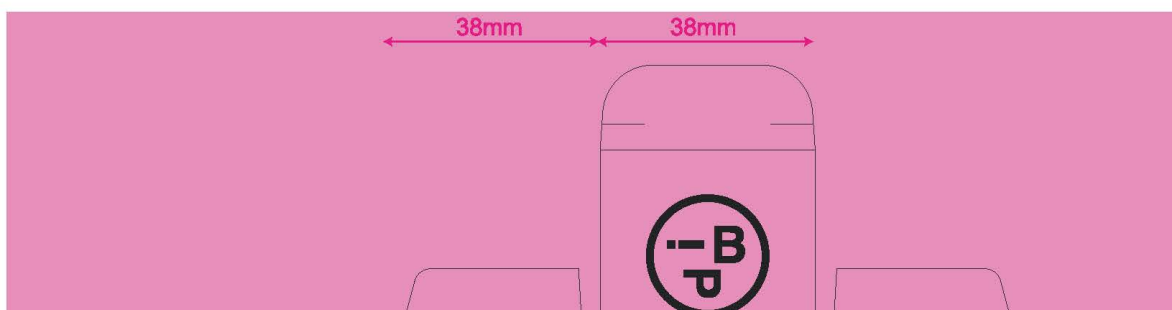
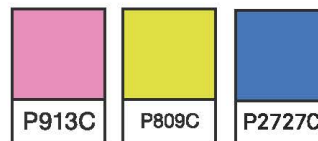
Water/Aqua, Propanediol, Glycerin, Caprylic/Capric Triglyceride, Dimethyl Isosorbide, Lactobacillus Ferment, Coconut Alkanes, Coco-Caprylate, Niacinamide, Candelilla/Jobba/Rice Bran Polyglyceryl-3 Esters, Tranexamic Acid, Hexyl Laurate, Glycine Soja Soybean, C15-19 Alkane, Potassium Azeloyl Diglycinate, Hydrogenated Polydecene, Glyceryl Stearate, Ceramide NP, Ceramide AP, Bakuchiol, Fucus Spiralis Extract, Rhodomyrtus Tomentosa Fruit Extract, Tasmannia Lanceolata Fruit/Leaf Extract, Acetyl Glucosamine, Hydrolyzed Sodium Hyaluronate, Zinc Sulfate, Melia Azadirachta Leaf Extract, Centella Asiatica Leaf Extract, Silybum Marianum Seed Extract, Vitex Agnus - Castus Extra, Helianthus Annuus (Sunflower) Extract, Oryza Sativa (Rice) Bran Extract, Oryza Sativa (Rice) Extract, Oryza Sativa (Rice) Germ Extract, Allantoin, Panthenol, 1,2 - Hexanediol, Sodium Stearoyl Lactylate, Citric Acid, Xanthan Gum, Polyglyceryl - 3 Diisostearate, Polyacrylate Crosspolymer - 6, Coco - Caprylate/Caprates, Caprylhydroxamic Acid, Sodium Phytate, Tocopherol, Sodium Benzoate, Potassium Sorbate, Biosaccharide Gum - 1, Phenoxyethanol, Sodium Anisate.

ORDER:	PRINTING AREA	DATE:
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PRINTING AREA

REMARKS	<p>1.The Space Between Two Letters And The Width Of Letter Should Be More Than 0.2 mm.</p> <p>2.If there Is Hot-stamping, The Space Between Two Letters And The Width Of Letter Should Be More Than 0.2mm.</p> <p>3.The Blue Frame Is The Printing Area ,The Red Frame Is The Actual Size.</p> <p>4.If the Colors Of Silkscreen Printing Is More Than Two Colors, There Will Be 1mm Tolerance.</p> <p>5.Please Provide The Panton Number Or Color Sample.</p>	CLIENT CONFIRMATION:
核准:	制图:	





<b>SALICYLIC ACID</b> (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)		SALICYLIC ACID	1.5 mg	in 100 mg	
<b>Inactive Ingredients</b>					
<b>Ingredient Name</b>			<b>Strength</b>		
<b>NIACINAMIDE</b> (UNII: 25X51I8RD4)			3 mg		in 100 mg
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)			2.5 mg		in 100 mg
<b>C15-19 ALKANE</b> (UNII: CI87N1IM01)			1.2 mg		in 100 mg
<b>DIMETHYL ISOSORBIDE</b> (UNII: SA6A6V432S)			4 mg		in 100 mg
<b>COCONUT ALKANES</b> (UNII: 1E5KJY107T)			3.76 mg		in 100 mg
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)			5.5 mg		in 100 mg
<b>COCO-CAPRYLATE</b> (UNII: 4828G836N6)			3.5 mg		in 100 mg
<b>LIMOSILACTOBACILLUS FERMENTUM</b> (UNII: 2C1F12C6AP)			3.97 mg		in 100 mg
<b>TRANEXAMIC ACID</b> (UNII: 6T84R30KC1)			2 mg		in 100 mg
<b>BAKUCHIOL</b> (UNII: OT12HJU3AR)			0.5 mg		in 100 mg
<b>POTASSIUM AZELOYL DIGLYCINATE</b> (UNII: N02RVN6NYP)			1 mg		in 100 mg
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)			6.07 mg		in 100 mg
<b>DOCOSANOL</b> (UNII: 9G1OE216XY)			2.5 mg		in 100 mg
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)			1.3 mg		in 100 mg
<b>1,2-HEXANEDIOL</b> (UNII: TR046Y3K1G)			0.75 mg		in 100 mg
<b>SODIUM STEAROYL LACTYLATE</b> (UNII: IN99IT31LN)			0.5 mg		in 100 mg
<b>HEXYL LAURATE</b> (UNII: 4CG9F9W01Q)			1.5 mg		in 100 mg
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)			1 mg		in 100 mg
<b>HYDROGENATED POLYDECENE TYPE I</b> (UNII: U333RI6EB7)			1 mg		in 100 mg
<b>CANDELILLA WAX</b> (UNII: WL0328HX19)			2.5 mg		in 100 mg
<b>WATER</b> (UNII: 059QF0KO0R)			38.78 mg		in 100 mg
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)			7.47 mg		in 100 mg
<b>Packaging</b>					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:61354-099-01	1 in 1 CARTON	06/26/2023		
1		100 mg in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			
<b>Marketing Information</b>					
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final		M006	06/26/2023		

**Labeler** - Oxygen Development LLC (137098492)

## Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development LLC		137098492	manufacture(61354-099)

