

**SETT MINERAL SUNSCREEN SPF 50- zinc oxide, titanium dioxide cream**  
**Sett Surf, Ltd.**

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**SETT Mineral Sunscreen SPF 50**

**DRUG FACTS**

**ACTIVE INGREDIENTS**

Zinc Oxide (non-nano) 12.5%

Titanium Dioxide (non-nano) 4.5%

**Purpose**

Sunscreen

**USES**

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

**WARNINGS**

For external use only.

**Do not use**

on damaged or broken skin.

**Stop use and ask a doctor**

if rash occurs.

**When using this product**

keep out of eyes. Rinse with water to remove.

**Keep out of reach of children.**

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

**DIRECTIONS**

- Shake well before use
- Apply liberally to all exposed skin 15 minutes before sun exposure
- - after 80 minutes of swimming or sweating
- Immediately after towel drying
- At least every 2 hours
- 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 value of 15 or higher and other sun protection measures including: • Limit time in the sun, especially between 10am and 2pm • Wear long-sleeved shorts, pants, hats and sunglasses • For children under 6 months of age - ask a doctor. **Reapply**

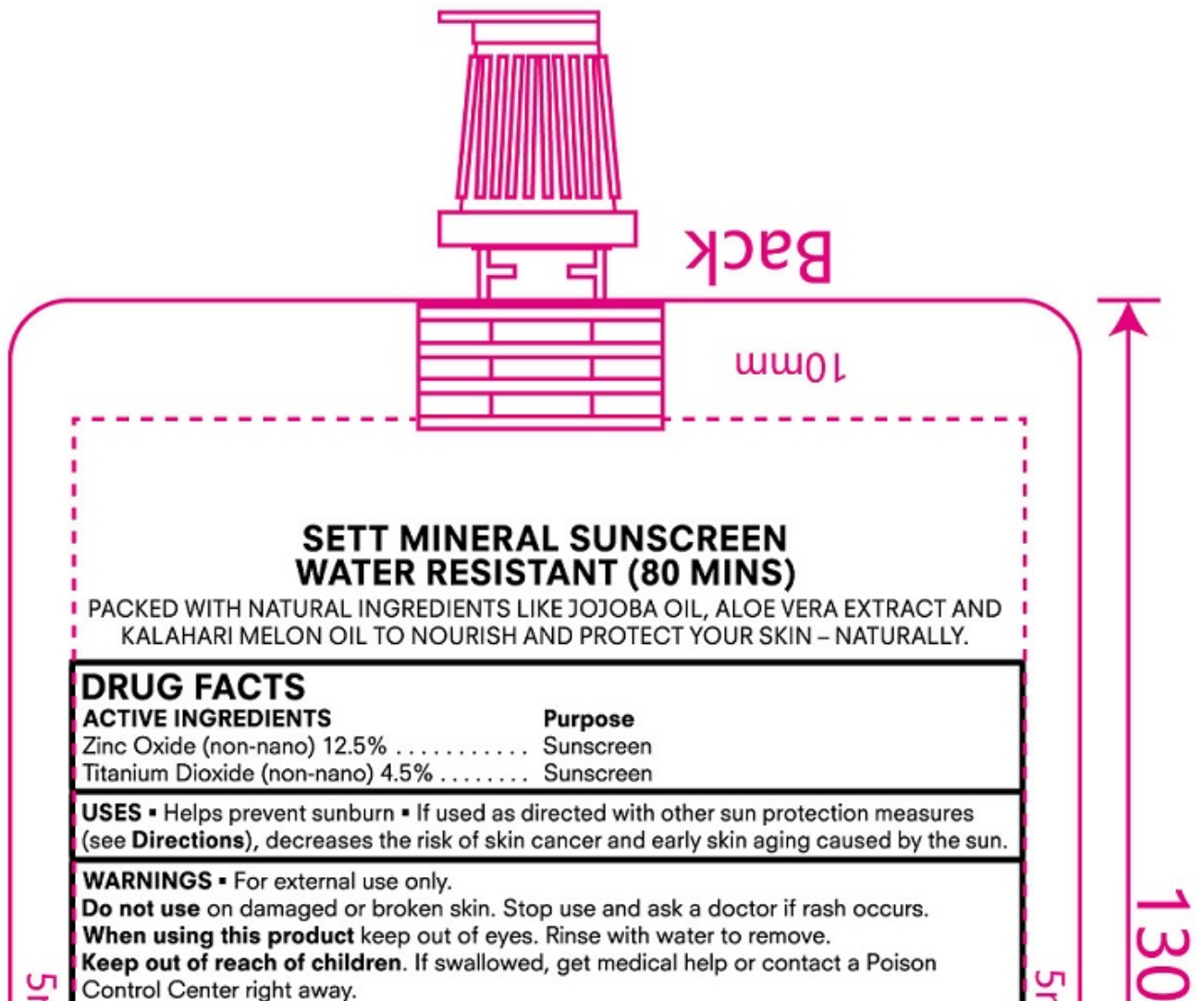
**OTHER INFORMATION**

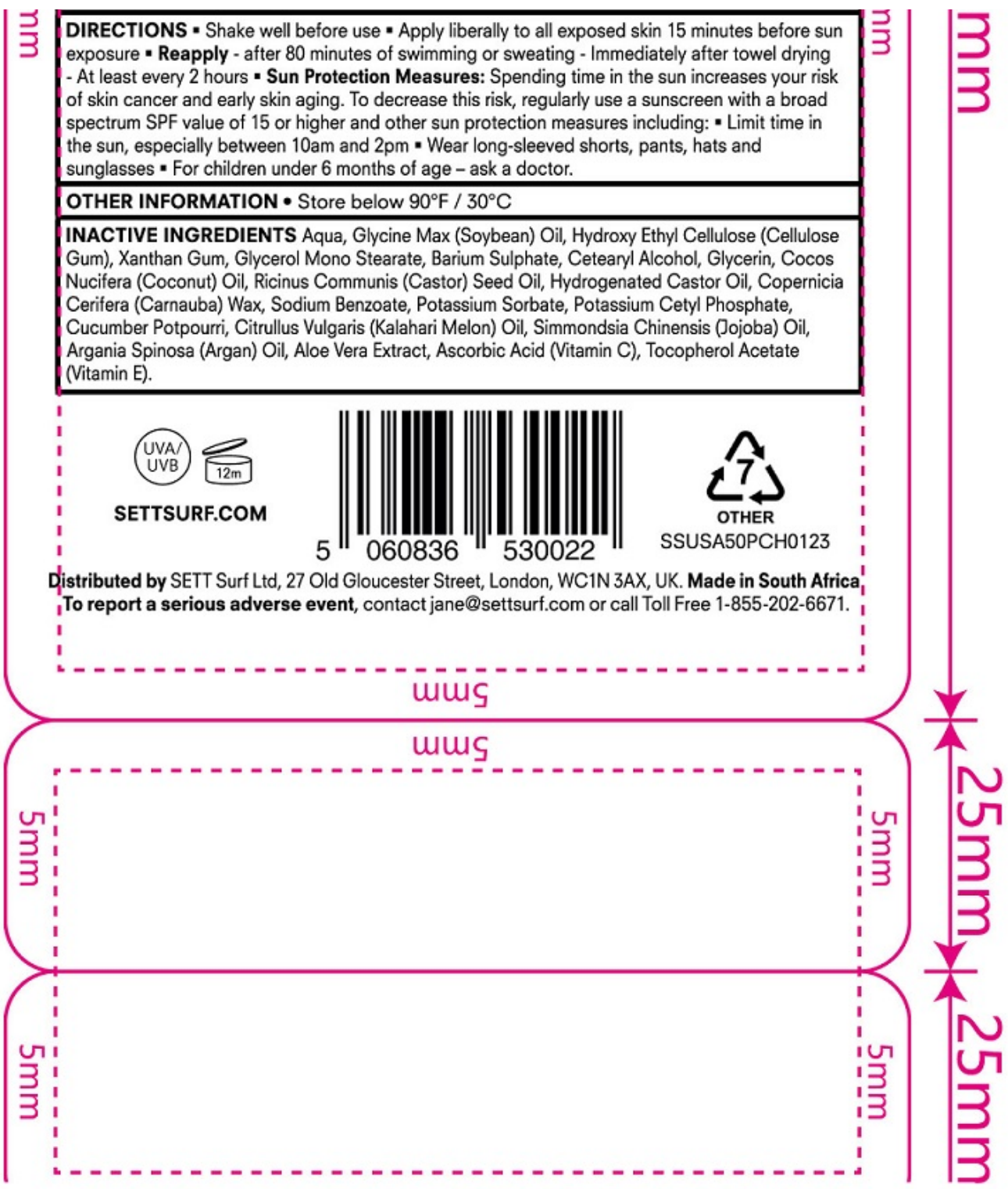
Store below 90°F / 30°C

**INACTIVE INGREDIENTS**

Aqua, Glycine Max (Soybean) Oil, Hydroxy Ethyl Cellulose (Cellulose Gum), Xanthan Gum, Glycerol Mono Stearate, Barium Sulphate, Cetearyl Alcohol, Glycerin, Cocos Nucifera (Coconut) Oil, Ricinus Communis (Castor) Seed