Health Canada Santé Canada

DRAFT: GUIDANCE DOCUMENT
Sunscreen Monograph

Health Products and Food Branch

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Canada

Health Canada Santé Canada

Health Canada is pleased to announce the release of the revised *Sunburn Protectants Monograph* for stakeholder consultation. The document is now titled "**Guidance Document *Sunscreen Monograph",*** to reflect the common Canadian term for this category of drugs.

This draft Monograph is intended to replace the existing *Sunburn Protectants Monograph* of October 12, 2006. The proposed Monograph applies to drugs subject to the *Food and Drug Regulations* administered by the Therapeutic Products Directorate (TPD) and natural health products subject to the *Natural Health Product Regulations* administered by the Natural Health Products Directorate (NHPD). It identifies the permitted ingredients, doses, directions and indications for use for these products, which will be required to appear on the product labels as well as the recommended supporting test methods.

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.

"Our mission is to help the people of Canada maintain and improve their health, while respecting individual choices and circumstances." *Health Canada*	HPFB's Mandate is to take an integrated approach to managing the health-related risks and benefits of health products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

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FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. Guidance documents also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. Alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents.

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1 INTRODUCTION

This monograph describes the requirements necessary to receive marketing authorization, that is (i.e.) a Drug Identification Number (DIN) or a Natural Product Number (NPN), for topical sunscreen products generally regarded as safe and effective, without additional supporting scientific data. Sunscreens may include products for use only as sunscreens and products which provide sun protection in addition to a cosmetic attribute. Products which do not meet the criteria outlined in this document should apply outside of the monograph stream.

Sunscreens are classified as natural health products (NHPs) if they contain ingredients from Table 1. Applicants applying for a natural product number (NPN) can access the appropriate forms and guidance at: http://www.hc-sc.gc.ca/dhp-mps/prodnatur/applications/licen-prod/form/index_e.html [Accessed 2012-09-10].

Sunscreens are classified as drugs if they contain at least one ingredient from Table 2. Applicants applying for a DIN can access the appropriate forms and templates at: http://hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/index_e.html [Accessed 2012-09-10].

The requirements set forth in this guidance align with the United States Food and Drug Administration *Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule* (2011). As such, sunscreens meeting the requirements established by the US FDA Final Rule are also meeting the requirements outlined in this monograph.

2 DEFINITIONS AND ACRONYMS

Sunscreens: Products that are intended to provide protection against sunburn and Ultraviolet (UV) rays. Sunscreen products are classified as drugs and must meet the requirements set out in Canada's *Food and Drugs Act* before they may be imported, advertised, or sold in Canada.

Note: Sunscreens include products intended to be applied to the face or skin as makeup or some skincare products which also carry sunscreen claims. These may be foundations (in any form), facial moisturizers, lipsticks, lip gloss, makeup powder, and skin moisturizers (as long as it is clear that there is a primary moisturizing purpose).These do not include eye shadows (due to safety concerns regarding application to the area around the eye), or any product without an explicit primary cosmetic function included on the inner and outer panels of labelling. Acceptable cosmetic claims can be found in Health Canada's *Guidelines for Cosmetic Advertising and Labelling Claims*.

Broad Spectrum: A critical wavelength of at least 370 nanometers (nm).

Ultraviolet A (UVA): Ultraviolet sun radiation in the spectrum of 320-400 nm; also referred to as "longer" rays. The UVA waveband has been further

	subdivided into UVA II (320-340 nm) and UVA I (340-400 nm)[1]. UVA rays are the principle cause of long term skin damage due to sun but may also contribute to sunburn.
Ultraviolet B (UVB):	Ultraviolet sun radiation in the spectrum of 290-320 nm; also referred to as "shorter" rays. UVB rays are the principle cause of sunburn due to sun exposure.
SPF:	Sun Protection Factor[2]

[1] Beasley et al. 2010; Wang et al. 2010; Nash et al. 2006

[2] Sun Protection Factor (SPF) only communicates the level of UVB protection

3 MEDICINAL INGREDIENTS

3.1 Formulation

In order to provide adequate protection from UV rays, all broad spectrum sunscreen products are required to[3]:

1. Contain both a recognized UVA and a UVB absorber;
2. Have a minimum of Sun Protection Factor (SPF) 15;
3. Have a critical wavelength protection of at least 370 nm[4]

3.1.1 UVA: UVB Optional Ratio Formulation

Sunscreen products may provide a UVA: UVB ratio labelling claim of not less than 1:3[5].

