**DCH CALASPRAY ITCH RELIEF- pramoxine hcl 1%, zinc acetate 0.1% spray**
**Derma Care Research Labs, LLC**

*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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**DCH Calaspray Itch Relief Spray, Pramoxine HCl 1%, Zinc Acetate 0.1%**

Pramoxine HCl 2%, Zinc Acetate 0.1%

Topical Analgesic, Skin Protectant

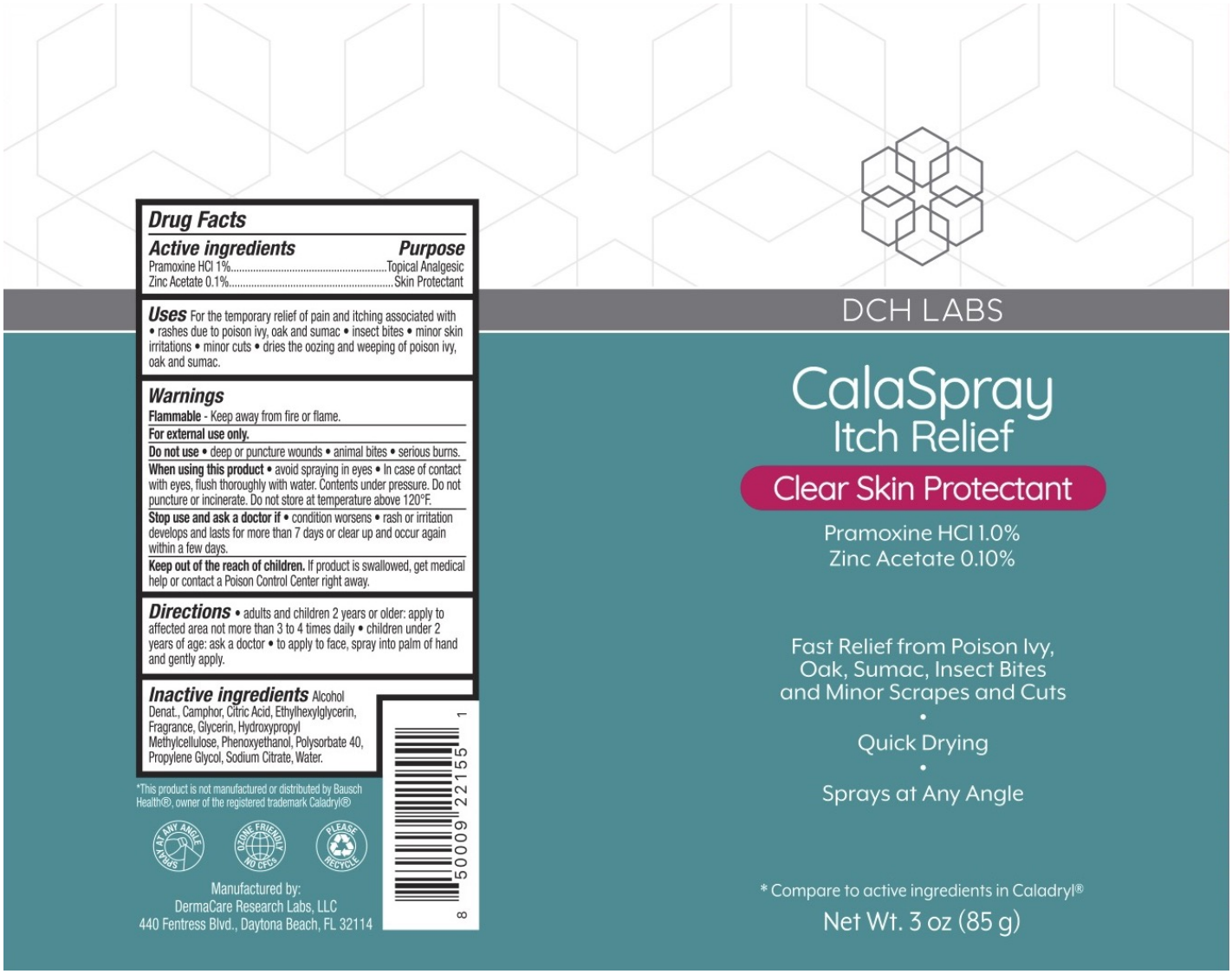
For the temporary relief of pain and itching associated with insect bites, minor burns, sunburn, minor cuts, scrapes, minor skin irritations, and rashes due to poison ivy, oak, and sumac. Dries the oozing and weeping of poison ivy, oak, and sumac.

**For external use only. Flammable--**Keep away from fire or flame. **Do not use on** deep or puncture wounds, animal bites, or serious burns. **When using this product** avoid contact with eyes. In case of contact with eyes, flush thoroughly with water. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120F. . **Stop use and ask a doctor if** condition worsens, if symptoms persist for more than 7 days or clear up and occur again within a few days.

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

Shake well before use. Adults and children 12 years of age and older, apply to the affected area not more than 3 to 4 times daily. Children under 12 years of age: ask a doctor. To apply to face, spray into palm of hand and gently apply.

Alcohol Denat., Camphor, Citric Acid, Ethylhexylglycerin, Fragrance, glycerin, Hydroxypropyl Methylcellulose, Phenoxyethanol, Polysorbate 40, Propylene Glycol, Sodium Citrate, Water.




# DCH CALASPRAY ITCH RELIEF

pramoxine hcl 1%, zinc acetate 0.1% spray

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72839-013 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **PRAMOXINE HYDROCHLORIDE** (UNII: 88AYB867L5) (PRAMOXINE - UNII:068X84E056) | PRAMOXINE HYDROCHLORIDE | 1 g in 100 g |
| **ZINC ACETATE** (UNII: FM5526K07A) (ZINC CATION - UNII:13S1S8SF37) | ZINC ACETATE | 0.1 g in 100 g |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |

| | |
|---|---|
| **ETHYLHEXYLGLYCERIN** (UNII: 147D247K3P) | |
| **HYPROMELLOSES** (UNII: 3NXW29V3WO) | |
| **CAMPHOR (SYNTHETIC)** (UNII: 5TJD82A1ET) | |
| **ALCOHOL** (UNII: 3K9958V90M) | |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **POLYSORBATE 40** (UNII: STI11B5A2X) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:72839-013-03 | 85 g in 1 CAN; Type 0: Not a Combination Product | 02/18/2021 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part348 | 02/18/2021 | |

## Labeler - Derma Care Research Labs, LLC (116817470)

## Registrant - Derma Care Research Labs, LLC (116817470)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Derma Care Research Labs, LLC | | 116817470 | manufacture(72839-013) |

Revised: 6/2023 Derma Care Research Labs, LLC