



Sunscreen Monograph

Health Products and Food Branch

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FOREWORD

Health Canada is pleased to announce the release of the final *Sunburn Protectants Monograph*. The document is now titled "*Sunscreen Monograph*" to reflect the common Canadian term for this category of products.

This monograph is intended to replace the existing *Sunburn Protectants Monograph* of October 12, 2006. This monograph describes the requirements necessary to receive market authorization [i.e. a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for topical sunscreen products. The monograph identifies the permitted medicinal and non-medicinal ingredients, concentrations, indications, directions and conditions of use for these products to be licensed without the submission to Health Canada of additional evidence. It also contains 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.

Applicants are reminded that sunscreens, like other drugs or natural health products, are subject to the *Food and Drug Regulations* administered by the Therapeutic Products Directorate (TPD) or the *Natural Health Products Regulations* administered by the Natural Health Products Directorate (NHPD). 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 cosmetic claims are acceptable as long as they meet the *Guidelines for Cosmetic Advertising and Labelling Claims* or are not false, misleading or counterintuitive to the use of the product.

The development of this monograph is the result of a thorough survey 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)

Sunscreens are classified as natural health products (NHPs) if they contain medicinal ingredients from Table 1 only. Applicants applying for an NPN should use the appropriate forms, templates, and guidance.

Sunscreens are classified as drugs if they contain one or more of the medicinal ingredients from Table 2 or a combination of medicinal ingredients from Tables 1 and 2. Applicants applying for a DIN should use the appropriate forms, templates, and guidance.

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

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*¹. This information is required to be made available to Health Canada upon request.

Table 1: NHP Medicinal Ingredients, Source Ingredients and Concentrations

Proper name ²	Common name ²	Source ingredient	UV protection ³	Concentration ⁴
Titanium dioxide (TiO ₂)	• Titanium dioxide	Titanium dioxide	UVA UVB	≤ 25%
Zinc oxide (ZnO)	• Zinc oxide	Zinc oxide	UVA UVB	≤ 25%
4-Aminobenzoic acid	• p-Aminobenzoic acid • PABA	p-Aminobenzoic acid	UVB	≤ 15%

¹ Health Canada 2011a

² At least one of the following references was consulted: TGA 2012; CTFA 2008; USP 34; Merck Index 2006

³ At least one of the following references was consulted: Wang et al. 2010; Antoniou et al. 2008; Ferguson and Dover 2006

⁴ At least one of the following references was consulted: TGA 2012; Wang et al. 2010; US FDA 1999

Table 2: Drug Medicinal Ingredients, Synonyms and Concentrations

Medicinal ingredient preferred name ⁵	Synonym(s) ²	UV protection ⁶	Concentration ⁷
Avobenzene	<ul style="list-style-type: none"> Butyl methoxydibenzoylmethane 	UVA I	≤ 3%
Ensulizole	<ul style="list-style-type: none"> 2-Phenylbenzimidazole-5-sulfonic acid 	UVB	≤ 4%
Homosalate	<ul style="list-style-type: none"> Homomenthyl salicylate 	UVB	≤ 15%
Meradimate	<ul style="list-style-type: none"> Menthyl 2-aminobenzoate Menthyl anthranilate 	UVA II	≤ 5%
Octinoxate	<ul style="list-style-type: none"> 2-Ethylhexyl methoxycinnamate Octyl methoxycinnamate 	UVB	≤ 7.5%
Octisalate	<ul style="list-style-type: none"> 2-Ethylhexyl salicylate Octyl salicylate 	UVB	≤ 5%
Octocrylene	<ul style="list-style-type: none"> 2-Ethylhexyl-2-cyano-3,3-diphenylacrylate 	UVA II UVB	≤ 10%
Oxybenzone	<ul style="list-style-type: none"> Benzophenone-3 2-Hydroxy-4-methoxybenzophenone 	UVA II UVB	≤ 6%
Sulisobenzene	<ul style="list-style-type: none"> Benzophenone-4 	UVA II UVB	≤ 10%
Drometrizole trisiloxane	<ul style="list-style-type: none"> Meroxyl XL 	UVA UVB	≤ 15%
Enzacamene	<ul style="list-style-type: none"> 4-Methylbenzylidene camphor 	UVB	≤ 4%
Padimate O	<ul style="list-style-type: none"> Octyl dimethyl PABA 	UVB	≤ 8%
Ecamsule	<ul style="list-style-type: none"> Mexoryl SX Terephthalylidene dicamphor sulfonic acid 3,3'-(1,4-Phenylenedimethylidene)bis[7,7-dimethyl-2-oxobicyclo[2.2.1]heptane-1-methanesulfonic acid 	UVA UVB	≤ 10%
Cinoxate	<ul style="list-style-type: none"> 2-Ethoxyethyl-p-methoxycinnamate 	UVB	≤ 3%
Diethanolamine methoxycinnamate	<ul style="list-style-type: none"> DEA-methoxycinnamate 	UVB	≤ 10%
Dioxybenzone	<ul style="list-style-type: none"> Benzophenone-8 (2-Hydroxy-4-methoxyphenyl)(2-hydroxyphenyl)methanone 	UVA II UVB	≤ 3%