3.2 Monograph Ingredients[6]

Table 1: Natural Health Products Medicinal Ingredients, Source Materials and Concentrations[7]

Medicinal ingredient name	UV protection[8]	Source material[1]	Quantity
Titanium dioxide (TiO_2)	UVA II UVB	Titanium dioxide CAS No. 13463-67-7	≤ 25%
Zinc oxide (ZnO)	UVA I UVA II UVB	Zinc oxide CAS No. 1314-13-2	≤ 25%
Para-aminobenzoic acid	UVB	Para-aminobenzoic acid CAS No. 150-13-0	≤ 15%

1. The chemical abstracts service (CAS) number may be provided as additional information.

Table 2: Drug Medicinal Ingredients and Concentration (Monograph Ingredients)

Medicinal ingredient preferred name	Synonyms and other recognized names	UV protection	Quantity
Avobenzone	Butyl methoxydibenzoylmethane	UVA I UVB	≤ 3%
Ensulizole	2-Phenylbenzimidazole-5-sulfonic acid	UVB	≤ 4%

3 See Appendix 2 for further details.
4 Nash et al. 2006
5 Colipa, June 2009; United States Food and Drug Administration (US FDA) 2011
6 If the proposed sunscreen contains an ingredient (whether listed in the application as an active or as non-medicinal ingredient) which provides protection from UV ray exposure and/or treats skin damage resulting from UV ray exposure, then the product will be considered to fall outside the scope of this Monograph.
7 Merck 2012; United States Pharmacopeia (USP) 35; CTFA 2008; Ph.Eur. 2012
8 Wang et al. 2010; El-Boury et al. 2007

Medicinal ingredient preferred name	Synonyms and other recognized names	UV protection	Quantity
Homosalate	Homomenthylsalicylat	UVB	≤ 15%
Meradimate	Menthyl 2-minobenzoate menthylanthranilate	UVA II	≤ 5%
Octinoxate	2-Ethylhexyl methoxycinnamate octylmethoxycinnamate	UVB	≤ 7.5%
Octisalate	2-Ethylhexyl salicylate octyl salicylate	UVB	≤ 5%
Octocrylene	2-Ethylhexyl-2-cyano-3,3 diphenylacrylate	UVA II UVB	≤ 10%
Oxybenzone	Benzophenone-3 2-Hydroxy-4-methoxybenzophenone	UVA II UVB	≤ 6%
Sulisobenzone	Benzophenone-4	UVA II UVB	≤ 10%
Drometrizoletrisiloxane	Mexoryl XL	UVA UVB	≤ 15%
Enzacamene	4-Methylbenzylidene camphor	UVB	≤ 6%
Padimate-O	Octyl dimethyl PABA σ-PABA	UVB	≤ 8%
Terephthalylidene dicamphor sulfonic acid	Mexoryl SX 3,3'-(1,4-Phenylenedimethylidene) bis[7,7-dimethyl-2-oxobicylclo[2.2.1] hept-1-yl methanesulfonic acid)	UVA UVB	≤ 10%
Cinoxate	2-Ethoxyethyl 3-(4-methoxyphenyl) propenoate	UVA	≤ 3%
Diethanolamine-methoxycinnamate		UVB	≤ 10%
Dioxybenzone	Benzophenone-8 (2-Hydroxy-4-methoxyphenyl)-(2-hydroxyphenyl) methanone	UVA UVB	≤ 3%
Triethanolamine salicylate	Trolamine salicylate	UVB	≤ 12%

3.3 Nano Zinc Oxide and/ or Nano Titanium Dioxide

Certain ingredients that are formulated as nano size, such as titanium dioxide and/or zinc oxide are acceptable ingredients. Refer to Section 10.2.1.

