

ACNE CLEANSER- salicylic acid gel
MONAT GLOBAL CORP

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.

MONAT Be Clarified Acne Gel-Cream Cleanser

Active Ingredient

Salicylic Acid 2.00%

Purpose

Acne Treatment

Uses

- For the treatment of acne
- Helps prevent new acne blemishes from forming

For external use only

When using this product

- skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne treatment at a time.
- Avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water.

Keep out of reach of children. If product is swallowed, get medical help or contact a poison control center right immediately.

Directions

Directions

- Shake well before use
- Start with damp skin
- Apply small amount onto your fingertips and emulsify
- Gently cleanse the skin using circular motions.
- Rinse with warm water and gently pat the skin dry
- Follow with your MONAT skincare Routine

Inactive Ingredients

Water, Sodium Cocoyl Glutamate, Propanediol, Sorbeth-230 Tetraoleate, Cocamidopropyl Betaine, Sodium C14-16 Olefin Sulfonate, Sodium Cocoyl Isethionate, PEG-120 Methyl Glucose Dioleate, Niacinamide, Cocamide MIPA, Glycerin, Coconut Acid, Sodium Isethionate, Sodium PCA, Maclura Cochinchinensis Leaf Prenylflavonoids, Glycol Distearate, Laureth-4, Sodium Chloride, Sodium Benzoate, Potassium Sorbate, Polyquaternium-10, Decyl Glucoside, Sorbitan Laurate, Isopropyl Alcohol.

Questions or Comments

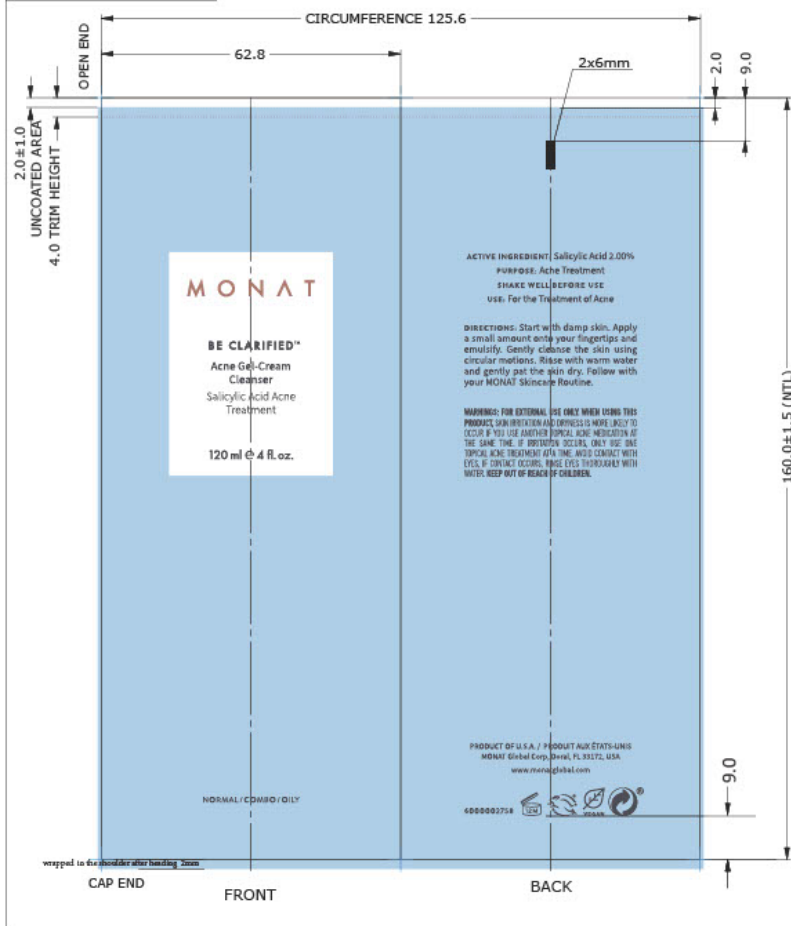
Questions or comments?

