

# HYPOALLERGENIC CBD SENSITIVE SKIN THERAPY ULTRA-LIGHTWEIGHT CALMING VEIL SPF 35- zinc oxide cream

## NV Perricone 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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**Perricone MD**  
REGISTERED PROPERTY OF PERRICONE MD. MUST BE REFERENCED TO: 1000 LAKESIDE DRIVE, SUITE 200 SAN FRANCISCO, CA 94115 • (415) 774-7777

**PRODUCT LINE:** HA CBD Sensitive Skin Therapy      **START DATE:** 03/01/21  
**PRODUCT:** HA CBD Calming SPF 30 1.7oz Tube      **DATE DATE:** N/A  
**PART #:** 150772      **SHIP TO TRADE (STT):** N/A  
**MFG:** 651473712633      **FORMAT SIZE:** See Define  
**SKU #:** 57200001      **SUBSTRATE:** Match Custom Bone  
**FILE NAME:** 150772\_HA\_CBD\_CalmingSPF\_1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH/PASTE MATERIAL TO THE COLOR OF THE ELECTRONIC DOCUMENT. THEY ARE FOR LAYOUT PURPOSE ONLY.

**Custom Brown**      Custom Brown Color, similar to PMS 4055 C  
**PMS 575 G**

**INDU LISTING**  
 \* INCLUDE THE INDU NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| INDU # | INDU MASS/BULK CODE | DESCRIPTION                                   | MFG I/P # | MFG U/P # |
|--------|---------------------|---|-----------|-----------|
| N/A    | N/A                 | HA CBD Ultra-Lightweight Calming SPF 30 1.7oz | N/A       | N/A       |
|        |                     |   |           |           |
|        |                     |   |           |           |

**HISTORY**  
 \* CREATE, RELEASE DATE, INITIAL AND DISPOSE CHANGED TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CMB     | 1          | Mechanical created     |
| 04/01/21 | CMB     | 2          | Revisions per mark-ups |
| 04/26/21 | CMB     | 3          | Confirmed SP-SPF       |
|          |         |            |                        |
|          |         |            |                        |
|          |         |            |                        |
|          |         |            |                        |
|          |         |            |                        |
|          |         |            |                        |

**FINAL APPROVED MECHANICAL AS OF 05.05.21**



**Perricone MD**  
ARTICLE IS PROPERTY OF PERRICONE MD & MUST REFERENCED TO: 400 MONTECARY ST. STE. 2004 W. SAN FRANCISCO, CA 94111 • 415.231.5600

PRODUCT LINE: HA-CEC Sensitive Skin Therapy      START DATE: 03/01/21  
 PRODUCT: HA-CEC Calming SPF 35 1.7oz Tube      DUE DATE: N/A  
 PART #: 150772      SHIP TO TRADE (STT): N/A  
 UPI #: 651472712533      FORMAT SIZE: See Define  
 SKU #: 57200001      SUBSTRATE: Match Custom Bone

FILE NAME: 150772\_HA\_CEC\_CalmingSPF\_1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH/PASTE MATERIAL TO THE EDGE OF THE ELECTRONIC DOCUMENT. THEY ARE FOR LAYOUT PURPOSES ONLY.

Custom Brown      Custom Brown Color, similar to PMS 4005 C

PMS 475 G

**INCI LISTING**  
 \* RECIPE FIELD NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMERGENCY # | MASS/BULK CODE | DESCRIPTION                                   | WIP IFC # | WIP UFS # |
|-------------|----------------|---|-----------|-----------|
| N/A         | N/A            | HA-CEC Ultra-Lightweight Calming SPF 35 1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CHB     | 1          | Mechanical contact     |
| 04/20/21 | CHB     | 2          | Revisions per mark-ups |
| 04/26/21 | CHB     | 3          | Confirmed SS-SPF       |
| 05/05/21 | CHB     | 4          | Mechanical contact     |

**FINAL APPROVED MECHANICAL AS OF 05.05.21**



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PRODUCT LINE: HA-CEC Sensitive Skin Therapy      START DATE: 03/01/21  
 PRODUCT: HA-CEC Calming SPF 35 1.7oz Tube      DUE DATE: N/A  
 PART #: 150772      SHIP TO TRADE (STT): N/A  
 UPI #: 651472712533      FORMAT SIZE: See Define  
 SKU #: 57200001      SUBSTRATE: Match Custom Bone

FILE NAME: 150772\_HA\_CEC\_CalmingSPF\_1.7oz\_Tube\_US

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Custom Brown      Custom Brown Color, similar to PMS 4005 C

