## CBD GLOBAL FREEZE- methyl salicylate, menthol, camphor spray Cosmetic Specialty Labs, 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.

## Active Incredients

Methyl Salicylate 30\%
Menthol 10\%
Camphor Oil 4\%

## Purpose

Topical analgesi

## Uses

temporarily relieves minor pain associated with: • arthritis • simple backache • muscle strains • sprains • bruises • cramps

## Warnings

for external use only
When using this prodcut • use only as directed • avoid contact with eyes or mucous membranes • do not apply to wounds or damaged skin •do not bandage tightly
Stop use and ask a doctor if • condition worsens • symptoms persist for more than 7 days or clear up and occur again within a few days • redness is present • irritation develeps
If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. If swallowed, get medical help or contact Poison Control Center right away.

## Directions:

Adults and children over 2 years:• apply generously to affected area • massage into painful area until throughly absorbed into skin - repeat as necessary, but no more than 4 time daily
Children 2 years or younger: ask a doctor

## Inactive ingredients

## Package Label



## CBD GLOBAL FREEZE

methyl salicylate, menthol, camphor spray

## Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) |  | NDC:58133-954 |
| :---: | :---: | :---: | :---: | :---: |
| Route of Administration | TOPICAL |  |  |  |
| Active Ingredient/Active Moiety |  |  |  |  |
| Ingredient Name |  |  | Basis of Strength | Strength |
| MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A) |  |  | MENTHOL | $\begin{aligned} & 10 \mathrm{~g} \\ & \text { in } 100 \mathrm{~mL} \end{aligned}$ |
| METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ) |  |  | METHYL SALICYLATE | $\begin{aligned} & 30 \mathrm{~g} \\ & \text { in } 100 \mathrm{~mL} \end{aligned}$ |
| CAMPHOR (SYNTHETIC) (UNII: 5TJD82A1ET) (CAMPHOR (SYNTHETIC) UNII:5TJD82A1ET) |  |  | CAMPHOR <br> (SYNTHETIC) | 4 g in 100 mL |

## Inactive Ingredients

Ingredient Name

## Packaging

| \# | Item Code | Package Description | Marketing Start <br> Date | Marketing End <br> Date |
| :--- | :--- | :--- | :--- | :--- |
| NDC:58133- <br> $954-02$ | 25 mL in 1 BOTTLE, SPRAY; Type 0: Not a <br> Combination Product | $09 / 28 / 2022$ |  |  |

## Marketing Information

| Marketing <br> Category | Application Number or Monograph |
| :--- | :--- | :--- | :--- | :--- |
| Citation |  |$\quad$| Marketing Start |
| :---: |
| Date |$\quad$| Marketing End |
| :---: |
| Date |

## Labeler - Cosmetic Specialty Labs, Inc. (032973000)

## Establishment

| Name | Address | ID/FEI | Business Operations |
| :---: | :---: | :---: | :---: |
| Cosmetic Specialty Labs, Inc. | 032973000 manufacture(58133-954), pack(58133-954), label(58133-954) |  |  |

Revised: 9/2022