⁵ At least one of the following references was consulted: TGA 2012; US FDA 2010; CTFA 2008; USP 34; Merck Index 2006

⁶ At least one of the following references was consulted: Wang et al. 2010; Antoniou et al. 2008; Ferguson and Dover 2006

⁷ At least one of the following references was consulted: TGA 2012; US FDA 2010; Wang et al. 2010; US FDA 1999

Medicinal ingredient preferred name ⁵	Synonym(s) ²	UV protection ⁶	Concentration ⁷
Triethanolamine salicylate	• Trolamine salicylate	UVB	≤ 12%

ROUTE(S) OF ADMINISTRATION

Topical

DOSAGE FORMS

The only acceptable dosage forms are balm, butter, cream, emulsion, gel, lotion, mousse, oil, ointment, powder, paste, spray [including non-pressurized sprays, continuous (bag-on-valve) sprays, and aerosol {non-chlorofluorocarbons (CFC)-based sprays}], stick, and suspension.

USE(S) OR PURPOSE(S)⁸

Statement(s) to the effect of⁹:

For all products:

- Helps prevent sunburn; and
- Sun Protection Factor "X" or SPF "X"^{10,11}.

For products with a critical wavelength of ≥ 370 nm¹², the following statement may be made:

- Broad Spectrum SPF "X".

For products with a critical wavelength of ≥ 370 nm 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.

For products that are water resistant¹³, the following statements may be made:

⁸ US FDA 2012

⁹ Consult Appendices 1 and 2 for unacceptable use(s) or purpose(s) and additional optional use(s) or purpose(s), respectively.

¹⁰ As determined using a standardized and reproducible method, such as the one referenced in US FDA 2012 or as ISO 2010.

¹¹ The SPF value must be ≥ 2 and values greater than 50 are to be declared as SPF 50+.

¹² As determined using a standardized and reproducible method, such as the one referenced in US FDA 2012 or as ISO 2012 and Colipa 2011.

¹³ 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).

- Water/Sweat Resistant [40 minutes]; or
- Water/Sweat Resistant [80 minutes].

DOSE(S)

Subpopulation(s)

Subpopulation does not need to be specified.

Direction(s) for Use¹⁴

Statement(s) to the effect of:

For all products:

- Apply liberally/generously (and evenly) 15 minutes before sun exposure;
- Reapply at least every 2 hours; and
- For use on children less than 6 months of age, consult a health care practitioner.

For products with a critical wavelength of ≥ 370 nm and SPF ≥ 15 :

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

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 [or 80] minutes of swimming or sweating; and
- Reapply immediately after towel drying.

For products that are applied to the lips:

- Reapply after eating or drinking.