4 ROUTE(S) OF ADMINISTRATION

Topical

5 DOSAGE FORM(S)

5.1 Acceptable Dosage Forms

Balm, cream, emulsion, gel, lotion, mousse, oil, ointment, powders, paste, spray [including non-pressurized sprays, continuous (bag-on-valve) sprays, and aerosol [non-chlorofluorocarbons (CFC) based sprays],[9] stick, and suspension.

5.2 Unacceptable Dosage Forms

The following forms require review outside of the monograph (including but not limited to):

Aerosols containing chlorofluorocarbons (CFCs), shampoos, soaps, shower gels, sustained-release products, washes, wipes, and any non-topical delivery system.

The use of the generic form "Liquid" is also not acceptable. As sunscreens are mixtures of substances not in pure form, a more accurate dosage form should be employed to communicate the finished product delivered at time of use.[12]

6 INDICATIONS

6.1 Acceptable Indications[10]

6.1.1 Required Use(s) or Purpose(s)[11]

For all Products

The principal display panel should clearly communicate the following information:

- Sun Protection Factor "X", or SPF "X";
- For broad spectrum products, SPF "X", or SPF $\geq$ 15;

All sunscreens providing broad spectrum protection with a SPF value ≥ 15, may use the following statement verbatim and bolded:

"**The sun may cause sunburn, premature aging of the skin and skin cancer. Avoiding the sun, wearing protective clothing and regular use of sunscreens over**

[9] Spray dosage forms must be accompanied by a further qualifier of the delivered dosage form, e.g. lotion, cream, powder, etc.

[10] Refer to Appendix 1 for the product's UVA and UVB protection characteristics

[11] These statements must appear together and prominently on the principle display panel of all labelling.

the years reduces the chance of these harmful effects."[Adapted from the Canadian Cancer Society (2010) and the Canadian Dermatology Association (2011)].

The sun alert statement may not be broken down, displayed on separate locations on the labelling material and no substitution of words or phrases are permitted. This statement may not include a reference to the name of the product.

Notes

- SPF values greater than 50 are to be declared as SPF 50+
- Sun Protection Measures (optional): statement to the effect of[12]
  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.
  - wear long-sleeved shirts, pants, hats, and sunglasses.

  Optional:
  - Watch for the UV index
  - Use shade wisely

Sunscreens without broad spectrum protection or sunscreens with SPF value of < 15, must use the following statement verbatim:

"**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."

6.1.2 Additional Use(s) or Purpose(s)

Statement(s) to the effect of:[13]

- Sunburn protectant; helps prevent or protects from sunburn;
- Sunscreen;
- Filters/screens harmful UVA/UVB rays;
- Absorbs throughout the UVA/UVB spectrum to provide sunburn protection.

6.1.3 Other Product-Related Label Claims[14]

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

- Hypoallergenic;
- For sensitive skin;
- Non-comedogenic (won't block pores);

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[12] Alternative statements can be used such as those included in the *Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule* (2011).

[13] All iterations of the acceptable indications are referenced to Shaath 2005; APhA 2002.

[14] This information applies to the premarket assessment of drug products only, as the Natural Health Products Directorate requires that manufacturers are solely responsible for non-sunscreen claims.

- Paediatrician tested/recommended, dermatologist tested/recommended; "Water resistant" / "Sweat resistant" as long as testing has been performed according to the efficacy testing recommendations outlined in Section 11: Efficacy Test 286 Methods.

The following additional information may also be included on labelling:

- Logos from the Canadian Dermatology Association (CDA) may be used, provided that the application for a DIN or NPN is accompanied by a letter from the CDA accepting this representation.[15]
- For acceptability of cosmetic claims, please refer to the *Guidelines for Cosmetic Advertising and Labelling Claims*.

