

# THE GREEN BEAVER COMPANY SPF 40 KIDS SUNSCREEN- sunscreen lotion lotion

## The Green Beaver Company

*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.*

### The Green Beaver Kids Sunscreen SPF 40

#### Active ingredients:

Zinc oxide 8%

Titanium dioxide 8%

Uses

#### Purpose

Sunscreen

Sunscreen

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

#### 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.

#### Directions

• apply liberally 15 minutes before sun exposure.

• children under 6 months of age: Ask a doctor.

• **Sun Protection Measures:** Spending time in the sun.

**Warnings** • For external uses 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

**Inactive ingredients** Helianthus Annuus (Sunflower) Seed Oil<sup>®</sup>, Dicaprylyl Carbonate, Beeswax<sup>®</sup>, Caprylic/Capric Triglyceride, Pongamia Glabra (Karanja) Seed Oil, Alumina, Rubus Idaeus (Raspberry) Seed Oil<sup>®</sup>, Hydrolyzed Jojoba Esters, Polyhydroxystearic Acid, Jojoba Esters, Aqua, Trihydroxystearin, d-alpha Tocopherol, Beta-sitosterol, Isostearic Acid, Squalene, Polyglyceryl-3 Polyricinoleate, Lecithin. <sup>®</sup> Ingredients from Organic Farming.



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sunscren lotion lotion

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:76098-002 |
| Route of Administration | TOPICAL        |                    |               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)             | ZINC OXIDE        | 8 g in 100 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE  | 8 g in 100 g |

**Inactive Ingredients**

| Ingredient Name   | Strength |
|---|----------|
| CEROTIC ACID (UNII: D42CQN6P36)                         |          |
| HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W) |          |
| SQUALENE (UNII: 7QWM220FJH)                             |          |
| ALUMINUM OXIDE (UNII: LM26O6933)                        |          |
| POLYGLYCERYL-3 RICINOLEATE (UNII: MZQ63P0N0W)           |          |
| TRIHYDROXYSTEARIN (UNII: 06YD7896S3)                    |          |
| .ALPHA.-TOCOPHEROL ACETATE, D- (UNII: A7E6112E4N)       |          |
| SODIUM BETA-SITOSTERYL SULFATE (UNII: I289C8TPSV)       |          |
| LECITHIN, SUNFLOWER (UNII: 834K0WOS5G)                  |          |
| WATER (UNII: 059QF0K00R)                                |          |
| KARUM SEED OIL (UNII: 62160PU6FJ)                       |          |
| HELIANTHUS ANNUUS SEED WAX (UNII: 42DG15CHXV)           |          |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)                 |          |
| CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)  |          |
| RUBUS IDAEUS FRUIT VOLATILE OIL (UNII: 276X2YNL0K)      |          |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F)    |          |
| ISO STEARIC ACID (UNII: X33R8U0062)                     |          |

**Packaging**

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:76098-002-01 | 94 g in 1 TUBE; Type 0: Not a Combination Product | 01/26/2018           |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 01/26/2018           |                    |

**Labeler** - The Green Beaver Company (243807018)**Registrant** - Regulatory Matters Consulting (080711165)