

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 January 2006 (05.01.2006)

PCT

(10) International Publication Number
WO 2006/001940 A1

(51) International Patent Classification⁷: **A61K 7/42**, 7/40

(21) International Application Number:
PCT/US2005/017256

(22) International Filing Date: 18 May 2005 (18.05.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/579,735 14 June 2004 (14.06.2004) US

(71) Applicant (for all designated States except US): **SCHERING-PLOUGH HEALTHCARE PRODUCTS, INC.**
[US/US]; 3030 Jackson Avenue, Memphis, TN 38151 (US).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **FOWLER, Kevin, C.**
[US/US]; 1280 Locke-Cuba Road, Millington, TN 38053 (US).

(74) Agent: **LIPKA, Robert, J.**; Schering-Plough Corporation,
2000 Galloping Hill Road, Patent Dept. K-6-1- 1990, Kenilworth, NJ 07033-0530 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM,

AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NG, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

— as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

Published:

— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SKINCARE COMPOSITIONS

(57) Abstract: Disclosed are skin care compositions that are emulsion formulations comprising an aqueous phase, an oil phase, at least one emulsifier, and an Ethylenediamine/Neopentyl Glycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer water resistance forming agent.



WO 2006/001940 A1

SKINCARE COMPOSITIONS

BACKGROUND OF THE INVENTION

5 It is now generally recognized that exposure to solar radiation can have adverse health consequences, sometimes not appearing until several years following the exposure. Of course, the immediately appearing "sunburn" from an overexposure can itself be a serious acute health problem.

10 Many products are available to reduce the amount of solar ultraviolet radiation received by the skin during exposure to the sun's rays. Typical product formulations are lotions, creams, ointments or gels containing chemical and/or physical barriers to ultraviolet transmission. These vary considerably in their abilities to protect the skin against the physical and biochemical effects of ultraviolet radiation.

15 Earlier sunscreensing formulations were designed to protect against sunburn from a limited solar exposure period, while transmitting sufficient radiation to permit skin tanning. However, the current focus is on eliminating as much ultraviolet exposure as possible, it being recognized that skin tanning, while esthetically pleasing to some, is a clear indication of tissue damage from overexposure to solar radiation. It has been recently discovered
20 that any amount of unprotected exposure can potentially cause immune system suppression and lead to future health problems, such as skin carcinomas and other dermatological disorders.

The SPF (Sun Protection Factor) rating system has been developed to
25 provide consumer guidance in selecting suitable sunscreens for any given outdoor activity. In general, the SPF number approximately corresponds to the multiple of time during which the properly applied sunscreen will prevent obvious reddening of the skin, over the exposure time that causes unprotected skin to exhibit reddening. Thus, if an SPF 8 sunscreen
30 formulation has been properly applied, a person should be able to remain in the sun without visible effects for eight times the usual unprotected duration.

-2-

Of course, the duration of unprotected exposure which produces a visible effect on the skin varies from one individual to another, due to differences in their skin cells. Currently popular are high-SPF "sunblocker" products, having SPF values of at least 30.

5 Most of the commercially available sunscreen formulations are not well suited for use by those engaged in strenuous outdoor activities, such as construction work, gardening, athletic events and many others, due to the tendency for perspiration from the body to interact with the applied formulation. For example, perspiration, or moisture from other sources,
10 including rain, can cause sunscreen active ingredients and other irritating components of the formulation to enter the eyes and cause discomfort. It is also frequently detrimental, particularly in activities such as tennis or golf which require a reliable grip on equipment, to have an applied sunscreen formulation remain lubricious after application or become lubricious when
15 mixed with perspiration or other moisture.

 It is advantageous to have a suncare formulation that is waterproof. Waterproof formulations allow the user to engage in activities such as swimming while still being protected against ultraviolet radiation. Hydrophobic materials typically serve as waterproofing agents that impart film forming and waterproofing characteristics to an emulsion. However, there is still a need
20 for products having physical attributes that display improved waterproof performance, and that have a reduction in migration of the formulation across the formulation wearer's skin, as well as providing a limited slip grip performance attribute.