6.2 Unacceptable Indications

6.2.1 Unacceptable Use(s) or Purpose(s) which are misleading or counterintuitive to the safety and efficacy of sunscreen use

- Statements 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;[16]
- 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;
- Sunscreens with insect repellents.[17]
- A "+" ("plus") indication next to the SPF value, with the exception of SPF 50+.

6.2.2 Unacceptable Use(s) or Purpose(s) which require assessment of supporting scientific data outside of the monograph[18]

- Sustained-release;
- Sustained action/long-lasting (i.e. longer than 2 hours or longer than 80 minutes in water);
- Products for bald adult scalps
- Non-acnegenic (will not cause or contribute to acne);
- Non-irritating;
- Representation for the prevention of cancer (only the complete Sun Alert statement may be used);

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[15] Only logos from the Canadian Dermatology Association are acceptable. Any other logo would need to be considered for its acceptability in context outside of the Monograph stream.

[16] Sunless tanners containing skin dyes (for example. dehydroxyacetone) are permitted

[17] As the frequency of use and required dosage are contradictory for the safe use of such combinations, insect repellents and sunscreens may not be combined either as Monograph applications or outside of the Monograph.

[18] This list is not considered to be exhaustive as other innovative claims may be subject to review outside of the monograph.

- 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;
- Claims that the product can be applied directly to wet or sweaty skin;
- Claims that the product offers instant protection or protection immediately upon application.

7 DOSAGE DIRECTIONS

7.1 Dose(s)

Subpopulation

- **For sunscreens providing broad spectrum protection with a SPF value ≥ 15**: Adults and children older than 6 months of age.

Concentration: See Tables 1 and 2.

7.2 Permitted Combinations

Titanium dioxide (TiO_2) reflects short UVA range (320-340 nm), which is referred to as UVA-2 (or UVA-II), and UVB.[19] As this range of protection does not meet the critical wavelength requirement of at least 370 nm if used as a single medicinal ingredient, it must always be used in combination with other acceptable sunscreen medicinal ingredients to meet the broad spectrum requirement of this monograph. See examples of combinations of NHPs in Table 3.

Zinc oxide (ZnO) reflects both short (320-340 nm, UVA-II) and long (340-400 nm, UVA-I) UVA radiation as well as UVB; however, ZnO at 25% provides a maximum of SPF 7 as a single ingredient.[20] As this ingredient would not meet the minimum SPF value of SPF 15 if used as a single medicinal ingredient, it must always be used in combination with other medicinal ingredients. See examples of combinations of NHPs in Table 3.

Table 3: Combination of Natural Health Product Ingredients and their SPF Values

Concentration	Sun Protection Factor (SPF)		
	Titanium dioxide	Zinc oxide	Total
10%	13[1]	3[1]	16
25%	38[2]	7[2]	45

1. Couteau et al. 2008
2. El Boury et al. 2007

[19] Beasley and Meyer 2010; El Boury et al. 2007
[20] El Boury et al. 2007

Any combination of the ingredients listed in Table 1 and 2 is permitted in which case the product will be considered a drug. Combinations with active ingredients not included in this monograph will not be considered monograph applications.

The upper limit for use as a single ingredient also applies when the ingredient is used in combinations.

7.3 Directions for Use[21]

Statement(s) to the effect of[22]:

7.3.1 For Sunscreen Products with broad spectrum protection and SPF≥ 15

Adults and children > 6 months old:

- Apply generously 15 minutes prior to sun exposure.
- For non-water resistant products only:

  Reapply every 2 hours or after swimming, towel drying, perspiring heavily, washing, or in the case of products applied to the lips, after eating or drinking.

- For "water resistant" or "sweat resistant" products only[23]:

  Reapply at least every 2 hours **or** [insert 40/80 minutes as appropriate] after swimming or perspiring heavily **or** immediately after towel drying or washing,

- In the case of products applied to the lips:

  Reapply after eating or drinking.

7.3.2 For Sunscreen Products that are not broad spectrum or with SPF< 15

- Apply 15 minutes prior to sun exposure; and either:
  - Reapply every 2 hours for sun protection; OR
  - Sun protection lasts for up to 2 hours unless rubbed off.