PMS 475 G

**INCI LISTING**  
 \* RECIPE FIELD NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMERGENCY # | MASS/BULK CODE | DESCRIPTION                                   | WIP IFC # | WIP UFS # |
|-------------|----------------|---|-----------|-----------|
| N/A         | N/A            | HA-CEC Ultra-Lightweight Calming SPF 35 1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CHB     | 1          | Mechanical contact     |
| 04/20/21 | CHB     | 2          | Revisions per mark-ups |
| 04/26/21 | CHB     | 3          | Confirmed SS-SPF       |
| 05/05/21 | CHB     | 4          | Mechanical contact     |

**FINAL APPROVED MECHANICAL AS OF 05.05.21**



**Perricone MD**  
 ARTICLES PROPERTY OF PERRICONE MD MUST REFERENCED TO: 400 MONTECARYLO CT, SUITE 200, SAN FRANCISCO, CA 94111 + 415.233.5600

PRODUCT LINE: HA-CE0 Sensitive Skin Therapy    START DATE: 03/01/21  
 PRODUCT: HA-CE0 Calming SPF 30 1.7oz Tube    DUE DATE: N/A  
 PART #: 150772    SHIP TO TRADE (STT): N/A  
 UPO: 65147072533    FORMAT SIZE: See Define  
 SKU #: 57200001    SUBSTRATE: Match Custom Bone

FILE NAME: 150772\_HA\_CEO\_CalmingSPF\_1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH/PASTE MATERIAL TO THE DOUBLE OF THE ELECTRONIC DOCUMENT, THEY ARE FOR LAYOUT PURPOSES ONLY.

Custom Brown    Custom Brown Color, similar to PMS 4005 C  
 PMS 475 C

**INCI LISTING**  
 \* RECIPE FIELD NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMERGENCY # | MASS BULK CODE | DESCRIPTION                                   | WIP IFC # | WIP UFS # |
|-------------|----------------|---|-----------|-----------|
| N/A         | N/A            | HA-CE0 Ultra-Lightweight Calming SPF 30 1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CHB     | 1          | Mechanical created     |
| 04/06/21 | CHB     | 2          | Revisions per mark-ups |
| 04/26/21 | CHB     | 3          | Confirmed 3D SFF       |

FINAL APPROVED MECHANICAL AS OF 05.05.21



**Perricone MD**  
 ARTICLES PROPERTY OF PERRICONE MD MUST REFERENCED TO: 400 MONTECARYLO CT, SUITE 200, SAN FRANCISCO, CA 94111 + 415.233.5600

PRODUCT LINE: HA-CE0 Sensitive Skin Therapy    START DATE: 03/01/21  
 PRODUCT: HA-CE0 Calming SPF 30 1.7oz Tube    DUE DATE: N/A  
 PART #: 150772    SHIP TO TRADE (STT): N/A  
 UPO: 65147072533    FORMAT SIZE: See Define  
 SKU #: 57200001    SUBSTRATE: Match Custom Bone

FILE NAME: 150772\_HA\_CEO\_CalmingSPF\_1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH/PASTE MATERIAL TO THE DOUBLE OF THE ELECTRONIC DOCUMENT, THEY ARE FOR LAYOUT PURPOSES ONLY.

Custom Brown    Custom Brown Color, similar to PMS 4005 C  
 PMS 475 C

**INCI LISTING**  
 \* RECIPE FIELD NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMERGENCY # | MASS BULK CODE | DESCRIPTION                                   | WIP IFC # | WIP UFS # |
|-------------|----------------|---|-----------|-----------|
| N/A         | N/A            | HA-CE0 Ultra-Lightweight Calming SPF 30 1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CHB     | 1          | Mechanical created     |
| 04/06/21 | CHB     | 2          | Revisions per mark-ups |
| 04/26/21 | CHB     | 3          | Confirmed 3D SFF       |

FINAL APPROVED MECHANICAL AS OF 05.05.21



**Perricone MD**  
ARTICLE IS PROPERTY OF PERRICONE MD & MUST RETURN TO: 400 MONTECARY ST. STE. 2004 450A FRANCISCO, CA 94111 +1 415 393 5600

PRODUCT LINE: HA-CEO Sensitive Skin Therapy      START DATE: 03/01/21  
 PRODUCT: HA-CEO Calming SPF 30 1.7oz Tube      DUE DATE: N/A  
 PART #: 150772      SHIP TO TRADE (STT): N/A  
 UPO: 65147272533      FORMAT SIZE: See Define  
 SKU #: 57200001      SUBSTRATE: Match Custom Bone

FILE NAME: 150772\_HA\_CEO\_CalmingSPF\_1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH/PASTE MATERIAL TO THE EDGE OF THE ELECTRONIC DOCUMENT. THEY ARE FOR LAYOUT PURPOSES ONLY.

