

SUNSCREEN- zinc oxide sunscreen stick
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.

Protekt SPF 30 Regular Sunstick

OTC - ACTIVE INGREDIENT SECTION

Active Ingredient

Zinc Oxide 20%

OTC - KEEP OUT OF REACH OF CHILDREN

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

OTC - PURPOSE

Purpose

Sunscreen

ARTWORK - FRONT

**Keep out of reach of children.
If swallowed, get medical help or contact a
Poison Control Center right away.**

ARTWORK - BACK LABEL



SUNSCREEN

zinc oxide sunscreen stick

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:62932-241 |
| Route of Administration | 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 |
|---|----------|
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| .ALPHA.-TOCOPHEROL, D- (UNII: N9PR3490H9) | |
| COCONUT OIL (UNII: Q9L0O73W7L) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| .GAMMA.-TOCOPHEROL (UNII: 8EF1Z1238F) | |
| .DELTA.-TOCOPHEROL (UNII: JU84X1I0N) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| WHITE WAX (UNII: 7G1J5DA97F) | |
| CANDELILLA WAX (UNII: WL0328HX19) | |
| COCOA BUTTER (UNII: 512OYT1CRR) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CASTOR OIL (UNII: D5340Y2I9G) | |
| .BETA.-TOCOPHEROL (UNII: 9U6A490501) | |

Product Characteristics

| | | | |
|----------|-------|--------------|--|
| Color | white | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62932-241-33 | 14 g in 1 CONTAINER; Type 0: Not a Combination Product | 02/01/2020 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 02/01/2020 | |

Labeler - Private Label Select Ltd CO (005415463)

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Private Label Select Ltd CO