7.3.3 For all Spray Products (Aerosol and Non-aerosol)

- Do not spray directly onto the face. Spray into hands, and apply to the face. Rub into skin.

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[21] Diffey 2001; United States Food and Drug Administration (US FDA) 1999, 2006 and 2007.

[22] Alternative statements can be used such as those included in the Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule (2011).

[23] Water resistance testing indicates that the product will retain its efficacy for longer than a regular sunscreen under these conditions, but still for less than 2 hours. Note that washing is still included as the physical friction of washing and the use of cleansing agents may remove the product. Water resistance testing is insufficient to demonstrate otherwise.

7.4 Duration of Use

No additional statement is required.

8 CAUTIONS AND WARNINGS

8.1 For all Sunscreens

- Stop use and ask a doctor if rash occurs.
- Do not use on broken or damaged skin.
- When using this product keep out of eyes. Rinse with water to remove.
- For external use only.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.
- Children under 6 months: Ask a doctor.
- For spray products only: Avoid inhaling, using in an enclosed space or exposing others to spray.

8.2 For all Sunscreens with Alpha-Hydroxy Acids (AHAs) and/or Retinol

For all products containing the non-medicinal ingredient(s) alpha-hydroxy acids (AHA), such as glycolic acid and lactic acid[24], at concentrations ranging from 3-1 % and/or retinol (or its acceptable derivatives, such as retinal acetate and retinal palmitate) at concentrations ranging from 0.1-1.0%:

> "This product contains [*insert as appropriate:* an alpha-hydroxy acid (AHA) and/or retinol] that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Please limit sun exposure while using this product and for a week afterwards."

9 LABELLING

9.1 Drug Product Labelling

All drug products are subject to labelling requirements outlined in the *Food and Drugs Act*[25] and the *Food and Drug Regulations*[26](including but not limited to C.01.004, C.01.005, etc.). See Appendix 3 for some detailed examples.

Legibility of Labels:

Although no specific type size is mentioned in the *Regulations*, Section A.01.016 specifies that all information required to appear on a label must be:

- Clearly and prominently displayed; and

[24] Health Canada 2012, List of Prohibited and Restricted Cosmetic Ingredients (Cosmetic Ingredient Hotlist)
[25] Justice Canada 2008
[26] Justice Canada 2011

- Readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

A person with normal vision, or those with corrective glasses that restore normal vision, should be able to read the information without straining. The colour, contrast, the position, and the spacing of the information are all to be taken into consideration in complying with these requirements. A type size of 10 point for text and 9 point minimum for tables are recommended for any sunscreen product package inserts, in keeping with section 2.2 of Health Canada's *Guidance to Industry: Product Monograph*. It is recommended that sunscreen product labels have a minimum of font size 9.

9.2 Natural Health Products Labelling

All NHPs are subject to labelling requirements outlined in the *Natural Health Product Regulations* (including but not limited to sections 86(1) to 97).

10 SPECIFICATIONS

This monograph describes those requirements that are specific to this class of drugs and to NHPs. Note that requirements described in the *Food and Drug Regulations* or the *Natural Health Products Regulations* (as applicable) must be met.

10.1 General Specifications

For products containing Table 1 medicinal ingredients only:

The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.

The medicinal ingredients from Table 1 may comply with the specifications outlined in the appropriate monograph from the following *Food and Drugs Act*, Schedule B list of standards:

- Pharmacopée française;
- Pharmacopoeia Internationalis;
- The British Pharmacopoeia;
- The Canadian Formulary;
- The European Pharmacopoeia;
- The National Formulary;
- The Pharmaceutical Codex: Principles and Practices of Pharmaceuticals;
- The United States Pharmacopeia.

For products containing Table 2 medicinal ingredients:

All ingredient (medicinal and non-medicinal) and finished product specifications should, as a minimum, meet the standards described in the publications referred to in Schedule B of the *Food and Drugs Act*, or equivalent standards. Where no Schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form.