Toll-free number 1-800-878-1978

PRIMARY PACKAGE

Printed Date:

DO NOT SCALE DRAWING



PO#: P2779
 Name: _____
 Code: 600002758
 Spec: D40x160mm

MONAT GLOBAL CORP., DIST	
ITEM NUMBER: 600002758	BE CLARIFIED™ Acne Gel-Cream Cleanser 120 ml e 4 oz
COLOR REQUIREMENTS:	
■ PANTONE 545 U	■ SOFT TOUCH
■ PANTONE Black 6 U	
■ CUSTOM ROSE GOLD HS	
■ WHITE	

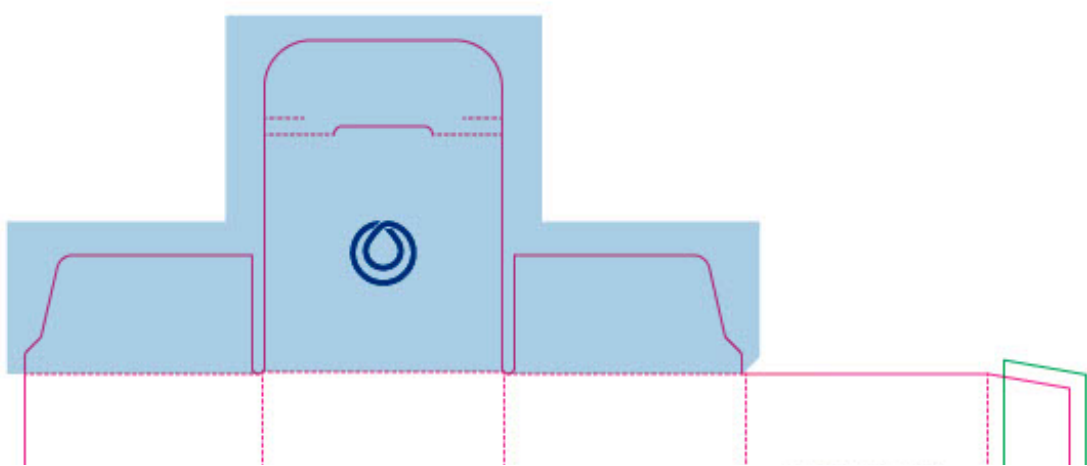
ART HISTORY AND NOTES	
CREATED:	02/18/2022
LAST REVISED BY:	02/18/2022 ED: Created File
	02/24/2022 ED: Product description, skin type, warnings format
	03/14/2022 NT: Shake well

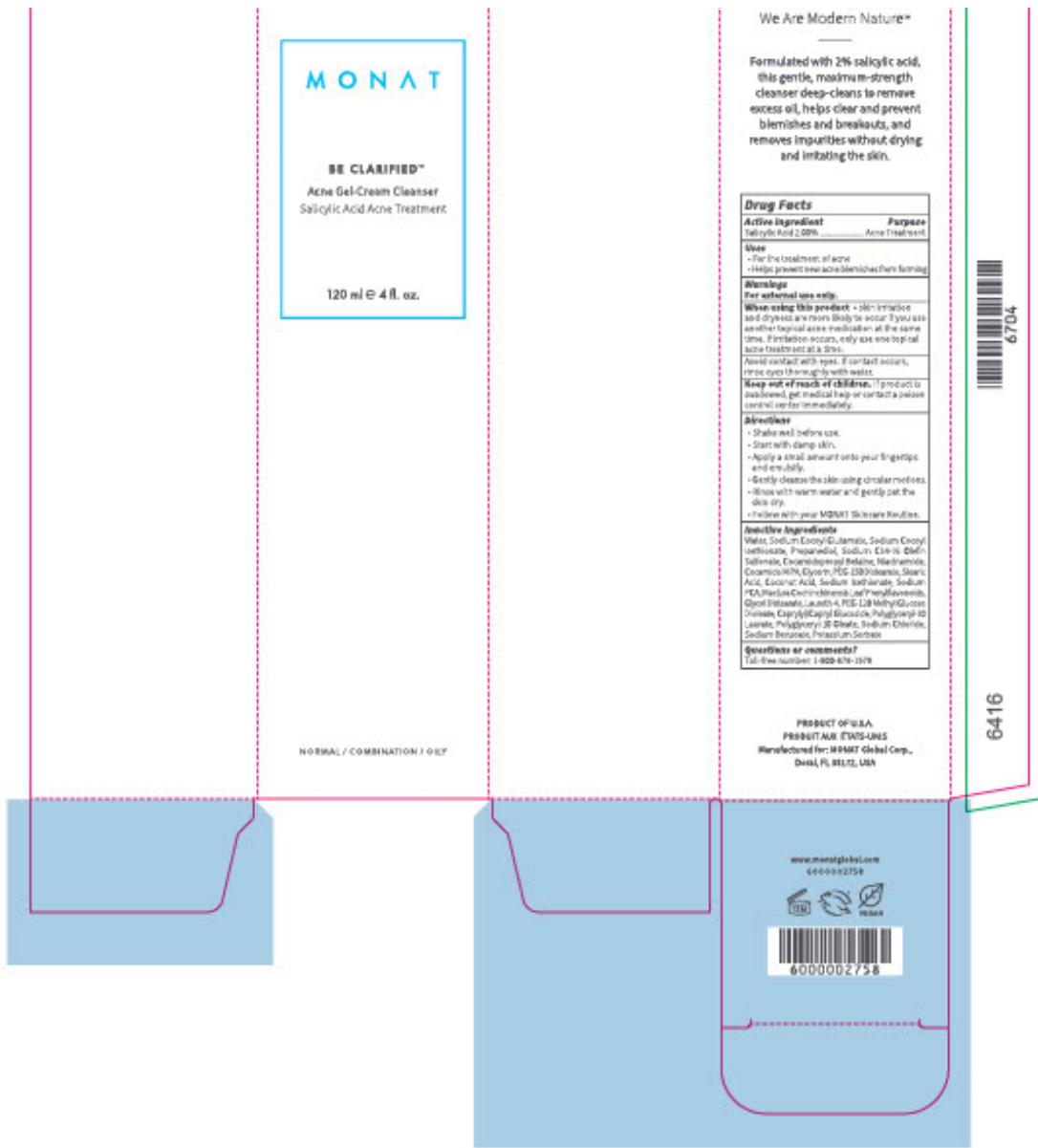
- Tube Color: White
- Print Process: 2C Offset Printing
- PANTONE 545 U
 - PANTONE Black U (eyemark)
- Print Process: 1C Silk Screen Printing
- PANTONE Black 6 U
- Print Process: 1C Hot stamp Printing
- CUSTOM ROSE GOLD HS
- Coating: Soft Touch
- Soft Touch
 - Overall Varnish

