Primary Sunscreen Monograph

Primary Sunscreen Monograph Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 135 KB) Date 2022-11-25 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% Table 1 Footnotes Table 1 Footnote 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. Return to Table 1 footnote 1 referrer Table 1 Footnote 2 Ingredient must be pharmacopoeial grade (for a list of acceptable pharmacopoeial grades, see the Quality of Natural Health Products Guide). Return to Table 1 footnote 2 referrer Table 2 Footnote 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. Return to Table 1 footnote 3 referrer Table 1 Footnote 4 At least one of the following references was consulted for the dosage: TGA 2016; Wang et al. 2010; US FDA 1999. Return to Table 1 footnote 4 referrer 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)phenylmethanone 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-meth yl-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) Terephthalylidene-3,3'-dicamphor-10,10'-disulfonic acid Terephthalylidene dicamphor sulfonic acid Ecamsule Ecamsule UVA UVB ≤10% 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 acid, compd. with 2,2',2''-nitrilotris(ethanol) (1:1) Salicylic acid, compound with 2,2',2''-nitrilotriethanol (1:1) Triethanolamine salicylate Trolamine salicylate Trolamine salicylate UVB ≤12% Table 2 Footnotes Table 2 Footnote 1 Only permitted when combined with (an) ingredient(s) listed in Table 1 or 2. Return to Table 2 footnote 1 referrer Route 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. Direction(s) 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) *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. References 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. Krinsky DL, Ferreri SP, Hemstreet B, Hume AL, Newton GD, Rollins CJ, Tietze KJ, Handbook of Nonprescription Drugs: An interactive approach for Self-Care, 19 ième édition. Washington (DC): American Pharmaceutical Association; 2017 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]. https://www.cosmeticseurope.eu/files/7314/8613/0213/Method_in_vivo_SPF-UVA.pdf Colipa 2005. Cosmetics Europe: the Personal Care Association. Guidelines for Evaluating Sun Product Water Resistance. URL:https://www.cosmeticseurope.eu/files/7914/6407/7400/Guidelines_for_Evaluating_Sun_Product_Water_Resistance_-_2005.pdf Ferguson J., Dover J.S. editors. 2006. Photodermatology. Manson Publishing Ltd. London, UK. Health Canada 2011a. Policy Statement on Health Canada's Working Definition for Nanomaterial. https://www.canada.ca/en/health-canada/services/drugs-health-products/nanotechnology-based-health-products-food.html ISO 2012. International Organization for Standardization. ISO 24443. Determination of sunscreen UVA photoprotection in vitro. URL: https://www.iso.org/standard/46522.html ISO 2011. International Organization for

Standardization. ISO 24442. Cosmetics - Sun protection test methods - In vivo determination of sunscreen UVA protection. URL: https://www.iso.org/standard/46521.html ISO 2010. International Organization for Standardization. ISO 24444. Cosmetics --Sun protection test methods - In vivo determination of the sun protection factor (SPF). URL: https://www.iso.org/standard/46523.html Nikitakis J, Lange B, éditeurs. International Cosmetic Ingredient Dictionary and Handbook. 16th edition. Washington (DC): Cosmetic, Toiletry and Fragrance Association; 2016 O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals, 13th edition 2018. WhitehouseStation (NJ): Merck & Co., Inc. 2018 Shaath N.A., ed. 2005. Sunscreens: Regulations and Commercial Development. 3rd edition. White Plains (NY): Taylor & Francis Group. TGA 2016. Department of Health, Therapeutic Goods Administration: Australian regulatory guidelines for sunscreens https://www.tga.gov.au/publication/australian-regulatory-guidelines-sunscreens-args USP 41: United States Pharmacopeia and the National Formulary (USP 41/NF 36). Rockville (MD): The United States Pharmacopeial Convention, Inc.; 2018 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: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm330696.pdf 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. https://www.gpo.gov/fdsys/pkg/FR-2011-06-17/pdf/2011-14768.pdf 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 https://www.gpo.gov/fdsys/pkg/FR-2010-06-02/pdf/2010-13001.pdf US FDA 2006. Center for Drug Evaluation and Research. CDER Data Standards Manual Definitions for Topical Dosage Forms. URL: https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/ucm071122.pdf 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. 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. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

RISK INFORMATION

Caution(s) and warning(s) For all products: For external use onlyWhen using this productavoid contact with eyes. If contact occurs, rinse thoroughly with waterStop use and ask/consult a doctor/physician/health care practitioner/health care provider/health care professional ifrash 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 theGuidance Document: Labelling Requirements for Non-prescription Drugs. For products with a critical wavelength of < 370 nm or with SPF value of <15: Other warningsSkin 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 useon broken skin Known adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

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.

STORAGE CONDITION(S)

No statement required.

SPECIFICATIONS

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.

