#### BOY BUTTER EXTREME H2O DESENSITIZING LUBRICANT- benzocaine cream Boy Butter Lubes

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.

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#### **Drug Facts:**

#### **Active Ingredient**

Benzocaine 5%

#### Purpose:

Male genital desensitizer

#### Indications:

Helps in the prevention of premature ejaculation.

- For temporary male genital desensitization, helping to slow the onset of ejaculation
- Helps in temporarily slowing the onset of ejaculation
- For reducing oversensitivity in the male in advance of intercourse.

#### Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

#### Warnings:

Premature ejaculation may be due to a condition requiring medical supervision.

- If this product, used as directed, does not provide relief, discontinue use and consult a physician.
- Avoid contact with the eye. If you or your partner develop a rash or irritation, such as burning or itching, discontinue use.
- If symptoms persist, consult a physician.

#### Directions:

Apply a small amount to head and shaft of penis before intercourse, or use as directed by a physician

• Wash product off after intercourse.

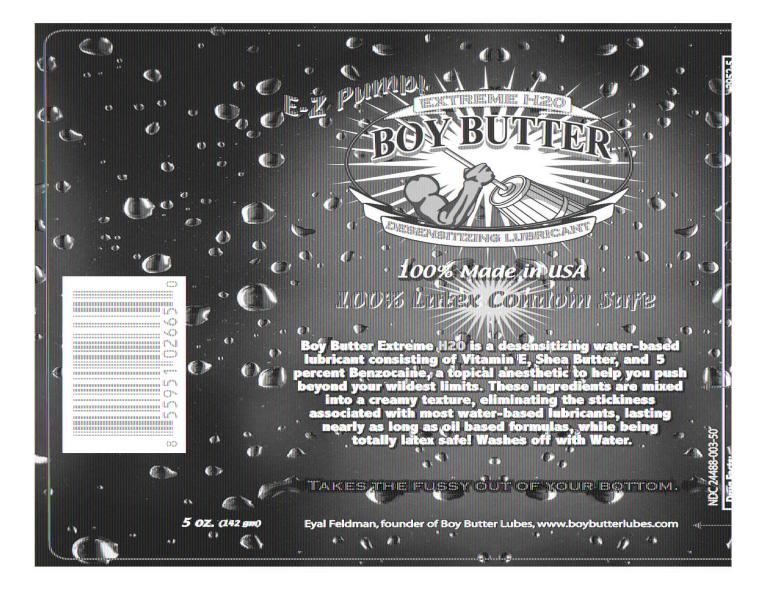
#### Inactive Ingredients:

Water, Cyclopentasiloxane, Propylene Glycol, Glyceryl Stearate and PEG-100 Stearate, Paraffinum Liquidum (Mineral Oil), Butyrospermum Parkii (Shea Butter), Tricaprylin, Cocos Nucifera (Coconut) Oil, Glycerin, Triethanolamine, Carbomer, Aloe Barbadensis Leaf Juice, Tocopheryl (Vitamin E) Acetate, Methylparaben, Diazolidinyl Urea, Propylparaben, Yellow 5, Fragrance

#### **Questions or Comments:**

For questions or comments, please call 1-818-888-6825

Placeholder Text



### BOY BUTTER EXTREME H20 DESENSITIZING LUBRICANT

benzocaine cream

| Product Information  |                 |               |                        |       |                |  |
|--|-----------------|---------------|------------------------|-------|----------------|--|
| Product Type   | HUMAN OTC DRUG  | Item Code (So | Item Code (Source) NDC |       | 2:24488-003    |  |
| Route of Administration  | TOPICAL         |               |                        |       |                |  |
|  |                 |               |                        |       |                |  |
|  |                 |               |                        |       |                |  |
| Active Ingredient/Active N   | Ioiety          |               |                        |       |                |  |
| Ingredient Name Basis of   |                 |               |                        | ength | Strength       |  |
| BENZO CAINE (UNII: U3RS Y48 JW5) (BENZO CAINE - UNII:U3RS Y48 JW5) BENZO CAINE |                 |               |                        |       | 7.1 g in 142 g |  |
|  |                 |               |                        |       |                |  |
|  |                 |               |                        |       |                |  |
| Inactive Ingredients   |                 |               |                        |       |                |  |
|  | Ingredient Name |               |                        |       | Strength       |  |
| WATER (UNII: 059QF0KO0R)   |                 |               |                        |       |                |  |
| - ,  |                 |               |                        |       |                |  |
| CYCLOMETHICONE 5 (UNII: 0 TH   | T5PCI0R)        |               |                        |       |                |  |

