

**MINERAL TINTED MOISTURIZER SPF 15- titanium dioxide lotion**  
**Aveda Corporation**

*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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MINERAL TINTED MOISTURIZER SPF 15  
OIL FREE LOTION

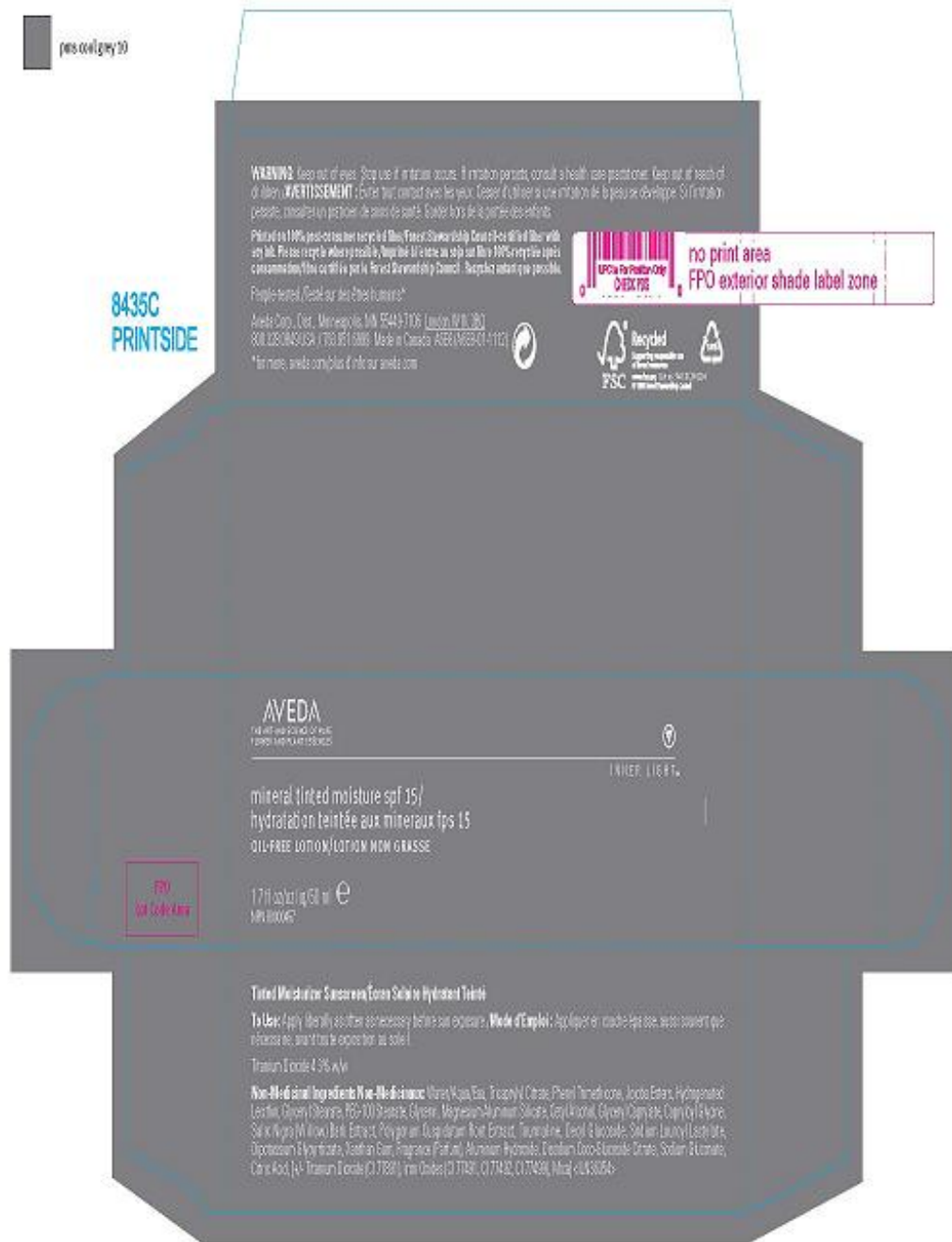
1.7 FL . OZ/ 50 ML

AVEDA CORPORATION DISTR.  
MINNEAPOLIS, MN 54499 7106

ACTIVE INGREDIENT: TITANIUM DIOXIDE, 4.3%

TO USE: APPLY LIBERALLY AS OFTEN AS POSSIBLE BEFORE SUN EXPOSURE

WARNING: KEEP OUT OF EYES. STOP USE IF IRRITATION OCCURS. IF IRRITATION PERSISTS CONSULT A HEALTH CARE PRACTITIONER. KEEP OUT OF REACH OF CHILDREN.



## MINERAL TINTED MOISTURIZER SPF 15

titanium dioxide lotion

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:57677-057 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength          |
|--|-------------------|-------------------|
| TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) | TITANIUM DIOXIDE  | 4.30 mL in 100 mL |

**Packaging**

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:57677-057-01 | 1 in 1 CARTON       |                      |                    |
| 1 | NDC:57677-057-02 | 50 mL in 1 TUBE     |                      |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352                                  | 11/01/2003           |                    |

**Labeler** - Aveda Corporation (071352058)**Establishment**

| Name                        | Address | ID/FEI    | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| ESTEE LAUDER COSMETICS, LTD |         | 205952385 | manufacture         |

**Establishment**

| Name              | Address | ID/FEI    | Business Operations |
|-------------------|---------|-----------|---------------------|
| ESTEE LAUDER N.V. |         | 370151326 | manufacture         |

**Establishment**

| Name  | Address | ID/FEI    | Business Operations |
|---|---------|-----------|---------------------|
| Len-Ron Manufacturing Division of Aramis Inc. |         | 809771152 | manufacture         |

**Establishment**

| Name        | Address | ID/FEI    | Business Operations |
|-------------|---------|-----------|---------------------|
| Aramis Inc. |         | 042918826 | manufacture         |

**Establishment**

| Name             | Address | ID/FEI    | Business Operations          |
|------------------|---------|-----------|------------------------------|
| Northtec Bristol |         | 949264774 | manufacture, relabel, repack |

**Establishment**

| Name              | Address | ID/FEI    | Business Operations          |
|-------------------|---------|-----------|------------------------------|