For spray products¹⁵:

- Spray liberally/generously and spread evenly by hand 15 minutes before sun exposure¹⁶;
- Hold container 4 to 6 inches from the skin to apply;

¹⁴ Diffey 2001; US FDA 1999, 2006 and 2007

¹⁵ US FDA 2011a; US FDA 2011b

¹⁶ Replaces the statement "Apply liberally/generously (and evenly) 15 minutes before sun exposure" indicated for all products.

- 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; and
- Avoid inhaling or exposing others to spray.

Duration(s) of Use

No statement is required.

RISK INFORMATION¹⁷

Cautions and Warning(s)

Statement(s) to the effect of:

For all products:

- For external use only;
- Do not use on damaged or broken skin;
- If rash occurs, discontinue use and consult a health care practitioner;
- When using this product keep out of eyes. Rinse with water to remove; and
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

For products without a critical wavelength of ≥ 370 nm or with SPF value of < 15 :

- **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.

Contraindications(s)

No statement required.

Known Adverse Reaction(s)

No statement required.

NON-MEDICINAL INGREDIENTS

Ingredients must be chosen from the current Natural Health Products Ingredients Database¹⁸ and must meet the limitations outlined in that database, the *Food and Drugs Regulations* (FDR)¹⁹, the Herbs used as Non-medicinal Ingredients in Nonprescription Drugs for Human Use²⁰, and/or the current Cosmetic Ingredient Hotlist²¹, when relevant.

¹⁷ US FDA 2012

¹⁸ Health Canada 2013

¹⁹ Government of Canada 2013a

²⁰ Health Canada 1995

SPECIFICATIONS

For all products:

The requirements described in the FDR or the *Natural Health Products Regulations*²², as applicable, must be met.

When applicable, the medicinal ingredient(s) should comply with the specifications outlined in the associated monograph from the standards listed on Schedule B to the *Food and Drugs Act*²³.

For products containing medicinal ingredients from Table 1 only:

The finished product must comply with the minimum specifications outlined in the NHPD Quality of Natural Health Products Guide²⁴.

For products containing one or more medicinal ingredients listed in Table 2:

Where no Schedule B monograph exists for the finished product's dosage form, specifications should be similar to those of a comparable compendial dosage form demonstrating the product's identity, potency, purity and quality.

Sunscreen products that contain medicinal ingredients not included in Table 2 may be considered New Drugs as per section C.08.001 of the *FDR*.

10 REFERENCES CITED

Antoniou C., Kosmadaki M.G., Stratigos A.J., Katsambas A.D. 2008. Sunscreens – what's important to know. *J.E.A.D.V.* 22: 1110-1119.

APhA 2002: Berardi R.R., DeSimone E.M., Newton G.D., Oszko M.A., Popovich N.G., Rollins C.J., Shimp L.A., Tietze K.J., editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association.

Colipa 2011. Cosmetics Europe: the Personal Care Association. *In vitro* Method for the Determination of the UVA Protection Factor and "Critical Wavelength" Values of Sunscreen Products. Guideline prepared by the COLIPA *In vitro* UV Protection Method Task Force. URL: <https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=33%3Amethod-for-in-vitro-determination-of-uva-protection-2011&catid=46%3Aguidelines> [Accessed 2013-05-15].

Colipa 2005. Cosmetics Europe: the Personal Care Association. Guidelines for Evaluating Sun Product Water Resistance. URL: <https://www.cosmeticseurope.eu/publications-cosmetics->

²¹ Health Canada 2011a

²² Government of Canada 2013b

²³ Government of Canada 2013c

²⁴ Health Canada 2012

europa-association/guidelines.html?view=item&id=18%3Aguidelines-for-evaluating-sun-product-water-resistance-2005&catid=46%3Aguidelines [Accessed 2013-05-15].

CTFA 2008: Gottschalck TE, Bailey JE, editors. International Cosmetic Ingredient Dictionary and Handbook. Twelfth edition, Volume 3. Washington (DC): The Cosmetic, Toiletry and Fragrance Association.