25 A sunscreen product which has been available for several years, but which does not exhibit disadvantages such as the foregoing, is sold by Schering-Plough HealthCare Products, Inc., Memphis, Tenn. U.S.A. as COPPERTONE™ SPORT™ SPF 30 lotion. This product contains the active ingredients octyl salicylate, octyl methoxycinnamate, homosalate and
30 oxybenzone, totaling 25.5 weight percent of the formulation, and is an oil-in-water emulsion formulated with 1.5 weight percent of a fumed silica having a hydrophobic surface treatment. It is thought that the silica serves to immobilize the active agents in the internal phase of the formulation and

-3-

inhibit their migration under the influence of skin oils and/or external moisture. The product also has a very desirable "dry" feel as it is being applied, quite unlike the very liquid nature of the usual lotion which does not contain particulate ingredients other than those approved for use as sunscreen active ingredients.

There is a need for products having physical and performance attributes as those of the Coppertone Sport SPF 30 product, but which have more predictable formulation behavior and stability.

SUMMARY OF THE INVENTION

Accordingly, there is disclosed an emulsion formulation for topical application to the skin comprising: an aqueous phase, an oil phase, at least one emulsifier, and an Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer.

There is also disclosed an emulsion formulation for topical application to the skin comprising: an aqueous phase, an oil phase, at least one emulsifier, Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer and at least one sunscreen active agent.

There is also disclosed an emulsion formulation for topical application to the skin comprising an aqueous phase, an oil phase, at least one emulsifier, Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer, and at least one insect repellent.

There is also disclosed an emulsion formulation for topical application to the skin comprising an aqueous phase, an oil phase, at least one emulsifier, Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer, at least one sunscreen active agent and an insect repellent.

There is also disclosed an emulsion formulation for topical application to the skin comprising: an aqueous phase, an oil phase, at least one emulsifier, and an Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer and at least one skin protectant.

There is also disclosed an emulsion formulation for topical application to the skin comprising: an aqueous phase, an oil phase, at least one

emulsifier, and an Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer, at least one sunscreen active agent and at least one skin protectant.

5

DETAILED DESCRIPTION OF THE INVENTION

Names given to chemical substances herein generally are either accepted chemical names, or are trade organization or regulatory agency approved names such as CTFA Adopted Names as listed in J. A. Wenninger et al., Eds., CTFA International Cosmetic Ingredient Dictionary, Eighth Ed.,
10 The Cosmetic, Toiletry and Fragrance Association, Washington, D.C., 2000.

The term "percent by weight" as used herein means the percent by weight of the ingredient per weight of the overall formulation.

Suitable water proofing agents for use in the present invention include a material that is a dimerized C₁₈ polyamide resin. The INCI name for this
15 material is Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer. The polyamide resin described herein results in formulas with a drier, more esthetically pleasing skin feel. In addition, formulas containing this material are not slippery on the hand, allowing a surer hand grip for the user. Unlike many other polyamide resins, this material has
20 a softening point below 80 degrees Celsius which is an added convenience in formulating because the addition of the waterproofing agent allows the formulation to be formulated at lower temperatures and thus is more convenient. Another advantage of this ingredient is that it does not thicken formulas to the same degree as many other water resistance imparting
25 agents, thus allowing more flexibility in viscosity control. Moreover, the use of this ingredient results in a composition that provides a degree of immediate water-proofing capability and thus obviates a waiting period before entering the water that is recommended with the use of conventional water-proof compositions. The material has been incorporated into an emulsion
30 sunscreen composition and has been found to form a film which is substantive under running water. This water-proofing agent is sold under the trade name "Sylvaclear® C75V" and is available commercially from the Arizona Chemical Company of Lakeland, Florida. It may reportedly be prepared according to

-5-

the procedures set forth in U.S. Patent No. 6,552,160, which is hereby incorporated by reference in its entirety.

The Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer may be present in an amount of about 0.05 percent to about 20 percent by weight, preferably about 1 percent to about 5 percent by weight, most preferably about 1 or 2 percent by weight.

The term "emulsion" shall be used herein to identify oil-in-water (o/w) or water-in-oil (w/o) type dispersion formulations intended for application to the skin, particularly lotions and creams providing cosmetic or therapeutic benefits. The emulsions may contain any of a number of desired "active" ingredients, including skin colorants, drug substances (such as anti-inflammatory agents, antibiotics, topical anesthetics, antimycotics, keratolytics, etc.), skin protectants or conditioners, humectants, ultraviolet radiation absorbers, sunless tanning agents and the like, anti-oxidants, anti-aging agents, skin lightening agents, and insect repellants, depending on the intended uses for the formulations.

Techniques for forming o/w and w/o emulsions are very well known in the art. The present invention is not dependent upon any particular formulation technique, it being recognized that the choice of specific formulation components may well make necessary some specific formulation procedure.

Suitable emulsifiers for one aspect of the invention are those known in the art for producing oil-in-water and/or water-in-oil type emulsions. An aqueous external phase is preferred by many people for skin contact, since it is not as likely to produce an oily or greasy sensation when it is being applied, as is an emulsion having an oil external phase. The typical oil-in-water emulsifier has a hydrophilic-lipophilic balance (frequently abbreviated as "HLB") value greater than about 9, as is well known in the art; however, this "rule" is known to have numerous exceptions. The chosen emulsifier, depending upon its chemical nature, will be a component of either the oil or aqueous phase, and assists with both the formation and the maintenance, or stability, of the emulsion. Suitable emulsifiers for another aspect of the invention are those known in the art for producing water-in-oil type emulsions.

-6-

The typical water-in-oil emulsifier has a HLB value of about 4 to about 6, as is well known in the art; however, this "rule" is also known to have numerous exceptions. Selection of suitable water-in-oil emulsifiers is well known in the formulation art.

5 Most of the widely used emulsifier systems for sunscreen formulations can be used in the invention. Particularly preferred emulsifiers are PEG-8 Distearate available under the trade name of Emerest 2712 from Henkel, PEG-5 Glyceryl Stearate available under the trade name POEM-S-105 from Riken Vitamin Oil, PEG-6 Hydrogenated Castor Oil, available under the trade
10 name Sabowax ELH6 from Sabo, PEG-6 Oleate, available under the trade name STEPAN PEG-300 MO from Stepan, Sorbitan Sesquioleate, available under the trade name Arlacel 83 and Arlacel C from ICI Surfactants, TEA-Stearate, available under the trade name of Cetasal from Gattefosse S.A. Another preferred emulsifier is neutralized cetyl phosphate, available under
15 the trade name Amphisol A from LaRoche. Most preferred is an Acrylate/C₁₀₋₃₀ alkyl acrylate cross polymer of C₁₀₋₃₀ alkyl acrylates and one or more monomers of acrylic acid, methacrylic acid or one of their simple esters crosslinked within allyl ether of sucrose or an allyl ether of pentaerythritol, available under the trade names of Pemulen TR-1 and Pemulen TR-2 from
20 B.F. Goodrich. The amount of emulsifier used in the present invention is present in an amount of about 0.1 to about 10% by weight, preferably about 0.5 percent to about 5 percent by weight, most preferably about 2 percent to about 4 percent by weight. The choice of an emulsifier is well within ordinary skill in the art and is not a critical aspect of the invention. Additional preferred
25 emulsifiers that may be employed include Sorbitan Triisostearate available under the trade name Crill 6 from Croda Oleochemicals, and Polyglyceryl-3 Distearate available under the trade name Cremophor GS 32 from BASF.

 As is known in the art, it is preferred that the individual emulsion droplets have a small and uniform size because these properties result in a
30 more stable emulsion. Conversely, a broad particle size distribution indicates that the interfacial tension between the droplets has not been substantially reduced, and thus the droplets tend to coalesce and form agglomerations that result in an unstable emulsion.

