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Health Canada Santé Canada

Primary Sunscreen Monograph

Health Products and Food Branch

Canada

FOREWORD

This monograph is intended to replace the existing Primary Sunscreen Monograph of December 7, 2018. This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for primary 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 all of 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 and 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 primary sunscreen products, like other non-prescription 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)

Primary 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.

Primary 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 information[1,2]	UV Protection[3]	Quantity[4]
		Source ingredient(s)		
Titanium dioxide	• C.I. No. 77891 • Titanium dioxide • Titanic anhydride	Titanium dioxide	UVA UVB	≤ 25%
Zinc oxide	• C.I. No. 77947 • Zinc oxide	Zinc oxide	UVA UVB	≤ 25%

[1]At least one of the following references was consulted per proper name, common name and source information: O'Neil et al. 2018; TGA 2016; Nikitakis and Lange 2016; 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 information	UV Protection	Quantity
		Source ingredient(s)		
• 1-(p-tert-Butylphenyl)-3-(p-methoxyphenyl)-1,3-propanedione • 1-[4-(1,1-Dimethylethyl)phenyl]-3-(4-methoxyphenyl)-1,3-propanedione • 4-tert-Butyl-4'-methoxydibenzoylmethane	Avobenzone	Avobenzone	UVA I	≤ 3%
2,2'-[6-(4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl]bis(5-[(2-ethylhexyl)oxy]phenol)	Bemotrizinol	Bemotrizinol	UVA UVB	≤ 6%[1]

• (2-Hydroxy-4-methoxyphenyl)phenyl methanone • 2-Hydroxy-4-methoxybenzophenone	• Benzophenone-3 • Oxybenzone	Oxybenzone	UVA II UVB	≤ 6%
• 2-Benzoyl-5-methoxy-1-phenol-4-sulfonic acid • 2-Hydroxy-4-methoxybenzophenone-5-sulfonic acid • 3-Benzoyl-4-hydroxy-6-methoxybenzenesulfonic acid • 5-Benzoyl-4-hydroxy-2-methoxybenzenesulfonic acid	• Benzophenone-4 • Sulisobenzone	Sulisobenzone	UVA II UVB	≤ 10%
• (2-Hydroxy-4-methoxyphenyl)(2-hydroxyphenyl) methanone • 2,2'-Dihydroxy-4-methoxybenzophenone	• Benzophenone-8 • Dioxybenzone	Dioxybenzone	UVA II UVB	≤ 3%
2,2'-Methylenebis-(6-(2H-benzotriazol-2yl)-4-(1,1,3,3-tetramethylbutyl)-phenol)	Bisoctrizole	Bisoctrizole	UVA UVB	≤ 5%[1]
• 2-Ethoxyethyl p-methoxycinnamate • 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) • p-Methoxycinnamic acid, compound with 2,2'-iminodiethanol (1:1)	• DEA-methoxycinnamate • Diethanolamine methoxycinnamate	Diethanolamine methoxycinnamate	UVB	≤ 10%
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 UVB	≤ 15%
• (+-)-(3E,3'E)-(p-Phenylenedimethylidyne)bis[2-oxo-10-bornanesulfonic acid] • 3,3'-(1,4 Phenylenedimethylidene)bis(7,7-dimethyl-2-oxobicyclo[2.2.1]heptane-1-methanesulfonic acid)	Ecamsule	Ecamsule	UVA UVB	≤ 10%

• Terephthalylidene-3,3'-dicamphor-10,10'-disulfonic acid • Terephthalylidene dicamphor sulfonic acid				
• 2-Phenyl-1H-benzimidazole-5-sulphonic acid • 2-Phenylbenzimidazole-5-sulfonic acid	Ensulizole	Ensulizole	UVB	≤ 4%
• (±)-3-(p-Methylbenzylidene)camphor • 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 • 3,3,5-Trimethylcyclohexyl salicylate • Salicylic acid 3,3,5-trimethylcyclohexyl ester	• Homomenthyl salicylate • Homosalate	Homosalate	UVB	≤ 15%
• 5-Methyl-2-(1-methylethyl)cyclohexanol 2-aminobenzoate • Anthranilic acid, p-menth-3-yl ester	• Menthyl anthranilate • Meradimate	Meradimate	UVA II	≤ 5%
• 2-Ethylhexyl p-methoxycinnamate • 3-(4-Methoxyphenyl)-2-propenoic acid, 2-ethylhexyl ester	• Octinoxate • Octyl methoxycinnamate	Octinoxate	UVB	≤ 7.5%
• 2-Ethylhexyl salicylate • 2-Hydroxybenzoic acid 2-ethylhexyl ester	Octisalate	Octisalate	UVB	≤ 5%
• 2-Cyano-3,3-diphenyl-2-propenoic acid, 2-ethylhexyl ester • 2-Ethylhexyl-2-cyano-3,3-diphenylacrylate	• Octocrilene • Octocrylene	Octocrylene	UVA II UVB	≤ 10%
• 2-Ethylhexyl p-(dimethylamino)benzoate • 4-(Dimethylamino) benzoic acid, 2-ethylhexyl ester	Padimate O	Padimate O	UVB	≤ 8%
• 2-Hydroxybenzoic	• Triethanolamine	Trolamine	UVB	≤ 12%

acid, compd. with 2,2',2"-nitrilotris(ethanol) (1:1) • Salicylic acid, compound with 2,2',2"-nitrilotriethanol (1:1)	salicylate • Trolamine salicylate	salicylate		

[1]Only permitted when combined with (an) ingredient(s) listed in Table 1 or 2.

