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Health Canada Santé Canada

# Secondary Sunscreen Monograph

## Health Products and Food Branch

Canada

## FOREWORD

This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for secondary sunscreen products. The monograph identifies the permitted medicinal and non-medicinal ingredients, concentrations, indications, directions and conditions of use for these products to be market authorized without the submission to Health Canada of additional evidence. It also may contain the test methods recommended to be used to comply with the requirements of this monograph. Products which do not meet the criteria outlined in this document can apply for market authorization outside of the monograph stream.

Primary sunscreen products are products that are intended to be applied to the skin to prevent sunburn and related conditions of sun exposure. Secondary sunscreen products are products that are intended to be applied to the face or skin as makeup or skincare products which carry limited sunscreen claims. If no explicit primary cosmetic function is evident from the inner and outer package labels and/or the brand name, then the sunscreen will be deemed to be a primary sunscreen and applicants should reference the Primary Sunscreen Monograph.

Applicants are reminded that secondary sunscreen products, like other drugs or natural health products, are subject to the Food and Drug Regulations or the Natural Health Products Regulations administered by the Natural and Non-prescription Health Products Directorate (NNHPD). This includes requirements related to labelling, manufacturing and product specifications. Additional information on labels, outside of those specified in the monograph, such as additional directions for use and/or non-therapeutic claims are acceptable as long as they meet the Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims, the Guidelines for Consumer Advertising of Health products for Nonprescription drugs, Natural Health Products, Vaccines and Medical Devices, and are not false, misleading or counterintuitive to the use of the product.

The development of this monograph is the result of a thorough review of existing regulations, guidance documents, policies and current practices within Health Canada and other leading regulatory agencies.

**Note:**
The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Text in parentheses is additional optional information which can be included on the Product Licence Application form and label at the applicant’s discretion.

## MEDICINAL INGREDIENT(S)

Secondary sunscreen products are classified as natural health products (NHPs) if they contain only ingredients from Table 1. Applicants applying for an NPN can access the appropriate forms and guidance at: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html.

Secondary sunscreen products are classified as non-prescription drugs if they contain at least one ingredient from Table 2. Applicants applying for a DIN can access the appropriate forms and guidance at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents.html.

Any combination of medicinal ingredients listed in Tables 1 and 2 are permitted, provided that the individual concentration limits outlined in the tables are respected.

**Table 1: NHP medicinal ingredients**

| Proper name(s)[1] | Common name(s)[1] | Source material(s)[1,2] | | | UV Protection[3] | Quantity[4] |
|---|---|---|---|---|---|---|
| | | Common name(s) | Proper name(s) | Part(s) | | |
| • 4-Aminobenzoic acid<br>• para-Aminobenzoic acid | • PABA<br>• para-Aminobenzoic acid | Para-aminobenzoic acid | *Saccharomyces cerevisiae* | Whole | UVB | ≤ 15% |
| Titanium dioxide | • C.I. No. 77891<br>• Titanium dioxide<br>• Titanic anhydride | S/O | Titanium dioxide | S/O | UVA<br>UVB | ≤ 25% |
| Zinc oxide | • C.I. No. 77947<br>• Zinc oxide | S/O | Zinc oxide | S/O | UVA<br>UVB | ≤ 25% |

1. At least one of the following references was consulted per proper name, common name and source material: O'Neil et al. 2018; TGA 2016; CTFA 2008; USP 41.
2. Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Quality of Natural Health Products Guide).
3. At least one of the following references was consulted for UV protection: Wang et al. 2010; Antoniou et al. 2008; Ferguson and Dover 2006.
4. At least one of the following references was consulted for the dosage: TGA 2016; Wang et al. 2010; US FDA 1999.