REFERENCES

Return to Table 1 footnote1referrer

er name(s)1	Common name(s)1	Source information1,2	UV Protection3	Quant
e ingredient(s)				
um dioxide	C.I. No. 77891Titanium dioxideTitanic anhydride	Titanium dioxide	UVAUVB	≤25%
xide	C.I. No. 77947Zinc oxide	Zinc oxide	UVAUVB	≤25%
1 FootnotesTable 1 Footnote 1At least one of the following references was consulted per proper name, common name and source information: O'Neil et al				

name(s)	Common name(s)	Source information	UV Protection	Qu
ngredient(s)				
-Butylphenyl)-3-(p-methoxyphenyl)-1,3-propanedione	Avobenzone1-[4-(1,1-Dimethylethyl)phenyl]-3-(4-methoxyphenyl)-1,3-propanedione	4-tert-Butyl-4'-methoxydibenzoylmethane	UVA	≤2
4-Methoxyphenyl)-1,3,5-triazine-2,4-diyl]bis[5-[(2-ethylhexyl)oxy]phenol)	Bemotrizinol	Bemotrizinol	UVAUVB	≤6
oxy-4-methoxyphenyl)phenylmethanone	Benzophenone-3Oxybenzone	Oxybenzone	UVA IIUVB	≤6
yl-5-methoxy-1-phenol-4-sulfonic acid	Benzophenone-4Sulisobenzone	Sulisobenzone	UVA IIUVB	≤1
oxy-4-methoxyphenyl)(2-hydroxyphenyl)methanone	Benzophenone-8,2'-Dihydroxy-4-methoxybenzophenone	Dioxybenzone	UVA IIUVB	≤3
hylenebis-(6-(2H-benzotriazol-2yl)-4-(1,1,3,3-tetramethylbutyl)-phenol)	Bisoctrizole	Bisoctrizole	UVAUVB	≤5
yethyl p-methoxycinnamate	3-(4-Methoxyphenyl)-2-propenoic acid 2-ethoxyethyl ester	Cinoxate	UVB	≤3
thoxyphenyl)-2-propenoic acid, compd. with 2,2'-iminobis[ethanol] (1:1)	DEA-Methoxycinnamate(E)-3-(4-Methoxyphenyl)-2-propenoic acid, compd. with 2,2'-iminodiethanol (1:1)	Diethanolamine methoxycinnamate	UVB	≤1
enzotriazol-2-yl)-4-methyl-6-(2-methyl-3-(1,3,3,3-tetramethyl-1-(trimethylsilyl)oxy-disiloxanyl)propyl)phenol	Drometrizole trisiloxane	Drometrizole trisiloxane	UVAUVB	≤15
3'E)-(p-Phenylenedimethylidyne)bis[2-oxo-10-bornanesulfonic acid]	Ecamsule3,3'-(1,4 Phenylenedimethylidene)bis(7,7-dimethyl-2-oxobicyclo[2.2.1]heptane-1- meth	Ecamsule	UVA IIUVB	≤1
l-1H-benzimidazole-5-sulphonic acid	2-Phenylbenzimidazole-5-sulfonic acid	Ensulizole	UVB	≤4
Methylbenzylidene)camphor	Enzacamene1,7,7-Trimethyl-3-[(4-methylphenyl)methylene]bicyclo[2.2.1]heptan-2-one	Enzacamene	UVB	≤4
xybenzoic acid 3,3,5-trimethylcyclohexyl ester	Homosalate3,3,5-Trimethylcyclohexyl salicylate	Homosalate	UVB	≤15
l-2-(1-methylethyl)cyclohexanol 2-aminobenzoate	Menthyl anthranilate2-Aminobenzoic acid menth-3-yl ester	Meradimate	UVA II	≤5
exyl p-methoxycinnamate	3-(4-Methoxyphenyl)-2-propenoic acid, 2-ethylhexyl ester	Octinoxate	UVB	≤7.
exyl salicylate	2-Hydroxybenzoic acid 2-ethylhexyl ester	Octisalate	UVB	≤5
-3,3-diphenyl-2-propenoic acid, 2-ethylhexyl ester	Octocrylene2-Ethylhexyl 2-cyano-3,3-diphenylacrylate	Octocrylene	UVA IIUVB	≤1
exyl p-(dimethylamino)benzoate	Padimate O4-(Dimethylamino)benzoic acid, 2-ethylhexyl ester	Padimate O	UVB	≤8
xybenzoic acid, compd. with 2,2',2''-nitrilotris[ethanol] (1:1)	Trolamine salicylateSalicylic acid, compound with 2,2',2''-nitrilotris[ethanol] (1:1)	Trolamine salicylate	UVB	≤12
FootnotesTable 2 Footnote 1Only permitted when combined with (an) ingredient(s) listed in Table 1 or 2.Return to Table 2 footnote1referrer				