In the absence of a Schedule B standard for any dosage form, testing must be adequate to demonstrate the product's identity, potency, purity and quality.

Manufacturers are reminded that sunscreens, like all drugs, are subject to Division 1A and 2 of the *Food and Drug Regulations,* so must ensure that their products are safe, effective, and of high quality. Further, all products must have established stability and are required to display the lot number and expiry date on packaging (C.01.004).

10.2 Manufacturing Process

Any change to the manufacturing process, requires supporting data concerning the manufacturing information, specification and the identity that will be submitted outside the monograph. This applies to both active and non-medicinal ingredients, in terms of the final finished formulation.

10.2.1 Nano Zinc Oxide and/ or Titanium Dioxide

Nanomaterials vary widely in composition, morphology, and other characteristics and cannot be considered a uniform group of substances. These substances may have physical, chemical, or biological properties that are different from those of their larger counterparts.

Nanomaterials and nano-enabled products continue to enter the Canadian marketplace in a variety of health products and food. Examples of current nanotechnology applications include food packaging, diagnostics and therapeutic products. While recognizing the potential health benefits of nanomaterials, it is important to ensure they are used safely and that their potential risks to the environment and human health are well understood and managed.

Therefore, licence holders are expected to continue monitoring and collecting new safety data as it emerges.

Applicants are required to keep information for record-keeping purposes when nano zinc oxide and/or nano titanium dioxide are used in sunscreen products. This information is required to be made available upon request. See Appendix 4 for a listing of the supplementary information related to nano ZnO and nano TiO_2.

11 EFFICACY TEST METHODS

The recommended testing outlined in this section is expected to be performed on the finished formulation for each product.

11.1 Sun Protection Factor (SPF) Testing

The degree of SPF protection should be measured using standardised, reproducible testing methods. Health Canada will accept SPF testing performed using any of the following *in vitro* or *in vivo* test methods:

a) United States FDA. Department of Health and Human Services: Food and Drug Administration. Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule. 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018] Federal Register /Vol. 76, No. 117 / Friday, June 17, 2011/Rules and Regulations 35661-35664. Available from: http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0698 [Accessed 2012-09-10]

OR

b) International Organization for Standardization. Cosmetics- Sun Protection test methods -In vivo determination of the sun protection factor (SPF) ISO 24444:2010. Geneva, 2010.[27]. Available from: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=46523 [Accessed 2012-09-10]

To ensure that at least 95% confidence that a sunscreen has a true SPF equal to or greater than that claimed on the label and that any potential retesting of the formulation will not yield a mean SPF lower than that claimed on the label, it is recommended that the claimed SPF should be calculated as recommended in the United States FDA method, regardless of the employed testing protocol.

Values obtained from SPF testing may be rounded down if so desired by a manufacturer. However the converse does not hold true and SPF values may not be rounded up, as this misrepresents the level of protection offered by a sunscreen.

11.2 Critical Wavelength Testing

The degree of UVA protection should be measured using standardised, reproducible testing methods. Health Canada will accept the critical wavelength testing performed using any of the following test methods:

11.2.1 In Vitro Critical Wavelength Assessment/ In vitro Method for the Determination for the UVA Protection Factor

In order to establish that the product has met the 370nm critical wavelength to establish the breadth of protection offered by a given product, the following test methods may be used:

a) Colipa. The European Cosmetics Association. *In vitro* method for the determination for the UVA protection factor and "critical wavelength" values of sunscreen products. Guideline, Prepared by the COLIPA *In vitro* UV Protection Method Task Force, June 2009.

