

BADGER ESSENTIAL BABY SET- zinc oxide
W.S. Badger Company, Inc.

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.

Set EOM's; Badger ® Essential Baby Set

Active Ingredient

Zinc oxide 10%

Purpose

Skin Protectant

Keep out of reach of children

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away

Uses

■ Treats and prevents diaper rash ■ Soothes irritated skin ■ Protects against moisture

Directions

■ Cleanse area, pat dry, then apply an even layer of cream ■ Use every day or if rash is present

*Helianthus Annuus (Sunflower) Seed Oil, *Cera Alba (Beeswax), *Calendula Officinalis (Calendula) Flower Extract, Tocopherol (Sunflower Vitamin E). * = Certified Organic

Warnings

For external use only

When using this product

When using this product: Keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if

Stop use and ask a doctor if: Rash or irritation develops and lasts. Condition persists for more than 7 days.

Diaper Cream

Keeps skin soft and dry. Zinc Oxide treats and prevents diaper rash.

BADGER DIAPER

zinc oxide cream

Product Information

Item Code (Source) NDC:62206-2850

Route of Administration TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 10 g in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| HIPPOPHAE RHAMNOIDES FRUIT (UNII: AVL0R9111T) | |
| CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:62206-2850-1 | 87 mL in 1 TUBE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 11/02/2015 | |

Part 2 of 3

BABY BALM BADGER

lotions, oils, powders, and creams cream

Product Information

Route of Administration TOPICAL

Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|-----------------|--|----------|
| INGR | OLIVE OIL (UNII: 6UYK2W1W1E) | |
| INGR | YELLOW WAX (UNII: 2ZA36H0S2V) | |
| INGR | CASTOR OIL (UNII: D5340Y2I9G) | |
| INGR | CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| INGR | CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|--|----------------------|--------------------|
| 1 | | 21 g in 1 CAN; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | 06/21/2017 | |

Part 3 of 3

BABY OIL BADGER

lotions, oils, powders, and creams oil

Product Information

| | |
|--------------------------------|---------|
| Route of Administration | TOPICAL |
|--------------------------------|---------|

Other Ingredients

| Ingredient Kind | Ingredient Name | Quantity |
|-----------------|--|----------|
| INGR | OLIVE OIL (UNII: 6UYK2W1W1E) | |
| INGR | JOJOBA OIL (UNII: 724GKU717M) | |
| INGR | CALENDULA OFFICINALIS FLOWER (UNII: P0M7O4Y7YD) | |
| INGR | CHAMOMILE FLOWER OIL (UNII: 60F80Z61A9) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|-----------|---|----------------------|--------------------|
| 1 | | 118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| Cosmetic | | 06/21/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 06/21/2017 | |

Labeler - W.S. Badger Company, Inc. (963242326)

Establishment

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|-------------------------|
| W.S. Badger Company, Inc. | | 963242326 | manufacture(62206-3360) |

Revised: 12/2022

W.S. Badger Company, Inc.