

UNID SEA FENNEL TINTED SUN PROTECTOR- titanium dioxide cream
Sage Pharmaceuticals Inc

UNID Sea Fennel Tinted Sun Protector

Active Ingredients

Titanium Dioxide 8.28%

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 skin aging caused by the sun.

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.
- **Stop use and ask a doctor if** rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Shake well before using.
- Apply liberally 15 minutes before sun exposure.
- Reapply at least every 2 hours.
- Use a water resistant sunscreen if 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 a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m.–2 p.m.
 - Wear long-sleeve shirts, pants, hats, and sunglasses.
- Children under 6 months of age: ask a doctor.
- Protect the product in this container from excessive heat and direct sun.

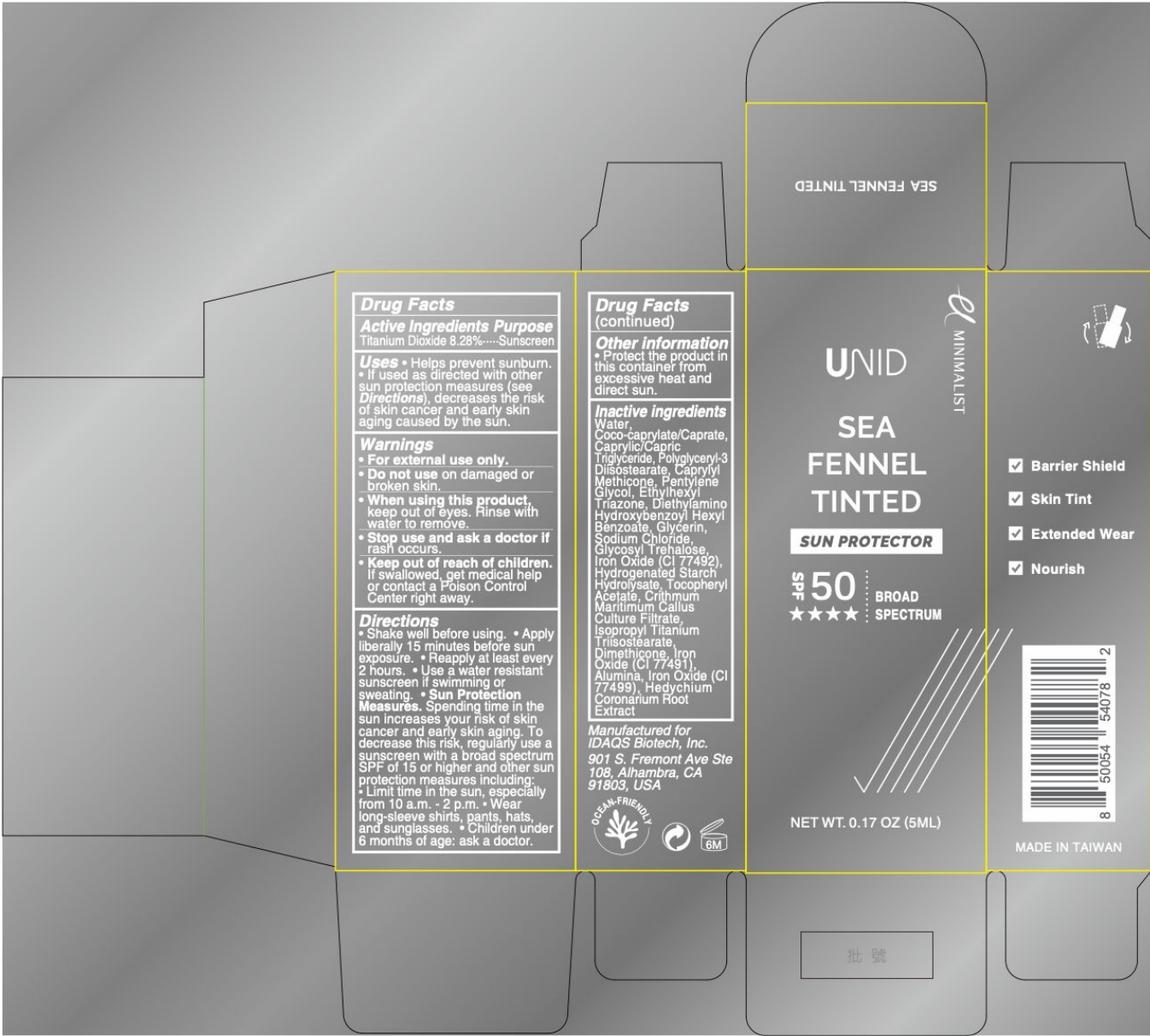
Inactive Ingredients

Water, Coco-caprylate/Caprate, Caprylic/Capric Triglyceride, Polyglyceryl-3 Diisostearate, Caprylyl Methicone, Pentylene Glycol, Ethylhexyl Triazone, Diethylamino Hydroxybenzoyl Hexyl Benzoate, Glycerin, Sodium Chloride, Glycosyl Trehalose, Iron Oxide (CI 77492), Hydrogenated Starch Hydrolysate, Tocopheryl Acetate, Crithmum Maritimum Callus Culture Filtrate, Isopropyl Titanium Triisostearate, Dimethicone, Iron Oxide (CI 77491), Alumina, Iron Oxide (CI 77499), Hedychium Coronarium Root Extract

Package Label (30mL)



Package Label (5mL)



UNID SEA FENNEL TINTED SUN PROTECTOR

titanium dioxide cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83119-245
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)		TITANIUM DIOXIDE	8.28 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
ALUMINA (UNII: LMI26O6933)	
CAPRYLYL METHICONE (UNII: Q95M2P1KJL)	
CRITHMUM MARITIMUM (UNII: J7IHY79BKY)	
CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)	
GLYCERIN (UNII: PDC6A3C0OX)	
CI 77491 (UNII: 1K09F3G675)	
HEDYCHIUM CORONARIUM ROOT (UNII: 92A6N0IQN9)	
.ALPHA.-TOCOPHEROL ACETATE, DL- (UNII: WR1WPI7EW8)	
COCO-CAPRYLATE/CAPRATE (UNII: 8D9H4QU99H)	
ISOPROPYL TITANIUM TRIISOSTEARATE (UNII: 949E3KBJ1I)	
POLYGLYCERYL-3 DIISOSTEARATE (UNII: 46P231IQV8)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
WATER (UNII: 059QF0KO0R)	
CI 77499 (UNII: XM0M87F357)	
DIETHYLAMINO HYDROXYBENZOYL HEXYL BENZOATE (UNII: ANQ870JD20)	
GLUCOSYL TREHALOSE (UNII: 76B4LOB2YC)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ETHYLHEXYL TRIAZONE (UNII: XQN8R9SAK4)	
CI 77492 (UNII: EX438O2MRT)	
HYDROGENATED STARCH HYDROLYSATE (UNII: 27F77DSJ5V)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83119-245-50	1 in 1 BOX	12/18/2025	
1		30 g in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:83119-245-51	1 in 1 BOX	12/18/2025	
2		5 g in 1 BOTTLE; 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	12/18/2025	

Labeler - Sage Pharmaceuticals Inc (656245476)

Registrant - Sage Pharmaceuticals Inc (656245476)

Establishment			
Name	Address	ID/FEI	Business Operations
Sage Pharmaceuticals Inc		656245476	manufacture(83119-245)

Revised: 12/2025

Sage Pharmaceuticals Inc