OR

[27] Until the ISO document is final, testing according to the *International Sun Protection Factor Test Method* (2006) will be acceptable.

b) Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule. 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018] Federal Register /Vol. 76, No. 117 / Friday, June 17, 2011/Rules and Regulations 35664-35665. (Critical Wavelength only)Available from: http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0698 [Accessed 10-09-2012]

11.2.2 In Vitro/In Vivo UVA Protection Measurement

In order to establish the magnitude of UVA protection offered by a given product, the following test methods may be used:

a) International Organization for Standardization. Cosmetics- Sun Protection test methods -*In vivo* determination of Sunscreen UVA Protection ISO 24442-2009. Geneva, December 2008;

OR

b) JCIA Japan Cosmetic Industry Association. Japan Cosmetic Industry Association Measurement Standards for UVA Protection Efficacy. Tokyo: November 15, 1995.[28]

11.3 UVA: UVB Protection Ratio Measurement

To establish that the product meets the optional claim for the ratio of UVA: UVB protection of 1:3, the following test method may be used:

Colipa.The European Cosmetics Association.In vitro method for the determination for the UVA protection factor and "critical wavelength" values of sunscreen products.Guideline, Prepared by the COLIPA In vitro UV Protection Method Task Force, June 2009.

11.4 Water and Sweat Resistance Testing

The terms "water resistant (40 minutes/ 80 minutes)", are acceptable provided data is available to show that the product meets the testing requirements for these terms outlined in the following documents:

a) United States FDA. Department of Health and Human Services: Food and Drug Administration. Labeling and Effectiveness Testing; Sunscreen Drug Products for Over-the-Counter Human Use: Final Rule. 21 CFR Parts 201 and 310 [Docket No. FDA-1978-N-0018] Federal Register /Vol. 76, No. 117 / Friday, June 17, 2011/Rules and Regulations 35664. Available from: http://www.regulations.gov/#!documentDetail;D=FDA-1978-N-0018-0698[29] [Accessed 10-09-2012]

OR

[28] Alternatively, the Japanese Cosmetic Industry Association (JCIA) PPD method as modified by the French health agency Agencefrançaise de sécurité sanitaire des produits de santé - Afssaps.

[29] Alternatively, the most recent United States Food and Drug Administration (US FDA) Monograph may be used.

b) Colipa. The European Cosmetic, Toiletry and Perfumery Association.Guidelines for Evaluating Sun Product Water Resistance. December 2005[30]

Similarly, products may carry a "sweat resistant" or "very sweat resistant" claim if the parameters for "water resistance" or "very water resistant" testing (respectively) have been met.

12 NON-MEDICINAL INGREDIENTS

12.1 For Drug Products

Non-medicinal ingredients: Nomenclature using recognized proper, common, or international names from a valid scientific reference may be used on drug packaging.

Non-medicinal ingredients must be restricted to those substances necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the bioavailability, therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives. Manufacturers are reminded that the presence of an ingredient in a published scientific reference [e.g. International Nomenclature of Cosmetic Ingredients (INCI) Dictionary] does not convey acceptability in a drug formulation, and should be relied on for nomenclature purposes only.

Ingredients of botanical origin added as non-medicinal ingredients must comply with the Drugs Directorate Policy, Herbs Used as Non-medicinal Ingredients in Non-prescription Drugs for Human Use[31].

All non-medicinal ingredients must also respect the limitations set out in the *Food and Drug Regulations*[32], the *Cosmetics Hotlist*[33] and the *New Drug List*[34]. Colourants are restricted to those outlined in Section C.01.040.2 of the *Food and Drug Regulations*[35] .

12.2 For Natural Health Products

For products containing Table 1 medicinal ingredients only:

Ingredients must be chosen from the current *Natural Health Product Ingredients Database* (NHPID)[36] and must meet the limitations outlined in that database.

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30 When this methodology is used the labelled Canadian Sun Protection Factor (SPF) value would be the SPF value of the final product formulation determined following immersion to ensure accuracy in labelling and consistency with other international test results.

31 Health Canada 1995

32 Justice Canada 2011

33 Health Canada 2011

34 Health Canada 1999

35 Justice Canada 2011

36 Health Canada 2007

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APPENDIX 1: UVA and UVB Protection Characteristics

Sunscreen products should be sufficiently effective against UVB and UVA radiation to ensure a high protection of public health. To this end, a sunscreen product should provide a minimum UVB and UVA protection.

