PRACTICAL ALCHEMY PURIFY AND PROTECT DUO- micellar water wipes and zinc oxide Over Here, LLC

Practical Alchemy - Purify + Protect Duo - Dual Sachet

ACTIVE INGREDIENTS:

Zinc Oxide 14.6%

WARNINGS:

For external use only • Do not use on damaged or broken skin when using this product • Keep out of eyes. Rinse with water to remove • Keep out of reach of children • If product is swallowed, get medical help or contact a Poison Control Center right away.

PURPOSE

Sunscreen

USES:

Helps prevent sunburn • If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.

DIRECTIONS:

Apply liberally 15 minutes before sun exposure • Reapply at least every 2 hours and immediately upon towel drying after 80 minutes of swimming or sweating. Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including: Limit time in the sun, especially from 10 a.m. - 2 pm • Wear long sleeve shirts, pants, hats, and sunglasses • Children under 6 months: Ask a doctor.

OTHER INFORMATION

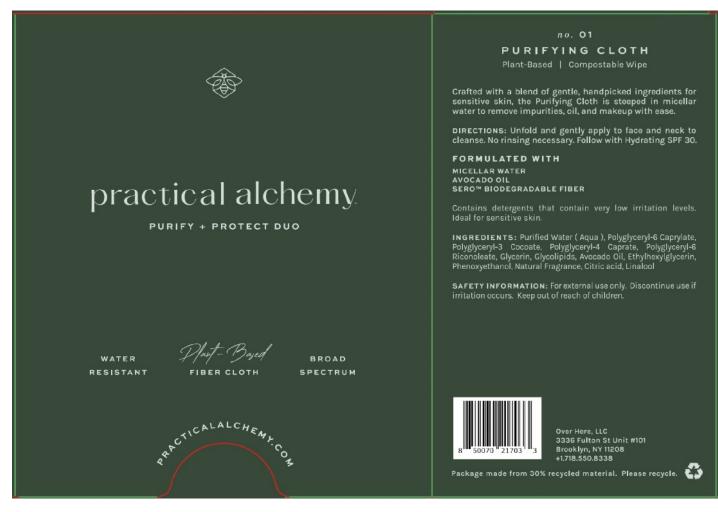
Protect this product from excessive heat and direct sun.

INACTIVE INGREDIENTS

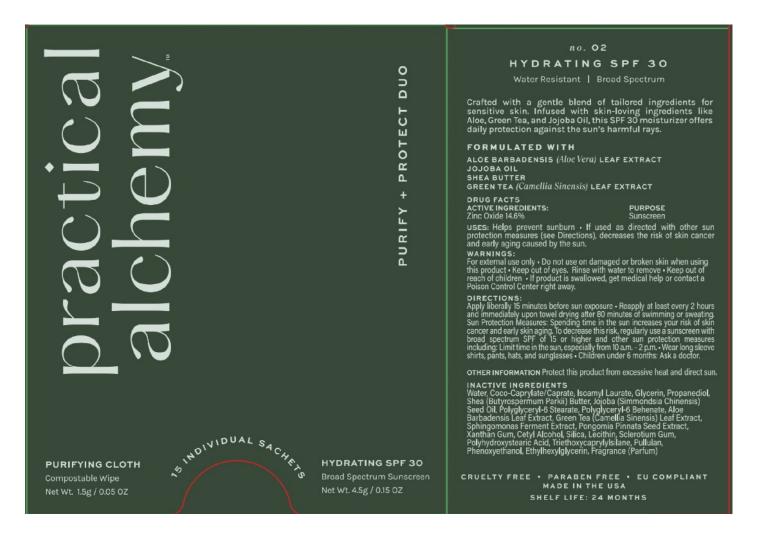
Water, Coco-Caprylate/Caprate, Isoamyl Laurate, Glycerin, Propanediol, Shea (Butyrospermum Parkii) Butter, Jojoba (Simmondsia Chinensis) Seed Oil, Polyglyceryl-6 Stearate, Polyglycerl-6 Behenate, Aloe Barbadensis Leaf Extract, Green Tea (Camellia Sinensis) Leaf Extract, Sphingomonas Ferment Extract, Pongomia Pinnata Seed Extract, Xanthan Gum, Cetyl Alcohol, Silica, Lecithin, Sclerotium Gum, Polyhydroxystearic Acid, Triethoxycaprylylsilane, Pullulan, Phenoxyethanol, Ethylhexylglycerin, Fragrance (Parfum)