**Table 2: Non-prescription drug medicinal ingredients**

| Proper name(s) | Common name(s) | Source material(s) | UV Protection | Quantity |
|---|---|---|---|---|
| | | Common name(s) | | |
| • 1-(p-tert-Butylphenyl)- | Avobenzone | Avobenzone | UVA I | ≤ 3% |

| | | | | |
|---|---|---|---|---|
| 3-(p-methoxyphenyl)-1,3-propanedione<br>• 1-[4-(1,1-Dimethylethyl)phenyl]-3-(4-methoxyphenyl)-1,3-propanedione<br>• 4-tert-butyl-4'-methoxydibenzoylmethane | | | | |
| • (2-Hydroxy-4-methoxyphenyl)phenylmethanone<br>• 2-Hydroxy-4-methoxybenzophenone | • Benzophenone-3<br>• Oxybenzone | Oxybenzone | UVA II<br>UVB | ≤ 6% |
| • 2-Benzoyl-5-methoxy-1-phenol-4-sulfonic acid<br>• 2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid<br>• 3-Benzoyl-4-hydroxy-6-methoxybenzenesulfonic acid<br>• 5-Benzoyl-4-hydroxy-2-methoxybenzenesulfonic acid | • Benzophenone-4<br>• Sulisobenzone | Sulisobenzone | UVA II<br>UVB | ≤ 10% |
| • (2-Hydroxy-4-methoxyphenyl) (2-hydroxyphenyl) methanone<br>• 2,2'-Dihydroxy-4-methoxybenzophenone | • Benzophenone-8<br>• Dioxybenzone | Dioxybenzone | UVA II<br>UVB | ≤ 3% |
| • 2-Ethoxyethyl p-methoxycinnamate<br>• 3-(4-Methoxyphenyl)-2-propenoic acid 2-ethoxyethyl ester | Cinoxate | Cinoxate | UVB | ≤ 3% |
| • 3-(4-Methoxyphenyl)-2-propenoic acid, compd. with 2,2'-iminobis(ethanol) (1:1)<br>• p-Methoxycinnamic acid, compound with 2,2'-iminodiethanol | • DEA-methoxycinnamate<br>• Diethanolamine methoxycinnamate | Diethanolamine methoxycinnamate | UVB | ≤ 10% |

| | | | | |
|---|---|---|---|---|
| (1:1) | | | | |
| 2-(2H-Benzotriazol-2-yl)-4-methyl-6-(2-methyl-3-{1,3,3,3-tetramethyl-1-[(trimethylsilyl)oxy]-1-disiloxanyl}propyl)phenol | Drometrizole trisiloxane | Drometrizole trisiloxane | UVA<br>UVB | ≤ 15% |
| • (+-)-(3E,3'E)-(p-Phenylenedimethylidyne)bis[2-oxo-10-bornanesulfonic acid]<br>• 3,3'-(1,4 Phenylenedimethylidene)bis[ 7,7-dimethyl-2-oxobicyclo[2.2.1]heptane-1-methanesulfonic acid<br>• Terephthalylidene-3,3'-dicamphor-10,10'-disulfonic acid<br>• Terephthalylidene dicamphor sulfonic acid | Ecamsule | Ecamsule | UVA<br>UVB | ≤ 10% |
| • 2-Phenyl-1H-benzimidazole-5-sulphonic acid<br>• 2-Phenylbenzimidazole-5-sulfonic acid | Ensulizole | Ensulizole | UVB | ≤ 4% |
| • (±)-3-(p-Methylbenzylidene)camphor<br>• 1,7,7-Trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one | Enzacamene | Enzacamene | UVB | ≤ 4% |
| • 2-Hydroxybenzoic acid 3,3,5-trimethylcyclohexyl ester<br>• 3,3,5-Trimethylcyclohexyl salicylate<br>• Salicylic acid 3,3,5-trimethylcyclohexyl este | • Homomenthyl salicylate<br>• Homosalate | Homosalate | UVB | ≤ 15% |
| • 5-Methyl-2-(1-methylethyl)cyclohex | • Menthyl anthranilate | Meradimate | UVA II | ≤ 5% |

| | | | | |
|---|---|---|---|---|
| anol 2-aminobenzoate<br>• Anthranilic acid, p-menth-3-yl ester | • Meradimate | | | |
| • 2-Ethylhexyl p-methoxycinnamate<br>• 3-(4-Methoxyphenyl)-2-propenoic acid, 2-ethylhexyl ester | • Octinoxate<br>• Octyl methoxycinnamate | Octinoxate | UVB | ≤ 7.5% |
| • 2-Ethylhexyl salicylate<br>• 2-Hydroxybenzoic acid 2-ethylhexyl ester | Octisalate | Octisalate | UVB | ≤ 5% |
| • 2-Cyano-3,3-diphenyl-2-propenoic acid, 2-ethylhexyl ester<br>• 2-ethylhexyl-2-cyano-3,3-diphenylacrylate | • Octocrilene<br>• Octocrylene | Octocrylene | UVA II<br>UVB | ≤ 10% |
| • 2-Ethylhexyl p-(dimethylamino)benzoate<br>• 4-(Dimethylamino)benzoic acid, 2-ethylhexyl ester | Padimate O | Padimate O | UVB | ≤ 8% |
| • 2-Hydroxybenzoic acid, compd. with 2,2',2''-nitrilotris(ethanol) (1:1)<br>• Salicylic acid, compound with 2,2',2''-nitrilotriethanol (1:1) | • Triethanolamine salicylate<br>• Trolamine salicylate | Trolamine salicylate | UVB | ≤ 12% |