-7-

The formulations of the present invention provide an elegant feel upon application to the skin, while also possessing an improved ability to withstand high temperature and shear during formulation, as well as, improved stability over time relative to other skin care products currently manufactured.

5 For purposes of the present invention, a "sunscreen active agent" shall include all of those materials, singly or in combination, that are regarded as acceptable for use as active suncreening ingredients. Approval by a regulatory agency is generally required for inclusion of active agents in formulations intended for human contact, and those active agents which have
10 been or are currently approved for sunscreen use in the United States include, without limitation, para aminobenzoic acid, avobenzene, cinoxate, dioxybenzone, homosalate, menthyl anthranilate, octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone, padimate O, phenylbenzimidazole sulfonic acid, sulisobenzene, trolamine salicylate,
15 titanium dioxide, zinc oxide, diethanolamine methoxycinnamate, digalloy trioleate, ethyl dihydroxypropyl PABA, glyceryl aminobenzoate, lawsone with dihydroxyacetone, red petrolatum.

Particularly preferred sunscreen active agents include homomenthyl salicylate available under the trade name Uniderm Homsal from Universal
20 Preserv-A-Chem, Benzophenone-3, available under the trade name Escalol 567 from ISP VanDyk, Uvinul MS-40 from BASF and Uvasorb MET/C from 3V Inc., Octyl Salicylate available under the trade name Neo Heliopan OS from Haarmann & Reimer, Octocrylene available under the trade name Uvinul N-539-SG from BASF and the trade name Neo Heliopan 303 from Haarmann &
25 Reimer, and Octyl methoxycinnamate, available under the trade name Parsol MCX from Givaudon Roure and LaRoche, or mixtures thereof.

It is typical to use combinations of two or more sunscreen ingredients in a formulation, to achieve higher levels of ultraviolet absorption or to provide useful absorption over a wider range of ultraviolet wavelengths than can be
30 the case with a single active component. Several other sunscreen active ingredients are accepted for use in other countries, such as terephthalylidene dicamphor sulfonic acid, sold under the trademark of Mexoryl® SX, and these are also considered to be within the scope of the present invention.

The formulations of the present invention will have either sunscreen capability (SPF <30) and/or sunblock capability (SPF >30). Preferably, the formulations of the present invention will have an SPF greater than at least about 30, preferably greater than at least about 40, and preferably about 50.

5 Insect repelling components are desirable in suncreening emulsions, since the emulsions are normally used primarily by persons engaged in outdoor activities. The most widely used active agent for personal care products is N,N-Diethyl-m-toluamide, frequently called "DEET" and available in the form of a concentrate containing at least about 95 percent DEET. Other
10 synthetic chemical repellents include dimethyl phthalate, ethyl hexanediol, indalone, di-n-propylisocinchonate, bicycloheptene, dicarboximide and tetrahydrofuraldehyde. Certain plant-derived materials also have insect repellent activity, including citronella oil and other sources of citronella (including lemon grass oil), limonene, rosemary oil and eucalyptus oil. Choice
15 of an insect repellent for incorporation into the sunscreen emulsion will frequently be influenced by the odor of the repellent. The amount of repellent agent used will depend upon the choice of agent; DEET is useful at high concentrations, such as up to about 15 percent or more, while some of the plant-derived substances are typically used in much lower amounts, such as
20 0.1 percent or less.

As used herein, an after sun emulsion formulation is defined as a formulation that can be administered after a user has been in the sun for any amount of time that provides a soothing or healing effect that is pleasant to the user. Such a formulation can contain, for instance, aloe vera, vitamins A,
25 C and E, green tea extract, etc.