Representative Images of Cosmetic Product and Drug Product Parts

Cosmetic Part



Drug Part



PRACTICAL ALCHEMY PURIFY AND PROTECT DUO

micellar water wipes and zinc oxide kit

Product Information						
Product Type HUMAN OTC DRUG Item Code		(Source)	NDC:84994-002			
Packaging	Packaging					
# Item Code Package Desc	Package Description		Marketing End Date			
1 NDC:84994-002- 01 1 in 1 CARTON; Type 1: Conv Package	enience Kit of Co-	02/24/2025				
Quantity of Parts						
Part # Package Quantity		Total Product Q	uantity			
Part 1 1 POUCH	1					
Part 2 1 PACKET	4.5 g					
Part 1 of 2						

PRACTICAL ALCHEMY PURIFYING

disposable wipes [personal cleanliness] cloth

Product Inform	mation				
Route of Administration TOPICAL					
Other Ingredie	ntc				
Ingredient Ki		Ingradiant	Namo	Quantity	
NGR	nt Kind Ingredient Name Quantity POLYGLYCERYL-6 CAPRYLATE (UNII: DGV8R54VG7)				
NGR		OXYETHANOL (UNII: HIE492ZZ3			
NGR		GLYCERYL-4 CAPRATE (UNII: 3N			
NGR	POLY	GLYCERYL-6 RICINOLEATE (UN	II: 8X57R183N7)		
NGR	LINAL	OOL (UNII: D81QY6I88E)			
NGR	ETHYI	LHEXYLGLYCERIN (UNII: 147D24	7K3P)		
NGR		R (UNII: 059QF0KO0R)			
NGR		C ACID (UNII: 2968PHW8QP)			
NGR	AVOC	ADO OIL (UNII: 6VNO72PFC1)			
Packaging					
# Item Code	Packa	ge Description	Marketing Start Date	Marketing End Date	
1 in 1 POUCH; Type 0: Not a Combination Product					
	nformat	ion			
		ion tion Number or Monograph Citation	n Marketing Start Date	Marketing End Date	
Marketing I Marketing Category		tion Number or Monograph			
Marketing I Marketing Category		tion Number or Monograph	Date		
Marketing I Marketing Category Cosmetic		tion Number or Monograph	Date		
Marketing I Marketing Category Cosmetic Part 2 of 2	Applica	tion Number or Monograph	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL	Applica ALCHEM	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL	Applica ALCHEM	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL zinc oxide cream	Applica	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL zinc oxide cream	Applica ALCHEM mation	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL zinc oxide cream Product Inform Item Code (Source	Applica ALCHEM mation ce)	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL zinc oxide cream Product Inform	Applica ALCHEM mation ce)	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2	Applica ALCHEM mation ce)	tion Number or Monograph Citation	Date 02/24/2025		
Marketing I Marketing Category Cosmetic Part 2 of 2 PRACTICAL zinc oxide cream Product Inform Item Code (Source	Applica ALCHEM mation ce) stration	tion Number or Monograph Citation	Date 02/24/2025		

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	14.6 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
SCLEROTIUM GUM (UNII: 2X51AD1X3T)	
SILICA (UNII: ETJ7Z6XBU4)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)	
PULLULAN (UNII: 8ZQ0AYU1TT)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
ISOAMYL LAURATE (UNII: M1SLX00M3M)	
JOJOBA OIL (UNII: 724GKU717M)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
PROPANEDIOL (UNII: 5965N8W85T)	
POLYGLYCERYL-6 BEHENATE (UNII: 4T2L7QI313)	
TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E)	
GLYCERIN (UNII: PDC6A3C0OX)	
SHEA BUTTER (UNII: K49155WL9Y)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84994-001- 01	4.5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	02/24/2025	

Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End DateOTC Monograph DrugM02002/24/202502/24/2025

Establishment			
Name	Address	ID/FEI	Business Operations
A.I.G. TECHNOLOGIES, INC.		086365223	manufacture(84994-001)

Establishment			
Name	Address	ID/FEI	Business Operations
JP Packaging LLC		151369456	label(84994-002) , pack(84994-002)

Revised: 2/2025

Over Here, LLC