## ROUTE(S) OF ADMINISTRATION

Topical

## DOSAGE FORM(S)

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

## USE(S) OR PURPOSE(S)

Secondary sunscreens have a function other than sun protection while still providing the skin and lips protection from UV rays, i.e. moisturizers, make-up, lip balm, anti-ageing, anti-wrinkle creams.

**Self-Care Framework Category I Uses or Purposes:**

For all products, the following statement must be made:

- Sun Protection Factor “X” / SPF “X”*

For products with a critical wavelength of ≥ 370 nm** and with medicinal ingredient(s) that provide UVA and UVB protection, the following statements may be made:

- Broad spectrum (Sun Protection Factor “X” / SPF “X”)
- Absorbs throughout the UVA/UVB spectrum
- UVA/UVB protection

For products that are water resistant***, the following statement may be made:

- Water/Sweat Resistant [40 minutes / 80 minutes]

* As determined using a standardized and reproducible method, such as the one referenced in US FDA 2012 or as ISO 2010. The SPF value must be ≥ 2 and values greater than 50 are to be declared as SPF 50+.

** As determined using a standardized and reproducible method, such as the one referenced in US FDA 2012 or as ISO 2012 and Colipa 2011

*** As determined using a standardized and reproducible method, such as the one referenced in US FDA 2012 or as Colipa 2005. When the Colipa methodology is used, the labelled SPF value must be the SPF value of the final product formulation determined following immersion (Antoniou et al. 2008).

## DOSE(S)

**Subpopulation(s):**
Infants 6 to 12 months, Children 1 to 11 years, Adolescents 12 to 17 years, Adults 18 years and older

**Quantity:**
See Tables 1 and 2.

**Directions for use:**

For all products excluding sprays:

- Apply as needed

For spray products:

- Apply as needed
- Hold container 4 to 6 inches / 10 to 15 centimetres from the skin to apply
- Do not spray directly onto face. Spray on hands then apply to face
- Do not apply in windy conditions
- Use in a well-ventilated area

- Avoid inhaling or exposing others to spray.

For all products, the following direction may be included:
- (Test on a small area of skin before first use. If irritation occurs (within 24 hours), use a different product.)

**Duration(s) of use:**
No statement is required.

## RISK INFORMATION

**Caution(s) and warning(s):**

**For all products:**
- **For external use only**
- **When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water.
- **Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if** rash occurs****
- **Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

****Note: This warning statement must appear on the outer label of all secondary sunscreen products, and is ineligible for Level 4 Graduated and Labelling for Low-Risk Non-prescription Drugs (Category I) flexibilities as described in the *Guidance Document: Labelling Requirements for Non-prescription Drugs*.

**Contraindication(s):**
**For all products:**
- **Do not use** on broken skin

**Known adverse reaction(s):**
No statement required

## NON-MEDICINAL INGREDIENTS
Ingredients must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in that database, the Food and Drug Regulations (FDR), and the current Cosmetic Ingredient Hotlist, when relevant.

## STORAGE CONDITIONS

No statement required.

## SPECIFICATIONS
This monograph describes those requirements that are specific to this class of drugs and to NHPs. Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the monograph.

**For products containing Table 1 NHP medicinal ingredients only:**

The finished product specifications must be established in accordance with the requirements described in the NNHPD Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID.

Applicants for market authorizations of secondary sunscreen products formulated with nano Zinc oxide and/or nano Titanium dioxide, meeting the Health Canada's working definition of nanomaterial, are expected to gather and keep information as outlined in Section 7 of the *Policy Statement on Health Canada's Working Definition for Nanomaterial*. This information is required to be made available to Health Canada upon request.

