# SPF 50 MINERAL SUNSCREEN FACE AND BODY- zinc oxide lotion Toddler Born Wild, Inc.

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## Toddle Mineral SPF 50 Sunscreen 1.7 fl oz, 1.3 fl oz, and 6 fl oz

Zinc Oxide 20.00%

Sunscreen

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.

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.

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

Stop use and ask a doctor if rash occurs.

Apply evenly to face and neck 15 minutes beofre sun exposure.

### Reapply:

- After 40 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:

- Limin time in the sun, especially from 10a.m 2p.m
- Wear long-sleeve shirts, pants, hats, and sunglasses.

#### Children under 6 months: Ask a doctor.

Protect this product from excessive heat and direct sun.

Aloe Barbadensis Leaf Juice

Butylene Glycol

**Butyloctyl Salicylate** 

Caprylic/Capric Triglyceride

Cetearyl Olivate

Dicaprylyl Carbonate

Dimethicone

Ethylhexyl Methoxycrylene

Ethylhexylglycerin

Helianthus Annuus (Sunflower) Seed Oil

Hydrogenated Castor Oil

Inulin

Isopropyl Myristate

Magnesium Sulfate

Niacinamide

Phenoxyethanol

Polyglyceryl-3 Polyricinoleate

Polyhydroxystearic Acid

Sorbitan Oleate

Sorbitan Olivate

Synthetic Beeswax

Tocopheryl Acetate

VP/Hexadecene Copolymer

Water

Xanthan Gum

Questions?

questions@toddleskincare.com



#### SPF 50 MINERAL SUNSCREEN FACE AND BODY

zinc oxide lotion

| Product Information     |                |                    |               |  |
|-------------------------|----------------|--------------------|---------------|--|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:85865-002 |  |
| Route of Administration | TOPICAL        |                    |               |  |

| Active Ingredient/Active Moiety                              |                   |                |  |
|--|-------------------|----------------|--|
| Ingredient Name  | Basis of Strength | Strength       |  |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 20 g in 100 mL |  |
|  |                   |                |  |

| Ingredient Name   | Strength |
|---|----------|
| MAGNESIUM SULFATE (UNII: DE08037SAB)                      |          |
| NIACINAMIDE (UNII: 25X51I8RD4)                            |          |
| DIMETHICONE (UNII: 92RU3N3Y10)                            |          |
| SORBITAN OLEATE (UNII: 06XEA2VD56)                        |          |
| PHENOXYETHANOL (UNII: HIE492ZZ3T)                         |          |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY)                |          |
| HELIANTHUS ANNUUS (SUNFLOWER) SEED OIL (UNII: 3W1JG795YI) |          |
| .ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)               |          |
| VP/HEXADECENE COPOLYMER (UNII: KFR5QEN0N9)                |          |
| INULIN (UNII: JOS53KRJ01)                                 |          |
| SYNTHETIC BEESWAX (UNII: 08MNR5YE2R)                      |          |
| ALOE BARBADENSIS LEAF JUICE (UNII: RUE8E6T4NB)            |          |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)                  |          |
| CAPRYLIC/CAPRIC TRIGLYCERIDE (UNII: C9H2L21V7U)           |          |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA)                   |          |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)                     |          |
| ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)                    |          |
| WATER (UNII: 059QF0KO0R)                                  |          |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA)                        |          |
| ETHYLHEXYL METHOXYCRYLENE (UNII: S3KFG6Q5X8)              |          |
| XANTHAN GUM (UNII: TTV12P4NEE)                            |          |
| SORBITAN OLIVATE (UNII: MDL271E3GR)                       |          |
| CETEARYL OLIVATE (UNII: 58B69Q84JO)                       |          |
| POLYGLYCERYL-3 PENTARICINOLEATE (UNII: 7Q00K5D0T4)        |          |

| Packaging |                                 |  |                         |                       |
|-----------|---------------------------------|--|-------------------------|-----------------------|
| #         | # Item Code Package Description |  | Marketing Start<br>Date | Marketing End<br>Date |
| 1         | NDC:85865-<br>002-01            | 50 mL in 1 TUBE; Type 0: Not a Combination Product     | 12/10/2025              |                       |
| 2         | NDC:85865-<br>002-02            | 100 mL in 1 TUBE; Type 0: Not a Combination Product    | 02/10/2026              |                       |
| 3         | NDC:85865-<br>002-03            | 177 mL in 1 PACKAGE; Type 0: Not a Combination Product | 12/10/2025              |                       |

| Marketing Information |   |                         |                       |  |
|-----------------------|---|-------------------------|-----------------------|--|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |  |
| OTC Monograph Drug    | M020  | 12/10/2025              |                       |  |
|                       |   |                         |                       |  |

# Labeler - Toddler Born Wild, Inc. (119537440)

| Establishment         |         |           |                        |  |  |
|-----------------------|---------|-----------|------------------------|--|--|
| Name                  | Address | ID/FEI    | Business Operations    |  |  |
| Inspec Solutions, LLC |         | 081030372 | manufacture(85865-002) |  |  |

Revised: 12/2025 Toddler Born Wild, Inc.