| GLYCERYL MONOSTE                               | ARATE (UNII: 230OU9XXE4)       |  |                                   |                      |  |  |  |  |  |
|--|--------------------------------|--|-----------------------------------|----------------------|--|--|--|--|--|
| PEG-100 STEARATE (U                            | NII: YD01N1999R)               |  |                                   |                      |  |  |  |  |  |
| MINERAL OIL (UNII: T5                          | L8 T28 FGP)                    |  |                                   |                      |  |  |  |  |  |
| SHEA BUTTER (UNII: K4                          | 9 155WL9 Y)                    |  |                                   |                      |  |  |  |  |  |
| TRICAPRYLIN (UNII: 6 P                         | 92858988)                      |  |                                   |                      |  |  |  |  |  |
| COCONUT OIL (UNII: Q                           | COCONUT OIL (UNII: Q9L0O73W7L) |  |                                   |                      |  |  |  |  |  |
| GLYCERIN (UNII: PDC6A                          | A3C0OX)                        |  |                                   |                      |  |  |  |  |  |
| TROLAMINE (UNII: 903                           | K93S3TK)                       |  |                                   |                      |  |  |  |  |  |
| CARBOMER HOMOPOLYMER TYPE C (UNII: 4Q93RCW27E) |                                |  |                                   |                      |  |  |  |  |  |
| ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)           |                                |  |                                   |                      |  |  |  |  |  |
| ALPHA-TOCOPHEROL                               | ACETATE (UNII: 9E8X80D2L0)     |  |                                   |                      |  |  |  |  |  |
| METHYLPARABEN (UN                              | I: A2I8C7HI9T)                 |  |                                   |                      |  |  |  |  |  |
| DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)           |                                |  |                                   |                      |  |  |  |  |  |
| PROPYLPARABEN (UNI                             | I: Z8IX2SC1OH)                 |  |                                   |                      |  |  |  |  |  |
| FD&C YELLOW NO.5 (                             | UNII: I753WB2F1M)              |  |                                   |                      |  |  |  |  |  |
| VANILLA (UNII: Q74T35078H)                     |                                |  |                                   |                      |  |  |  |  |  |
|  |                                |  |                                   |                      |  |  |  |  |  |
|  |                                |  |                                   |                      |  |  |  |  |  |
| Packaging                                      |                                |  |                                   |                      |  |  |  |  |  |
| # Item Code                                    | Package Description            | Marketii                                 | ng Start Date                     | Marketing End Date   |  |  |  |  |  |
| 1 NDC:24488-003-50                             | 142 g in 1 BOTTLE, PUMP        |  |                                   |                      |  |  |  |  |  |
|  |                                |  |                                   |                      |  |  |  |  |  |
|  |                                |  |                                   |                      |  |  |  |  |  |
| Marketing Info                                 | rmation                        |  |                                   |                      |  |  |  |  |  |
| Marketing Category                             |                                | Application Number or Monograph Citation |                                   | e Marketing End Date |  |  |  |  |  |
| OTC monograph final                            | part333B                       | -  | Marketing Start Dat<br>05/20/2011 | 0                    |  |  |  |  |  |
| 0.1  | 1                              |  |                                   |                      |  |  |  |  |  |

# Labeler - Boy Butter Lubes (961956229)

## **Registrant -** Creation's Garden Natural Products (961956229)

## Establishment

| Name                               | Address | ID/FEI    | <b>Business Operations</b> |
|------------------------------------|---------|-----------|----------------------------|
| Creation's Garden Natural Products |         | 961956229 | manufacture                |

Revised: 5/2011

Boy Butter Lubes