**For products containing Table 2 drug medicinal ingredients:**
Requirements described in the Regulations to the Food and Drugs Act must be met.

**DRUG FACTS TABLES (Format Optional for Self-Care Category I)**

## Drug Facts

| **Active ingredient** (w/w) | **Purpose** |
|---|---|
| Avobenzone XX % …… | Sun protectant |
| Ensulizole XX % …… | Sun protectant |
| Homosalate XX % …… …… | Sun protectant |
| Meradimate XX % …… …… | Sun protectant |
| Octinoxate XX % ……..…. | Sun protectant |
| Octisalate XX % …… | Sun protectant |
| Octocrylene XX % …… …… | Sun protectant |
| Oxybenzone XX % …… | Sun protectant |
| Sulisobenzone XX % …… | Sun protectant |
| Drometrizole trisiloxane XX % …… | Sun protectant |
| Enzacamene XX % …….. | Sun protectant |
| Padimate O XX % …… …… | Sun protectant |
| Ecamsule XX % …… | Sun protectant |
| Cinoxate XX % ……..…. | Sun protectant |
| Diethanolamine methoxycinnamate XX % …… | Sun protectant |
| Dioxybenzone XX % …… | Sun protectant |
| Triethanolamine salicylate XX % …… | Sun protectant |

### Uses

• Sun Protection Factor “X” / SPF “X”

[For products with a critical wavelength of ≥ 370 nm** and with medicinal ingredient(s) that provide UVA and UVB protection]: • Broad spectrum (Sun Protection Factor “X” / SPF “X”) • Absorbs throughout the UVA/UVB spectrum • UVA/UVB protection

[For products that are water resistant]: • Water/Sweat Resistant [40 minutes / 80 minutes]

### Warnings

**For external use only**

**Do not use** on broken skin.

**When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water.

**Stop use and ask/ consult a doctor/ physician/ health care practitioner/ health care provider/ health care professional if** rash occurs*

**Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

### Directions

Adults, adolescents and children over 6 months of age:
[For all products excluding sprays]: • Apply as needed

[For spray products]: • Apply as needed • Hold container 4 to 6 inches / 10 to 15 centimetres from the skin to apply • Do not spray directly onto face. Spray on hands then apply to face • Do not apply in windy conditions • Use in a well-ventilated area • Avoid inhaling or exposing others to spray

[Optional for all products]: • (Test on a small area of skin before first use. If irritation occurs (within 24 hours), use a different product.)

| |
|---|
| **Other information**<br>[If no other information, delete this section] |
| **Inactive ingredients**<br>List NMIs |
| **Questions?** 1-XXX-XXX-XXXX (or other contact information) |

*Note: This warning statement must appear on the outer label of all secondary sunscreen products, and is ineligible for Level 4 Graduated and Labelling for Low-Risk Non-prescription Drugs (Category I) flexibilities as described in the Guidance Document: Labelling Requirements for Non-prescription Drugs.

## REFERENCES

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## APPENDIX 1: Unacceptable Use(s) or Purpose(s)

**Unacceptable use(s) or purpose(s) which are misleading or counterintuitive to the safety and efficacy of secondary sunscreen use:**

Statement(s) to the effect of:

- “Sunblock”, “sun shield”, or any other term implying that the product either prevents UV ray penetration and/or provides total or complete protection;
- Provides “X” times your natural protection against sunburn;
- For sun-sensitive or fair-skinned persons, to prevent sunburn;
- For skin where exposure to UV light is contraindicated;
- Increases, perpetuates, or aids in the development of a tan;
- Allows you to stay longer in the sun;
- Waterproof, sweat proof;
- Representation that use of this product will repair or reverse any skin damage;
- Products for infants’ scalps; and/or
- A “+” (“plus”) indication next to the SPF value, with the exception of SPF 50+.
- Sustained-release;
- Sustained action/long-lasting (i.e. longer than 2 hours or longer than 80 minutes in water);
- Secondary sunscreens with insect repellents;
- Representation for the prevention of cancer
- Representation for the prevention of photoaging and/or related damage (i.e. age spots, wrinkles, etc.);
- Representation that the use of this product alone will prevent or minimize long term damage to the skin or skin cancer;
- UVC protection claims (or other UV rays apart from UVA/UVB);
- Claims that the product is photostable or photostabilized; and/or
- Claims that the product can be applied directly to wet or sweaty skin.