Custom Brown      Custom Brown Color, similar to PMS 4005 C

PMS 675 C

**INCI LISTING**  
 \* RECIPE FIELD NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMERGENCY # | MASS BULK CODE | DESCRIPTION                                   | WIP IFC # | WIP UFS # |
|-------------|----------------|---|-----------|-----------|
| N/A         | N/A            | HA-CEO Ultra-Lightweight Calming SPF 30 1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CHB     | 1          | Mechanical extend      |
| 04/20/21 | CHB     | 2          | Revisions per mark-ups |
| 04/26/21 | CHB     | 3          | Confirmed SS-SPF       |

**FINAL APPROVED MECHANICAL AS OF 05.05.21**



**Perricone MD**  
ARTICLE IS PROPERTY OF PERRICONE MD & MUST RETURN TO: 400 MONTECARY ST. STE. 2004 450A FRANCISCO, CA 94111 +1 415 393 5600

PRODUCT LINE: HA-CEO Sensitive Skin Therapy      START DATE: 03/01/21  
 PRODUCT: HA-CEO Calming SPF 30 1.7oz Tube      DUE DATE: N/A  
 PART #: 150772      SHIP TO TRADE (STT): N/A  
 UPO: 65147272533      FORMAT SIZE: See Define  
 SKU #: 57200001      SUBSTRATE: Match Custom Bone

FILE NAME: 150772\_HA\_CEO\_CalmingSPF\_1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH/PASTE MATERIAL TO THE EDGE OF THE ELECTRONIC DOCUMENT. THEY ARE FOR LAYOUT PURPOSES ONLY.

Custom Brown      Custom Brown Color, similar to PMS 4005 C

PMS 675 C

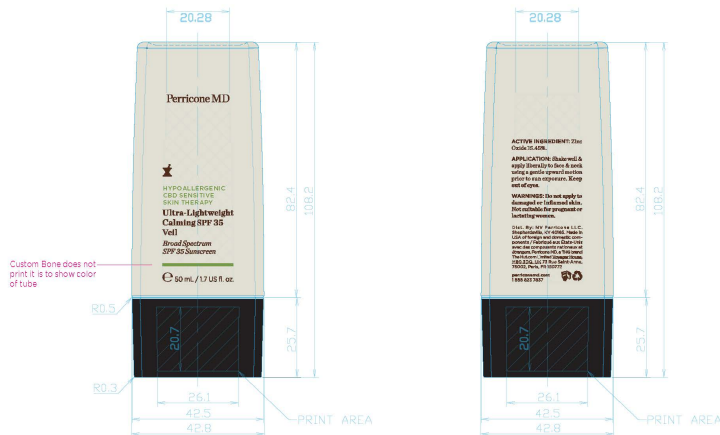
**INCI LISTING**  
 \* RECIPE FIELD NUMBER, BULK CODE & DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMERGENCY # | MASS BULK CODE | DESCRIPTION                                   | WIP IFC # | WIP UFS # |
|-------------|----------------|---|-----------|-----------|
| N/A         | N/A            | HA-CEO Ultra-Lightweight Calming SPF 30 1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 03/01/21 | CHB     | 1          | Mechanical extend      |
| 04/20/21 | CHB     | 2          | Revisions per mark-ups |
| 04/26/21 | CHB     | 3          | Confirmed SS-SPF       |

**FINAL APPROVED MECHANICAL AS OF 05.05.21**



**Perricone MD**  
 ATTORNEY: PERRICONE & ASSOCIATES, 1000 MONTGOMERY ST., SUITE 2000, SAN FRANCISCO, CA 94111-1201, USA

PRODUCT LINE: HA CBD Calming SPF 30-1.7oz Tube      START DATE: 03/01/21  
 PRODUCT: HA CBD Calming SPF 30-1.7oz Tube      DUE DATE: N/A  
 PART #: 150772      SHIP TO TRADE (STT): N/A  
 UFP #: 65147372533      FORMAT SIZE: See Define  
 SKU #: 57200001      SUBSTRATE: Match Custom Bone  
 FILE NAME: 150772\_HA\_CBD\_CalmingSPF-1.7oz\_Tube\_US

**PRINTING INSTRUCTIONS & LAYERS:**  
 \* DO NOT MATCH PAPER MATERIAL TO THE QUALITY OF THE ELECTRONIC DOCUMENT. THEY ARE FOR LAYOUT PURPOSES ONLY.