| Northtec Keystone |         | 618107429 | manufacture, relabel, repack |

**Establishment**

| Name   | Address | ID/FEI    | Business Operations          |
|--------|---------|-----------|------------------------------|
| PADC 1 |         | 110482184 | manufacture, relabel, repack |

**Establishment**

| Name  | Address | ID/FEI    | Business Operations          |
|---|---------|-----------|------------------------------|
| Estee Lauder Pennsylvania Distribution Center 2 |         | 828534516 | manufacture, relabel, repack |

| <b>Establishment</b>         |                |               |                            |
|------------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                  | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Estee Lauder Cosmetics, Ltd. |                | 255175580     | manufacture                |

| <b>Establishment</b>        |                |               |                            |
|-----------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                 | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Estee Lauder Cosmetics, Ltd |                | 253616536     | manufacture                |

| <b>Establishment</b>                       |                |               |                             |
|--|----------------|---------------|-----------------------------|
| <b>Name</b>                                | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b>  |
| Estee Lauder Cosmetics Distribution Center |                | 208579636     | manufacture, label, relabel |

| <b>Establishment</b>          |                |               |                            |
|-------------------------------|----------------|---------------|----------------------------|
| <b>Name</b>                   | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Estee Lauder Kabushiki Kaisha |                | 712808195     | relabel, repack            |

| <b>Establishment</b>      |                |               |                            |
|---------------------------|----------------|---------------|----------------------------|
| <b>Name</b>               | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Whitman Laboratories Ltd. |                | 216866277     | manufacture                |

| <b>Establishment</b> |                |               |                            |
|----------------------|----------------|---------------|----------------------------|
| <b>Name</b>          | <b>Address</b> | <b>ID/FEI</b> | <b>Business Operations</b> |
| Aveda Corporation    |                | 071352058     | manufacture                |