Oil, Hydrogenated Castor Oil, Copernicia Cerifera (Carnauba) Wax, Sodium Benzoate, Potassium Sorbate, Potassium Cetyl Phosphate, Cucumber Potpourri, Citrullus Vulgaris (Kalahari Melon) Oil, Simmondsia Chenensis (Jojoba) Oil, Argania Spinosa (Argan) Oil, Aloe Vera Extract, Ascorbic Acid (Vitamin C), Tocopherol Acetate (Vitamin E).

**Package Labeling:**







## SETT MINERAL SUNSCREEN SPF 50

zinc oxide, titanium dioxide cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:83478-000
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	125 mg in 1 mL
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	45 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SOYBEAN OIL</b> (UNII: 241ATL177A)	
<b>HYDROXYMETHYL CELLULOSE</b> (UNII: 273FM27VK1)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>BIARIUM SULFATE</b> (UNII: 25BB7EKE2E)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>COCONUT OIL</b> (UNII: Q9L0O73W7L)	
<b>CASTOR OIL</b> (UNII: D5340Y2I9G)	
<b>HYDROGENATED CASTOR OIL</b> (UNII: ZF94AP8MEY)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	
<b>POTASSIUM CETYL PHOSPHATE</b> (UNII: 03KCY6P7UT)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>ARGAN OIL</b> (UNII: 4V59G5UW9X)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>ASCORBIC ACID</b> (UNII: PQ6CK8PD0R)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83478-000-00	100 mL in 1 POUCH; Type 0: Not a Combination Product	08/01/2023	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M020	08/01/2023	

**Labeler** - Sett Surf, Ltd. (225883876)