Ferguson J., Dover J.S. editors. 2006. Photodermatology. Manson Publishing Ltd. London, UK.

Government of Canada 2013a. *Food and Drugs Regulations*. URL: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/ [Accessed 2013-05-15].

Government of Canada 2013b. *Natural Health Products Regulations*. URL: <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/?showtoc=&instrumentnumber=SOR-2003-196> [Accessed 2013-05-15].

Government of Canada 2013c. *Food and Drugs Act*. URL: <http://laws-lois.justice.gc.ca/eng/acts/F-27/> [Accessed 2013-05-15].

Health Canada 2013. Natural Health Products Ingredients Database. URL: <http://webprod.hc-sc.gc.ca/nhpid-bdipsn/search-rechercheReq.do> [Accessed 2013-05-15].

Health Canada 2012. Draft: Quality of Natural Health Products Guide. URL: http://www.hc-sc.gc.ca/dhp-mps/consultation/natur/consult_quality-qualite-eng.php [Accessed 2013-06-13].

Health Canada 2011a. Policy Statement on Health Canada's Working Definition for Nanomaterial. URL: <http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php> [Accessed 2013-05-15].

Health Canada 2011b. Cosmetic Ingredient Hotlist. URL: <http://www.hc-sc.gc.ca/cps-spc/cosmet-person/indust/hot-list-critique/hotlist-liste-eng.php> [Accessed 2013-05-15].

Health Canada 2007. Compendium of Monographs. URL: <http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/compendium-eng.php> [Accessed 2013-05-15].

Health Canada 2006. Guidelines for Cosmetic Advertising and Labelling Claims. URL: <http://www.hc-sc.gc.ca/cps-spc/pubs/indust/cosmet/index-eng.php> [Accessed 2013-05-16].

Health Canada 1995. Herbs used as Non-medicinal Ingredients in Nonprescription Drugs for Human Use. URL: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/pol/herbnonmed_pol-eng.php [Accessed 2013-05-15].

ISO 2012. International Organization for Standardization. ISO 24443. Determination of sunscreen UVA photoprotection in vitro. URL: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46522 [Accessed 2013-05-15].

ISO 2011. International Organization for Standardization. ISO 24442. Cosmetics – Sun protection test methods – In vivo determination of sunscreen UVA protection. URL: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46521 [Accessed 2013-05-15].

ISO 2010. International Organization for Standardization. ISO 24444. Cosmetics --Sun protection test methods – In vivo determination of the sun protection factor (SPF). URL: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46523 [Accessed 2013-05-15].

Merck Index 2006: O'Neil M.J., Heckelman P.E., Koch C.B., Roman K.J., editors. The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals; Fourteenth Edition. Merck Research Laboratories, Merck & Co., Inc. Whitehouse Station, NJ, USA.

Shaath N.A., ed. 2005. Sunscreens: Regulations and Commercial Development. 3rd edition. White Plains (NY): Taylor & Francis Group.

TGA 2012. Department of Health and Ageing, Therapeutic Goods Administration: Australian Government. Australian regulatory guidelines for sunscreens. URL: <http://www.tga.gov.au/industry/sunscreens-args.htm> [Accessed 2013-05-16].

USP 34: United States Pharmacopeia - National Formulary (USP 34 - NF 29). Rockville (MD): The United States Pharmacopeial Convention; 2011.

US FDA 2012. Department of Health and Human Services. Guidance for Industry: Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use – Small Entity Compliance Guide. URL: <http://www.regulations.gov/#!documentDetail;D=FDA-2012-D-1086-0002> [Accessed 2013-05-15].

US FDA 2011a. Department of Health and Human Services: Food and Drug Administration. Sunscreen Drug Products for Over-the-Counter Human Use; Request for Data and Information Regarding Dosage Forms. 21 CFR Part 352 [Docket No. FDA-1978-N-0018; formerly Docket No. 1978N-0038]. Federal Register / Vol 76, No. 117 / Friday, June 17, 2011 / Proposed Rules. URL: <http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0697> [Accessed 2013-05-15].