Also within the scope of the present invention are skin protectant active agents. Suitable examples include, among others: (a) Allantoin, 0.5 to 2 percent; (b) Aluminum hydroxide gel, 0.15 to 5 percent; (c) Calamine, 1 to 25 percent; (d) Cocoa butter, greater than 50; (e) Cod liver oil, 5 to 13.56
30 percent; (f) Colloidal oatmeal; (g) Dimethicone, 1 to 30 percent; (h) Glycerin, 20 to 45 percent; (i) Hard fat, greater than 50; (j) Kaolin, 4 to 20 percent; (k) Lanolin, 12.5 to 50 percent; (l) Mineral oil, greater than 50 percent; (m) Petrolatum, greater than 30 percent; (n) Sodium bicarbonate; (o) Topical

starch, 10 to 98 percent; (p) White petrolatum, greater than 30 percent; (q) Zinc acetate, 0.1 to 2 percent; (r) Zinc carbonate, 0.2 to 2 percent; and (s) Zinc oxide, 1 to 25 percent.

5 The compositions of the present invention may contain a wide range of additional, optional components. The CTFA Cosmetic Ingredient Handbook, Seventh Edition, 1997 and the Eighth Edition, 2000, which is incorporated by reference herein in its entirety, describes a wide variety of cosmetic and pharmaceutical ingredients commonly used in skin care compositions, which are suitable for use in the compositions of the present invention. Examples of
10 these functional classes disclosed in this reference include: absorbents, abrasives, anticaking agents, antifoaming agents, antioxidants, binders, biological additives, buffering agents, bulking agents, chelating agents, chemical additives, colorants, cosmetic astringents, cosmetic biocides, denaturants, drug astringents, external analgesics, film formers, fragrance
15 components, humectants, opacifying agents, pH adjusters, plasticizers, preservatives, propellants, reducing agents, skin bleaching agents, skin-conditioning agents (emollient, humectants, miscellaneous, and occlusive), skin protectants, solvents, foam boosters, hydrotropes, solubilizing agents, suspending agents (nonsurfactant), sunscreen agents, ultraviolet light
20 absorbers, waterproofing agents, and viscosity increasing agents (aqueous and nonaqueous).

Water is employed in amounts effective to form the emulsion. It is generally preferred to use water which has been purified by processes such as deionization or reverse osmosis, to improve the batch-to-batch formulation
25 inconsistencies which can be caused by dissolved solids in the water supply. The amount of water in the emulsion or composition can range from about 15 percent to 95 weight percent, preferably from about 45 to 75 percent, most preferably from about 60 percent to about 75 percent.

Alternatively, in another embodiment of the present invention, the
30 ingredients may be dissolved in a monohydric alcohol solvent. The present invention may contain up to 90% of monohydric alcohol(s). The preferred amount of the monohydric alcohol is about 25% to about 85% and most preferably from about 35% to about 75%. In this embodiment, the sunscreen

active agent or agents may be present in an amount of about 25% to about 30% and the waterproofing agent may be present in an amount of about 1% to about 5%. In a still further embodiment of the present invention, the formulation may be a monohydric alcohol based gel formulation.

5 An emollient is an oleaginous or oily substance which helps to smooth and soften the skin, and may also reduce its roughness, cracking or irritation. Typical suitable emollients include mineral oil having a viscosity in the range of 50 to 500 centipoise (cps), lanolin oil, coconut oil, cocoa butter, olive oil, almond oil, macadamia nut oil, aloe extracts such as aloe vera lipoquinone,
10 synthetic jojoba oils, natural sonora jojoba oils, safflower oil, corn oil, liquid lanolin, cottonseed oil and peanut oil. Preferably, the emollient is a cocoglyceride, which is a mixture of mono, di and triglycerides of cocoa oil, sold under the trade name of Myritol 331 from Henkel KGaA, or Dicaprylyl Ether available under the trade name Cetiol OE from Henkel KGaA or a C₁₂-
15 C₁₅ Alkyl Benzoate sold under the trade name Finsolv TN from Finetex. One or more emollients may be present ranging in amounts from about 1 percent to about 10 percent by weight, preferably about 5 percent by weight. Another suitable emollient is DC 200 Fluid 350, a silicone fluid, available Dow Corning Corp.