John
 03/17/2022

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN MILLIMETERS TOLERANCES PRECISION		Project Name:	40mm Cap and Tube	Supplier:	WWP Suzhou
US Standard 84.000	ASME Y14.5	Drawn By:	DECO 40x160	Part Name:	
03/17/22	A-4	DATE:	03/17/22	QTY:	360
		SIZE:	360 - 40x160	PROJ. NO.:	360
		PROJ. NO.:		STATUS:	Production
		DATE:		PROJ. CODE:	
					SHEET 1 OF 1

OUTER PACKAGE





Customer		Process Codes	
 3540 Princeton Oaks Dr. • Orlando, FL 32808			
Material		<input type="checkbox"/> No Print to Date Assembly Fee <input type="checkbox"/> No Print to Date Assembly Fee <input type="checkbox"/> No Print to Date Assembly Fee	<input checked="" type="checkbox"/> Case Break <input checked="" type="checkbox"/> Loose Order
Project Name / Description	Spot Colors	<input type="checkbox"/> Revised proof with indicated changes required. No number of copies or order date.	File Name / ID# 8784
8784 - 85, MONAT, BE CLARIFIED, Acne Gel-Cream Cleanser, 85, 811281		APPROVED FOR COPY	DIGITALLY APPROVED FOR COPY
Revisions	Full, Colors, Spot P/C, Verbal	 05/26/2022	
Colorist	Date	Revisions	Customer Digital Signature
Enfile 85-25-22			

SECONDARY-OUTER PACKAGE

ACNE CLEANSER

salicylic acid gel

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:78518-011

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	2 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength
LAURETH-4 (UNII: 6HQ855798J)	
SODIUM ISETHIONATE (UNII: 3R36J71C17)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL GLUTAMATE (UNII: BMT4RCZ3HG)	
PROPANEDIOL (UNII: 5965N8W85T)	
GLYCOL DISTEARATE (UNII: 13W7MDN21W)	
DECYL GLUCOSIDE, .ALPHA.- (UNII: 47YY6O286H)	
SODIUM PYRROLIDONE CARBOXYLATE (UNII: 469OTG57A2)	
COCONUT ACID (UNII: 40U37V505D)	
NIACINAMIDE (UNII: 25X51I8RD4)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
POLYQUATERNIUM-10 (400 CPS AT 2%) (UNII: HB1401PQFS)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MACLURA COCHINCHINENSIS WHOLE (UNII: X083FY34PH)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
SORBITAN MONOLAURATE (UNII: 6W9PS8B71J)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
COCO MONOISOPROPANOLAMIDE (UNII: 21X4Y0VTB1)	
PEG-120 METHYL GLUCOSE DIOLEATE (UNII: YM0K64F20V)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78518-011-01	1 in 1 CARTON	04/04/2023	
1		120 mg in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	04/04/2023	

Labeler - MONAT GLOBAL CORP (027036949)

Establishment

Name	Address	ID/FEI	Business Operations
Oxygen Development		137098492	manufacture(78518-011)

Revised: 3/2023

MONAT GLOBAL CORP