US FDA 2010. Department of Health and Human Services: Food and Drug Administration. Drometrizole Trisiloxane Eligibility for Potential Inclusion in Sunscreen Monograph; Over-the-Counter Sunscreen Drug Products for Human Use; Request for Safety, Effectiveness, and Environmental Data. [Docket No. FDA-2003-N-0196] (formerly Docket No. 2003N-0233). Notice of eligibility; request for data and information. Federal Register / Vol. 75, No. 105 / Wednesday, June 2, 2010 / Notices. URL: <http://www.regulations.gov/#!documentDetail;D=FDA-2003-N-0196-0023> [Accessed 2013-05-15].

US FDA 2006. Center for Drug Evaluation and Research. CDER Data Standards Manual Definitions for Topical Dosage Forms. URL: <http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4241B1-02-30-FDA-Topical%20Dosage%20Forms%20Definitions%20Old%20%20.pdf> [Accessed 2013-05-15].

US FDA 1999. Department of Health and Human Services: Food and Drug Administration. Sunscreen Drug Products For Over-The-Counter Human Use; Final Monograph. 21 CFR Parts 310, 352, 700 and 740 [Docket No. 78N-0038] RIN 09-AA01; Final Rule.

Wang S.Q., Balagula Y., Osterwalder U. 2010. Photoprotection: a review of the current and future technologies. *Dermatologic Therapy* 23(1):31–47.

11 REFERENCES REVIEWED

Beasley D.G., Meyer T.A. 2010. Characterization of the UVA protection provided by avobenzone, zinc oxide, and titanium dioxide in broad-spectrum sunscreen products. *American Journal of Clinical Dermatology* 11(6):413-421.

Canadian Cancer Society 2013. Sun and UV. URL: <http://www.cancer.ca/en/prevention-and-screening/live-well/sun-and-uv/?region=on> [Accessed 2013-05-15].

Canadian Dermatology Association 2013. Sun Safety. URL: <http://www.dermatology.ca/skin-hair-nails/skin/sun-safety/> [Accessed 2013-05-16].

Colipa 2006. Cosmetics Europe: the Personal Care Association. International Sun Protection Factor (SPF) Test Method. URL: <https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=21%3Ainternational-sun-protection-factor-spf-test-method-2006-cd-rom-included&catid=46%3Aguidelines> [Accessed 2013-05-15].

Couteau C., Chammas R., Alami-El Boury S., Choquenot B., Papis E., Coiffard L.J. 2008 Combination of UVA-filters and UVB-filters or inorganic UV filters-Influence on the sun protection factor (SPF) and the PF-UVA determined by in vitro method. *Journal of Dermatological Science* 50(2):159-161.

Diffey B.L. 2001. When should sunscreen be reapplied? *Journal of the American Academy of Dermatology* 45(6):882-885.

El-Boury S., Couteau C., Boulande L., Papis E., Coiffard L.J.M. 2007. Effect of the combination of organic and inorganic filters on the Sun Protection Factor (SPF) determined by *in vitro* method. *International Journal of Pharmaceutics* 340:1-5.

European Union 2006. Commission recommendation of 22 September 2006 on the efficacy of sunscreen products and the claims made relating thereto. *Official Journal of the European Union* L 265/39.

International Agency for Research on Cancer. IARC Handbooks of Cancer Prevention: Sunscreens (Volume 5). World Health Organization, Lyon 2001.

JCIA 1995. Japan Cosmetic Industry Association Measurement Standard for UVA Protection Efficacy. Appendix 3: JCIA/Persistent Pigment Darkening Protocol. URL: http://www.fda.gov/ohrms/dockets/dailys/00/Sep00/090600/c000565_appendix_03.pdf [Accessed 2013-05-16].