20 Other suitable emollients include squalane, castor oil, polybutene, sweet almond oil, avocado oil, calophyllum oil, ricin oil, vitamin E acetate, olive oil, silicone oils such as dimethylpolysiloxane and cyclomethicone, linolenic alcohol, oleyl alcohol, the oil of cereal germs such as the oil of wheat germ, isopropyl palmitate, octyl palmitate, isopropyl myristate, hexadecyl
25 stearate, butyl stearate, decyl oleate, acetyl glycerides, the octanoates and benzoates of (C₁₂ -C₁₅) alcohols, the octanoates and decanoates of alcohols and polyalcohols such as those of glycol and glyceryl, ricinoleates esters such as isopropyl adipate, hexyl laurate and octyl dodecanoate, dicaprylyl maleate, hydrogenated vegetable oil, phenyltrimethicone, jojoba oil and aloe vera
30 extract.

Other suitable emollients which are solids or semi-solids at ambient temperatures may be used. Such solid or semi-solid cosmetic emollients include glyceryl dilaurate, hydrogenated lanolin, hydroxylated lanolin,

acetylated lanolin, petrolatum, isopropyl lanolate, butyl myristate, cetyl myristate, myristyl myristate, myristyl lactate, cetyl alcohol, isostearyl alcohol and isocetyl lanolate. One or more emollients can optionally be included in the formulation.

5 A humectant is a moistening agent that promotes retention of water due to its hygroscopic properties. Suitable humectants include glycerin, polymeric glycols such as polyethylene glycol and polypropylene glycol, mannitol and sorbitol. Preferably, the humectant is Sorbitol, 70% USP or polyethylene glycol 400, NF. One or more humectants can optionally be
10 included in the formulation in amounts from about 1 percent to about 10 percent by weight, preferably about 5 percent by weight.

 A dry-feel modifier is an agent which when added to an emulsion, imparts a "dry feel" to the skin when the emulsion dries. Dry feel modifiers can include talc, kaolin, chalk, zinc oxide, silicone fluids, inorganic salts such
15 as barium sulfate, surface treated silica, precipitated silica, fumed silica such as an Aerosil available from Degussa Inc. of New York, N.Y. U.S.A. Another dry feel modifier is an epichlorohydrin cross-linked glyceryl starch of the type that is disclosed in U.S. Patent No. 6,488,916, issued in the name of Fowler and assigned to Schering-Plough Healthcare Products, Inc.

20 It may be advantageous to incorporate additional thickening agents, such as, for instance, Carbopol Ultrez, or alternatively, Carbopol ETD 2001, available from the B. F. Goodrich Co. The selection of additional thickening agents is well within the skill of one in the art.

 An additional waterproofing or water resistance agent is a hydrophobic
25 material that imparts film forming and waterproofing characteristics to an emulsion. A suitable additional waterproofing agent is a copolymer of vinyl pyrrolidone and eicosene and dodecane monomers such as Ganex V 220 and Ganex V 216 Polymers, respectively, trade names of ISP Inc. of Wayne, N.J. U.S.A. Still other suitable waterproofing agents include polyethylene polymer,
30 such as Performa V 825 available from New Phase Technologies and polyanhydride resin No. 18 available under the trade name PA-18 from Chevron. The waterproofing agent is used in amounts effective to allow the sunscreen to remain effective on the skin after exposure to circulating water

for at least 40 minutes for water resistance and at least 80 minutes for waterproofing using the procedures described by the U.S. Food and Drug Administration in "Sunscreen Drug Products for OTC Human Use," Federal Register, Vol. 43, Aug. 25, 1978, Part 2, pp. 38206-38269.