Custom Brown      Custom Brown Color, similar to PMS 4805 C  
 PMS 479 C

**INCI LISTING**  
 \* DO NOT TYPE IN A BULK CODE OR DESCRIPTION FOR THE PRODUCT OR MULTIPLE PRODUCTS

| EMPAFORMULA # | MASS/BULK CODE | DESCRIPTION                                   | WIP.P.R.# | WIP.U.S.# |
|---------------|----------------|---|-----------|-----------|
| N/A           | N/A            | HA CBD Ultra-Lightweight Calming SPF 30-1.7oz | N/A       | N/A       |

**HISTORY**  
 \* CREATE, PLEASE DATE, INITIAL AND DESCRIBE CHANGES TO THE MECHANICAL

| DATE     | INITIAL | REVISION # | DESCRIPTION            |
|----------|---------|------------|------------------------|
| 04/01/21 | CMB     | 1          | Manufacture started    |
| 04/06/21 | CMB     | 2          | Revisions per mark-ups |
| 04/26/21 | CMB     | 3          | Confirmed 30 SPF       |

**FINAL APPROVED MECHANICAL AS OF 05.05.21**

# HYPOALLERGENIC CBD SENSITIVE SKIN THERAPY ULTRA-LIGHTWEIGHT CALMING VEIL SPF 35

zinc oxide cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:45634-715 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

## Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength          |
|--|-------------------|-------------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 7.725 mg in 50 mg |

## Inactive Ingredients

| Ingredient Name                                      | Strength |
|--|----------|
| LEVOMENOL (UNII: 24WE03BX2T)                         |          |
| OCTYLDODECANOL (UNII: 461N1O614Y)                    |          |
| WATER (UNII: 059QF0KO0R)                             |          |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) |          |
| ISODODECANE (UNII: A8289P68Y2)                       |          |
| BUTYLOCTYL SALICYLATE (UNII: 2EH13UN8D3)             |          |
| GLYCERIN (UNII: PDC6A3C0OX)                          |          |
| PROPANEDIOL (UNII: 5965N8W85T)                       |          |

|  |
|--|
| <b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)  |
| <b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)  |
| <b>PROPYLENE CARBONATE</b> (UNII: 8D08K3S51E)  |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)  |
| <b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)  |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)  |
| <b>ROSEMARY</b> (UNII: IJ67X351P9)   |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)  |
| <b>HELIANTHUS ANNUUS FLOWERING TOP</b> (UNII: BKJ0J3D1BP)  |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)   |
| <b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)  |
| <b>CANNABIS SATIVA SEED OIL</b> (UNII: 69VJ1LPN1S)   |
| <b>COCO-CAPRYLATE/CAPRATE</b> (UNII: 8D9H4QU99H)   |
| <b>BUTYL ACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID COPOLYMER (18000 MW)</b> (UNII: JZ1374NL9E) |
| <b>STEAROYL GLUTAMIC ACID</b> (UNII: 4R4O71786G)   |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)  |
| <b>RICE BRAN</b> (UNII: R60QEP13IC)  |
| <b>POLYGLYCERYL-4 DIISOSTEARATE/POLYHYDROXYSTEARATE/SEBACATE</b> (UNII: 687U3PEB2Y)                |
| <b>STEARALKONIUM HECTORITE</b> (UNII: O LX698AH5P)   |
| <b>CASTOR OIL</b> (UNII: D5340Y2I9G)   |
| <b>CALCIUM GLUCONATE</b> (UNII: SQE6VB453K)  |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)   |
| <b>TRihePTANOIN</b> (UNII: 2P6O7CFW5K)   |
| <b>LINGONBERRY</b> (UNII: 0UNK9RZQ7X)  |
| <b>DILINOLEIC ACID/BUTANEDIOL COPOLYMER</b> (UNII: 1F2S8T535O)                                     |
| <b>GLYCYRRHIZINATE DIPOTASSIUM</b> (UNII: CA2Y0FE3FX)  |
| <b>C9-12 ALKANE</b> (UNII: 7J5R5W72QM)   |
| <b>GLUCONOLACTONE</b> (UNII: WQ29KQ9POT)   |
| <b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)   |

### Product Characteristics

|                 |       |                     |  |
|-----------------|-------|---------------------|--|
| <b>Color</b>    | white | <b>Score</b>        |  |
| <b>Shape</b>    |       | <b>Size</b>         |  |
| <b>Flavor</b>   |       | <b>Imprint Code</b> |  |
| <b>Contains</b> |       |                     |  |

### Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:45634-715-50 | 20000 mg in 1 TUBE; Type 0: Not a Combination Product | 09/05/2023           |                    |

### Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | M020                                     | 09/05/2023           |                    |

**Labeler** - NV Perricone LLC (054414243)

**Establishment**

| Name                                | Address | ID/FEI    | Business Operations    |
|-------------------------------------|---------|-----------|------------------------|
| Dimensional Merchandising Inc (DMI) |         | 076693183 | manufacture(45634-715) |

Revised: 9/2023

NV Perricone LLC