Nash JF, Tanner PR, Matts PJ. Ultraviolet A radiation: testing and labeling for sunscreen products. *Dermatologic Clinics* 2006; 24:63-74.

TGA 2010. Department of Health and Ageing, Therapeutic Goods Administration: Australian Government. Proposed Revisions to Chapter 10 'Sunscreens' in the *Australian Regulatory Guidelines for OTC Medicines* (ARGOM). URL: <http://www.tga.gov.au/pdf/archive/consult-otc-argom-sunscreens-100505.pdf> [Accessed 2013-05-16].

US FDA 2011b. Department of Health and Human Services: Food and Drug Administration. Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use. 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018] (Formerly Docket No. 1978N-0038) RIN 0910-AF43. Final Rule. Federal Register / Vol. 76, No. 117 / Friday, June 17, 2011 / Rules and Regulations 35620-35665. URL: <http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0698> [Accessed 2013-05-15].

US FDA 2007. Department of Health and Human Services: Food and Drug Administration. Sunscreen Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph. 21 CFR Parts 347 and 352 [Docket No. 1978N-0038] (formerly Docket No. 78N-0038) RIN 0910-AF43. Proposed Rule. URL: <http://www.fda.gov/OHRMS/DOCKETS/98fr/cd031.pdf> [Accessed 2013-05-15].

US FDA 1993. Department of Health and Human Services: Food and Drug Administration. Sunscreen Drug Products for Over-the-Counter Human Use; Tentative Final Monograph. 21 CFR Parts 352, 700, and 740 [Docket No. 78N-0038] RIN 0905-AA06. Notice of proposed rulemaking. URL: <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm090174.pdf> [Accessed 2013-05-16].

World Health Organization 2013. Ultraviolet radiation and the INTERSUN Programme. URL: http://www.who.int/uv/sun_protection/en/ [Accessed 2013-05-16].

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 tan²⁵;
- 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.); and/or
- 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.

²⁵ Sunless tanners containing skin dyes (for example, dehydroxyacetone) are permitted.

APPENDIX 2: Optional Label-related Information

Additional optional use(s) or purpose(s):

Statement(s) to the effect of²⁶:

- Sunscreen;
- Sunburn protectant;
- Helps protects from sunburn;

For products with a critical wavelength of ≥ 370 nm:

- Filters/screens UVA/UVB rays; and/or
- Absorbs throughout the UVA/UVB spectrum to provide sunburn protection.

The following claims may be used on the product label provided that there is scientific product-specific data on file to support the claim:

Statement(s) to the effect of:

- Hypoallergenic;
- For sensitive skin;
- Non-comedogenic (won't block pores);
- Non-acnegenic (will not cause or contribute to acne); and/or
- Non-irritating.

The following additional information may also be included on labelling:

- Logos from the Canadian Dermatology Association (CDA) may be used, provided that the license holder obtains a letter from the CDA accepting this representation;
- Other logos, such as the European Commission UVA logo, as long as all associated requirements for those logos, such as the UVA Protection Factor (UVAPF):SPF ratio $\geq 1:3$ ²⁷, are met; and/or
- Cosmetic claims that meet the requirements outlined in the Guidelines for Cosmetic Advertising and Labelling Claims²⁸.

²⁶ All iterations of the acceptable indications are referenced to Shaath 2005; APhA 2002.

²⁷ As determined using a standardized and reproducible method, such as the one referenced as ISO 1212, Colipa 2011, or ISO 2011.

²⁸ Health Canada 2006

APPENDIX 3: Labelling Requirements for Secondary Sunscreen Products

Secondary sunscreen products are products that are intended to be applied to the face or skin as makeup or skincare products which carry 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 full labelling requirements apply. Acceptable cosmetic claims can be found in Health Canada's *Guidelines for Cosmetic Advertising and Labelling Claims*.

Labelling requirements for secondary sunscreen products will be finalized and communicated at a later date.