5 An antimicrobial preservative is a substance or preparation which destroys, or prevents or inhibits the proliferation of, microorganisms in the sunscreen composition, and which may also offer protection from oxidation. Preservatives are frequently used to make self-sterilizing, aqueous based products such as emulsions. This is done to prevent the development of
10 microorganisms that may be in the product from growing during manufacturing and distribution of the product and during use by consumers, who may further inadvertently contaminate the products during normal use. Typical preservatives include the lower alkyl esters of para-hydroxybenzoates (parabens), especially methylparaben, propylparaben, isobutylparaben and
15 mixtures thereof, benzyl alcohol, phenyl ethyl alcohol and benzoic acid, diazolydiny, urea, chlorphenesin, iodopropynyl and butyl carbamate. The preferred preservative is available under the trade name of Germaben II from Sutton. One or more antimicrobial preservatives can optionally be included in an amount ranging from about 0.001 to about 10 weight percent, preferably
20 about 0.05 to about 1 percent.

 An antioxidant is a natural or synthetic substance added to the sunscreen to protect from or delay its deterioration due to the action of oxygen in the air (oxidation). They may also reduce oxidation reactions in skin tissue. Anti-oxidants prevent oxidative deterioration which may lead to the
25 generation of rancidity and nonenzymatic browning reaction products. Typical suitable antioxidants include propyl, octyl and dodecyl esters of gallic acid, butylated hydroxyanisole (BHA, usually purchased as a mixture of ortho and meta isomers), butylated hydroxytoluene (BHT), green tea extract, uric acid, cysteine, pyruvate, nordihydroguaiaretic acid, Vitamin A, Vitamin E and
30 Vitamin C and their derivatives. One or more antioxidants can optionally be included in the sunscreen composition in an amount ranging from about 0.001 to about 5 weight percent, preferably about 0.01 to about 0.5 percent.

-13-

Chelating agents are substances used to chelate or bind metallic ions, such as with a heterocyclic ring structure so that the ion is held by chemical bonds from each of the participating rings. Suitable chelating agents include ethylene diaminetetraacetic acid (EDTA), EDTA disodium, calcium disodium edetate, EDTA trisodium, albumin, transferrin, desferoxamine, desferal, 5 desferoxamine mesylate, EDTA tetrasodium and EDTA dipotassium. One or more chelating agents can optionally be included in the sunscreen in amounts ranging from about 0.001 to about 0.5 weight percent preferably about 0.01% weight percent.

10 Fragrances are aromatic substances which can impart an aesthetically pleasing aroma to the sunscreen composition. Typical fragrances include aromatic materials extracted from botanical sources (i.e., rose petals, gardenia blossoms, jasmine flowers, etc.) which can be used alone or in any combination to create essential oils. Alternatively, alcoholic extracts may be 15 prepared for compounding fragrances. However, due to the relatively high costs of obtaining fragrances from natural substances, the modern trend is to use synthetically prepared fragrances, particularly in high-volume products. The preferred fragrances for use in the present invention are Fragrance SZ-2108 and Fragrance SZ-1405 available from Sozio, Inc... One or more 20 fragrances can optionally be included in the sunscreen composition in an amount ranging from about 0.001 to about 5 weight percent, preferably about 0.01 to about 0.5 percent by weight.

A pH modifier is a compound that will adjust the pH of a formulation to a lower, e.g., more acidic pH value, or to a higher, e.g., more basic pH value. 25 The selection of a suitable pH modifier is well within the ordinary skill of one in the art.

The invention will be further described by means of the following examples, which are not intended to limit the invention, as defined by the appended claims, in any manner.

EXAMPLE 1

Percent W/W	Ingredient Description
Part A	
47.7	USP Purified Water
0.38	Pemulen TR-1
5	Propylene Glycol USP
0.01	Disodium EDTA
0.5	Allantoin
0.5	Benzyl Alcohol
0.2	Methylparaben, NF
Part B	
4	Lexfeel 7,
7.5	Octinoxate, USP
6	Oxybenzone, USP
0.01	Vitamin E, DL Alpha Tocopherol
0.2	Oleth-3
5	Octisalate, USP
0.1	Propylparaben NF
9	Homomenthyl Salicylate; Homosal
1.5	Sylvaclear C75V
2	Octocrylene
Part C	
10	USP Purified Water
0.35	Triethanolamine 99% NF
Part D	
0.05	Fragrance SZ-2108

- 5 The ingredients of part A were mixed with the exception of the Pemulen and allantoin. The Pemulen was slowly sprinkled in and then the allantoin was mixed in by stirring rapidly. The ingredients of part b were mixed in a second beaker and heated to about 175 degrees Celsius. The two phases were then mixed with a disperser for about 15 minutes.
- 10 Triethanolomine and water were then added. The fragrance was then added with stirring for about 2 minutes.

