ASSURED BUG BITE RELIEF- sodium bicarbonate liquid Huijing (Shanghai) Bio-tech Co., Ltd

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.

Active ingredient

Sodium Bicarbonate (Baking Soda) 5%

Purpose

Skin Protectant

Uses temporary relief of itching and irritation due to

•insect bites and stings •poison ivy, oak or sumac

Warnings

For external use only.

Do not use

- over large areas of the body
- •other than as directed

When using this product

avoid contact with eyes

Stop use and ask a doctor if

- •symptoms last for more than 7 days
- •the condition becomes worse
- •symptoms clear up and then occur again within a few days

Keep out of reach of children. If swallowed, get medical help

or contact a Poison control Center right away.

Directions

adults and children 2 years of age and over:

- •apply a small amount directly to the bite, sting or affected area and rub gently
- •re-apply as needed

children under 2 years of age: ask a doctor before use

Other information

store at room temperature 59° - 86° F (15° - 30°C).

Inactive ingredients ammonia, cyclohexasiloxane,

cyclopentasiloxane, glycerin, water



Bug Bite Relief - Sodium Bicutionate (Baking Sodia) 5142014 Provider - Relieves (Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract. NET 0.5 FL. 02. (14 mL) - Additional Ichae Assortines on contract on contract description of the solid contract of

ASSURED BUG BITE RELIEF

sodium bicarbonate liquid

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:71537-005

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

SODIUM BICARBONATE (UNII: 8 MDF5 V39 QO) (SODIUM CATION - UNII: LYR4M0 NH37) | SODIUM BICARBONATE | 5 g in 100 mL

Inactive Ingredients

| Ingredient Name | Strength |
|---------------------------------------|----------|
| AMMO NIA (UNII: 5138 Q 19 F1X) | |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) | |
| CYCLOMETHICONE 5 (UNII: 0 THT5PCI0 R) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| WATER (UNII: 059QF0KO0R) | |

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| | а | u | \mathbf{x} | 2 | | 12 |

| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---------------|---|-------------------------|-----------------------|
| NDC-71527 005 | 14 ml in 1 DOTTLE DI ACTIC, Type O. Not a Combination | | |

| | oduct | 08/01/2017 | | |
|-----------------------|--|----------------------|--------------------|--|
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| Marketing Information | | | | |
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| OTC monograph final | part347 | 08/01/2017 | | |
| O 1 C monograph mar | parts | | | |

Labeler - Huijing (Shanghai) Bio-tech Co., Ltd (544482337)

| Establishment | | | | |
|--------------------------------------|---------|-----------|------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| Huijing (Shanghai) Bio-tech Co., Ltd | | 544482337 | manufacture(71537-005) | |

Revised: 12/2017 Huijing (Shanghai) Bio-tech Co., Ltd