An increased sun protection factor (i.e. mainly UVB protection) should include an increase in the UVA protection as well. Therefore, the protection against UVA and UVB radiation should be related. Scientific findings show that certain biological damage to the skin can be prevented and reduced if the ratio of the protection factor measured in the persistent pigment darkening test (i.e. addressing mainly UVA radiation) is at least 1/3 of the factor measured by the sun protection factor testing method (i.e. addressing mainly UVB radiation).

Moreover, in order to ensure abroad protection, dermatologists recommend a critical wavelength of at least 370 nm. As such, in order to ensure that sunscreens offer sufficient protection for the user, all sunscreens must adhere to the following:

Table 4: Sunscreen UVA and UVB Protection Characteristics*

Labelled Category	**Sun Protection Factor range** [UVB protection measurement]	**Recommended minimum UVA protection factor**	**Required minimum critical wavelength**
Medium protection	15-29.9	Not less than 1/3 of sun protection factor	370 nm
High protection	30-50		
Very high protection	SPF 50+ (plus)		

*All results are to be determined using the recommended test methods outlined in Section 11.

APPENDIX 2: Monograph Submission Disclosures

A. Drug Applications:

The following information must accompany the cover letter and other standard documentation provided with a Sunscreen Monograph Drug Submission Application (for a DIN):

1. The actual test value, and the test method used to determine the:

    a) SPF value;
    b) Critical wavelength.

2. If zinc oxide or titanium dioxide is used in the product, the trade name of the ingredient, and specification including the particle size distribution of the raw material.

3. If applicable, confirmation that data determined in accordance with the test methods outlined in this monograph is on file with the manufacturer to support any claim under Section 6.1.3

Note that the evidence provided as requested may be audited during the course of the monograph review. In the course of an audit of the file or product, Health Canada may request additional specific test data (adhering to the test recommendations specific in this monograph) in support of the application.

B. NHP Applications:

For a Natural Health Product Licence Application (for a NPN), by submitting a compendial application according to this monograph, the attestation covers the above noted points for drug applications in Appendix 2, Section A. Additional evidence or documentation does not need to be submitted, but must be made available to Health Canada upon request.

APPENDIX 3: Labelling

All drug products are subject to labelling requirements outlined in the *Food and Drugs Act* and the *Food and Drug Regulations* (Justice Canada 2008 and 2011) (including but not limited to C.01.004, C.01.005, etc.).

Manufacturers are reminded that drug labelling must include the following information in addition to the information outlined in this monograph:

- Brand name (note that the brand name must be continuous and uninterrupted by translation wherever it appears);
- Drug Identification Number (DIN);
- Lot #/expiry date;
- Storage conditions;
- Medicinal ingredient declaration;
- Non-medicinal ingredients;
- Proper or common name of the finished drug product (including delivered dosage form);
- Name and address of the Canadian DIN owner, **or** if the DIN owner is international, the name and address of the international DIN owner and the name and address of the Canadian distributor.
- Flammability warning, if applicable;
- Pressurized container warning, if applicable;
- Net quantity declaration.

Manufacturers of sunscreen products are reminded that small packaging labelling exemptions do not usually apply to products presented in > 5 millilitre volumes (as a rough guide).

APPENDIX 4: Supplementary Information Related to Nano ZnO and Nano TiO_2

The following information must be made available upon request:

1. Specification or Certificate of Analysis.
2. Elemental composition including:
   - Degree of purity
   - Any known impurities or additives
3. Surface chemistry, including:
   - Zeta potential/surface charge and surface coating
4. Morphology including:
   - Shape
   - Surface area
   - Surface topology
   - Crystallinity
5. Characterization of the nanomaterials used in the formulation:
   - Chemical name, e.g., zinc oxide
   - Commercial name (form), e.g., Z-Cote® HP1
   - Manufacturer name (source), e.g., BASF
   - Crystal structure
   - Primary particle size, e.g., 20 nm
   - Particle size distribution
   - Aggregation/ agglomeration characteristics
   - Solubility
   - Density
   - Stability