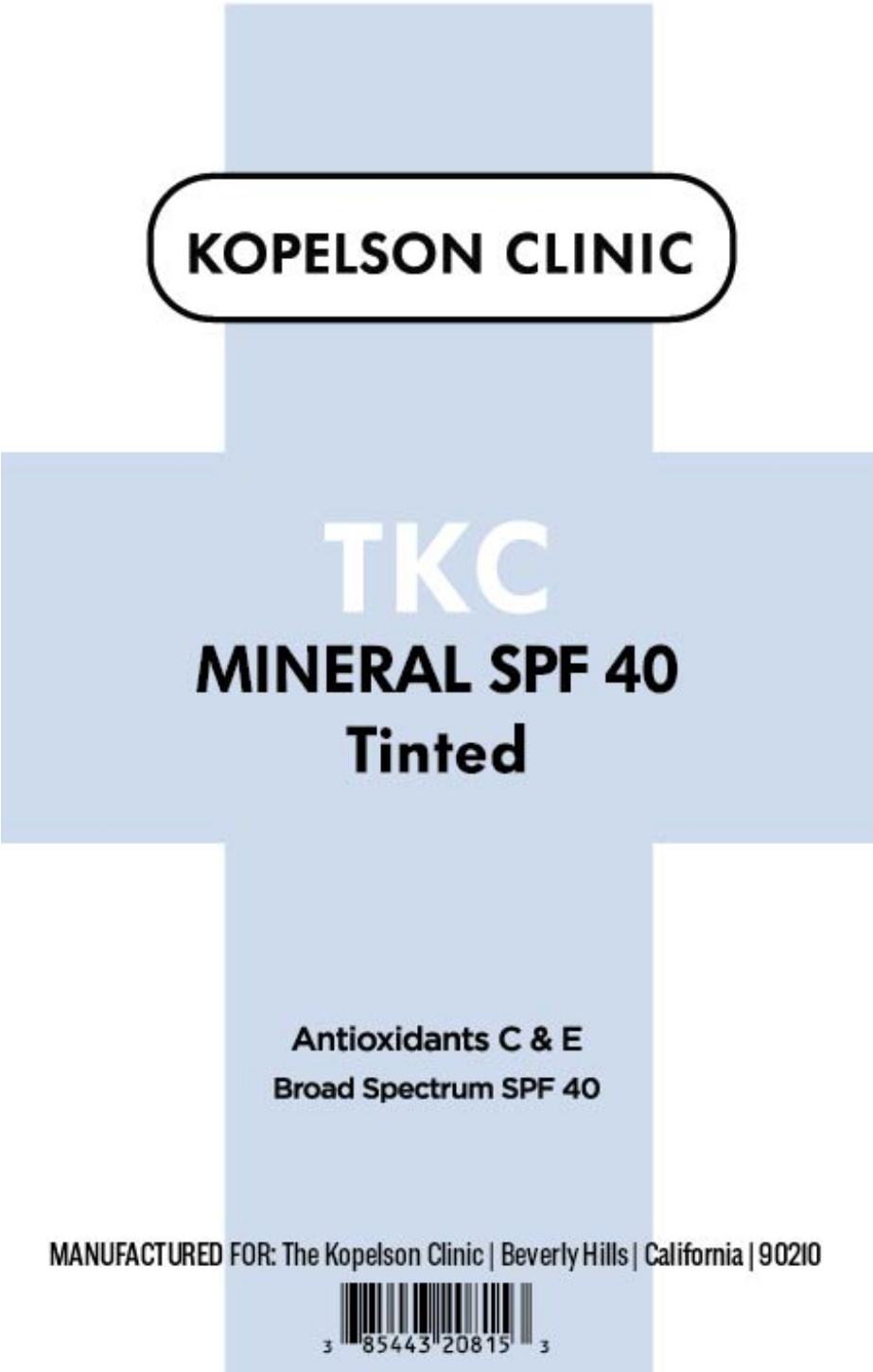


208- zinc oxide cream
PETER L. KOPELSON, M.D.



208
zinc oxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85443-208(NDC:58892-208)	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)		ZINC OXIDE	160 mg in 1 g	
Inactive Ingredients				
Ingredient Name			Strength	
CERAMIDE 3 (UNII: 4370DF050B)				
PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0)				
TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ)				
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)				
VINYL DIMETHICONE/METHICONE SILSESQUIOXANE CROSSPOLYMER (UNII: 9NH1UDD2RR)				
DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6)				
HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N)				
CI 77499 (UNII: XM0M87F357)				
DIMETHICONE (UNII: 92RU3N3Y1O)				
CI 77491 (UNII: 1K09F3G675)				
CI 77492 (UNII: EX438O2MRT)				
CYCLOHEXASILOXANE (UNII: XHK3U310BA)				
CYCLOPENTASILOXANE (UNII: 0THT5PCI0R)				
DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5)				
POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)				
DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y)				
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:85443-208-15	1.5 g in 1 PACKET; Type 0: Not a Combination Product	05/09/2022	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020		05/09/2022	

Labeler -
PETER L. KOPELSON, M.D. (170705078)

Establishment			
Name	Address	ID/FEI	Business Operations
Custom Analytics LLC		144949372	analysis(85443-208)

Establishment			
Name	Address	ID/FEI	Business Operations
Fragrance Manufacturing INC		793406000	manufacture(85443-208)

Establishment			
Name	Address	ID/FEI	Business Operations
Fallien Cosmeceuticals Ltd.		958388357	relabel(85443-208)

Revised: 12/2025

PETER L. KOPELSON, M.D.