

**SUNSCREEN- zinc oxide sunscreen ointment**  
**Private Label Select Ltd CO**

*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.*

Safe Screen Sunscreen SPF30 84g

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 <b>SAFESCREEN</b> <b>30</b> <b>SPF</b> <b>BROAD SPECTRUM SUNSCREEN</b> <b>SPF 30 UVA/UVB PROTECTION</b> <small>FRAGRANCE-FREE • NON-NANO ZINC OXIDE          ALL NATURAL • DERMATOLOGIST REVIEWED          WATER RESISTANT (80 MINUTES)</small>  3oz. (84g)	<table border="1"> <tr> <th colspan="2"><b>Drug Facts</b></th> </tr> <tr> <td><b>Active Ingredients</b></td> <td><b>Purpose</b></td> </tr> <tr> <td>Zinc Oxide 20%</td> <td>Sunscreen</td> </tr> <tr> <td colspan="2"><b>Uses</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>if used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and <b>early</b> skin aging caused by the sun</li> </ul> </td> </tr> <tr> <td colspan="2"><b>Warnings</b></td> </tr> <tr> <td colspan="2">For external use only</td> </tr> <tr> <td colspan="2">Do not use on damaged or broken skin</td> </tr> <tr> <td colspan="2">When using this product keep out of eyes. Rinse with water to remove.</td> </tr> <tr> <td colspan="2">Stop use and ask a doctor if rash occurs</td> </tr> <tr> <td colspan="2">Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</td> </tr> <tr> <td colspan="2"><b>Directions</b></td> </tr> <tr> <td colspan="2"> <ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply:               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><b>Sun Protection Measures.</b> Spending time in the sun increases your risk of skin cancer and <b>early</b> 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:               <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> <li>children under 6 months: Ask a doctor</li> </ul> </td> </tr> <tr> <td colspan="2"><b>Inactive ingredients</b></td> </tr> <tr> <td colspan="2">Helianthus Annuus (Sunflower) Seed Oil*, Ricinus Communis (Castor) Oil*, Olea Europaea (Olive) Oil*, Cera Alba (Beeswax)*, Cocos Nucifera (Coconut) Oil*, Simmondsia Chinensis (Jojoba) Oil*, Butyrospermum Parkii (Shea) Butter*, Tocopherol, * Certified Organic Ingredient</td> </tr> <tr> <td colspan="2"><b>Other information</b></td> </tr> <tr> <td colspan="2">protect this product from excessive heat and direct sun</td> </tr> </table> <p style="text-align: center;">         MANUFACTURED FOR TM-TECH, LLC.          101 FIFTH AVENUE, 11TH FLOOR • NEW YORK, NY 10003          TMSKINCARE.COM       </p> 	<b>Drug Facts</b>		<b>Active Ingredients</b>	<b>Purpose</b>	Zinc Oxide 20%	Sunscreen	<b>Uses</b>		<ul style="list-style-type: none"> <li>helps prevent sunburn</li> <li>if used as directed with other sun protection measures (see <b>Directions</b>), decreases the risk of skin cancer and <b>early</b> skin aging caused by the sun</li> </ul>		<b>Warnings</b>		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 product is swallowed, get medical help or contact a Poison Control Center right away.		<b>Directions</b>		<ul style="list-style-type: none"> <li>apply liberally 15 minutes before sun exposure</li> <li>reapply:               <ul style="list-style-type: none"> <li>after 80 minutes of swimming or sweating</li> <li>immediately after towel drying</li> <li>at least every 2 hours</li> </ul> </li> <li><b>Sun Protection Measures.</b> Spending time in the sun increases your risk of skin cancer and <b>early</b> 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:               <ul style="list-style-type: none"> <li>limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>wear long-sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> <li>children under 6 months: Ask a doctor</li> </ul>		<b>Inactive ingredients</b>		Helianthus Annuus (Sunflower) Seed Oil*, Ricinus Communis (Castor) Oil*, Olea Europaea (Olive) Oil*, Cera Alba (Beeswax)*, Cocos Nucifera (Coconut) Oil*, Simmondsia Chinensis (Jojoba) Oil*, Butyrospermum Parkii (Shea) Butter*, Tocopherol, * Certified Organic Ingredient		<b>Other information</b>		protect this product from excessive heat and direct sun	
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<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:62932-179
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	20 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)	
CASTOR OIL (UNII: D5340Y2I9G)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
SIMMONDSIA CHINENSIS SEED WAX (UNII: 47X6Y9FJJ2)	
SHEA BUTTER (UNII: K49155WL9Y)	
TOCOPHEROL (UNII: R0ZB2556P8)	
COCONUT OIL (UNII: Q9L0O73W7L)	

**Product Characteristics**

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62932-179-20	84 g in 1 TUBE; Type 0: Not a Combination Product	11/19/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	11/19/2018	

**Labeler** - Private Label Select Ltd CO (005415463)**Registrant** - Private Label Select Ltd CO (005415463)