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)

Self-Care Framework Category I Uses or Purposes:

For all products, the following statement must be made:

- Sun Protection Factor "X"/SPF "X"*

For all products, the following statements may be made:

- Helps prevent sunburn
- Sunscreen
- Sunburn protectant
- Helps protect from sunburn

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

- Broad spectrum

*For products with a critical wavelength of ≥ 370 nm**, with medicinal ingredient(s) that provide UVA and UVB protection, and SPF ≥15, the following statements may be made:*

- Filters/Screens UVA/UVB rays
- Absorbs throughout the UVA/UVB spectrum to provide sunburn protection
- UVA/UVB protection

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

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

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

For products with a critical wavelength of ≥ 370 nm, with medicinal ingredient(s) that provide UVA and UVB protection, and SPF ≥15, the following statement may be made:

- If used as directed with other sun protection measures [see Directions (for Use)], decreases the risk of skin cancer and early skin aging caused by the sun.

* 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 liberally/generously (and evenly) 15 minutes before sun exposure
- Reapply at least every 2 hours
- Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
    - limit time in the sun, especially from 10 a.m. – 2 p.m./11 a.m. – 3 p.m.; and
    - wear long-sleeved shirts, pants, hats, and sunglasses.

For spray products:

- Spray liberally/generously and spread evenly by hand 15 minutes before sun exposure
- 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
- Reapply at least every 2 hours
- Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
    - limit time in the sun, especially from 10 a.m. – 2 p.m./11 a.m. – 3 p.m.; and

- wear long-sleeved shirts, pants, hats, and sunglasses.

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)

For products that are non-water resistant:

- Use a water resistant sunscreen if swimming or sweating

For products that are water resistant:

- Reapply after 40/80 minutes of swimming or sweating
- Reapply immediately after towel drying

For products that are applied to the lips:

- Reapply after eating or drinking

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 primary 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*.

For products with a critical wavelength of < 370 nm or with SPF value of <15:

- **Other warnings** Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.

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 non-prescription 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 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 non-prescription drug medicinal ingredients:
Requirements described in the Regulations to the Food and Drugs Act must be met.

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

Drug Facts	
Active ingredient (w/w)	**Purpose**
Avobenzone XX %	Sun protectant
Bemotrizinol XX %	Sun protectant
Bisoctrizole 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" • Helps prevent sunburn • Sunscreen • Sunburn protectant • Helps protect from sunburn [For products that are water resistant]: • Water/Sweat Resistant [40 minutes/80 minutes] [For products with a critical wavelength of ≥ 370 nm and with medicinal ingredient(s) that provide UVA and UVB protection]: • Broad spectrum [For products with a critical wavelength of ≥ 370 nm, with medicinal ingredient(s) that provide UVA and UVB protection, and SPF ≥15]: • Filters/Screens UVA/UVB rays • Absorbs throughout the UVA/UVB spectrum to provide sunburn protection • UVA/UVB protection [For products with a critical wavelength of ≥ 370 nm, with medicinal ingredient(s) that provide UVA and UVB protection, and SPF ≥15]: • If used as directed with other sun protection measures [see Directions (for Use)], decreases the risk of skin cancer and early skin aging caused by the sun.	
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.*	
[For products with a critical wavelength of < 370 nm or with SPF value of <15]: **Other warnings** Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, not skin cancer or early skin aging.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children over 6 months of age: [For all products excluding sprays]: • Apply liberally/generously (and evenly) 15 minutes before sun exposure • Reapply at least every 2 hours • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ▪ limit time in the sun, especially from 10 a.m. – 2 p.m./11 a.m. – 3 p.m.; and ▪ wear long-	

sleeved shirts, pants, hats, and sunglasses. [For spray products]:• Spray liberally/generously and spread evenly by hand 15 minutes before sun exposure • 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 • Reapply at least every 2 hours • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: ▪ limit time in the sun, especially from 10 a.m. – 2 p.m./11 a.m. – 3 p.m.; and ▪ wear long-sleeved shirts, pants, hats, and sunglasses. [Optional for all products]: • (Test on a small area of skin before first use. If irritation occurs (within 24 hours), use a different product.) [For products that are non-water resistant]: • Use a water resistant sunscreen if swimming or sweating [For products that are water resistant]: • Reapply after 40/80 minutes of swimming or sweating • Reapply immediately after towel drying [For products that are applied to the lips]: • Reapply after eating or drinking
Other information [If no other information, delete this section]
Inactive ingredients List NMIs
Questions? 1-XXX-XXX-XXXX (or other contact information)

*Note: This warning statement must appear on the outer label of all primary 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.

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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 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+.

Unacceptable use(s) or purpose(s) which require assessment of supporting scientific data outside of the Monograph:

Statement(s) to the effect of:

- Sustained-release;
- Sustained action/long-lasting (i.e. longer than 2 hours or longer than 80 minutes in water);
- Sunscreens with insect repellents;
- Representation for the prevention of cancer (only the complete Sun Protection Measures statement may be used);
- 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.