EXAMPLE 2

Percent W/W	Ingredient Description
Part A	
48	USP Purified Water
0.38	Pemulen TR-1
5	Propylene Glycol USP
0.01	Disodium EDTA
1	Germaben
Part B	
7.5	Octinoxate, USP
6	Oxybenzone, USP
0.01	Vitamin E, DL Alpha Tocopherol
0.2	Oleth-3
5	Octisalate, USP
13	Homomenthyl Salicylate; Homosal
1.5	Sylvaclear C75V
2	Octocrylene
Part C	
10	USP Purified Water
0.35	Triethanolamine 99% NF
Part D	
0.05	Fragrance SZ-2108

5 The ingredients of part A were mixed with the exception of the Pemulen. The Pemulen was slowly sprinkled in. The ingredients of part B were mixed in a second beaker and heated to about 175 degrees Celsius. The two phases were then mixed with a disperser for about 15 minutes. Triethanolomine and water were then added. The fragrance was then added
10 with stirring for about 2 minutes.

The sunscreen lotion prepared in accord with the procedures set forth in this example produces a high SPF sun block with an SPF of about 50.

Although certain presently preferred embodiments of the invention have been described herein, it will be apparent to those skilled in the art to
15 which the invention pertains that variations and modifications of the described embodiments may be made without departing from the spirit and scope of the

-16-

invention. Accordingly, it is intended that the invention be limited only to the extent required by the appended claims and the applicable rules of law.

What is claimed is:

1. An emulsion formulation for topical application to the skin comprising:
an aqueous phase, an oil phase, at least one emulsifier, and an
5 Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate
Copolymer.
2. The formulation of claim 1, wherein the formulation is an oil-in water
emulsion.
3. The formulation of claim 2, wherein the at least one emulsifier is
10 present in an amount of about 1 to about 10 percent by weight.
4. The formulation of claim 1, wherein the formulation is a water-in-oil
emulsion.
5. The formulation of claim 4, wherein the at least one emulsifier is
present in an amount of about 1 to about 10 percent by weight.
- 15 6. The formulation of claim 1, wherein the
Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate
Copolymer is present in an amount of about 0.1 to about 20 percent by
weight.
7. The formulation of claim 1, further comprising at least one sunscreen
20 active agent.
8. The formulation of claim 7, wherein the formulation has an SPF of at
least about 30.
9. The formulation of claim 7, wherein the formulation has an SPF of at
least about 40.
- 25 10. The formulation of claim 1, further comprising at least one skin
protectant.
11. The formulation of claim 1, further comprising at least one insect
repellant.
12. The formulation of claim 7, further comprising at least one skin
30 protectant.
13. The formulation of claim 7, further comprising at least one insect
repellant.

14. A formulation for topical application to the skin comprising: a solvent comprising a monohydric alcohol and an
5 Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer.
15. The formulation of claim 14, wherein the Ethylenediamine/NeopentylGlycol/Stearyl Hydrogenated Dimer Dilinoleate Copolymer is present in an amount of about 0.1 to about 20 percent by
10 weight.
16. The formulation of claim 14, further comprising at least one sunscreen active agent.
17. The formulation of claim 14, wherein the formulation has an SPF of at least about 30.
- 15 18. The formulation of claim 17, wherein the formulation has an SPF of at least about 40.
19. The formulation of claim 14, further comprising at least one skin protectant.
20. The formulation of claim 14, further comprising at least one insect
20 repellent.
21. The formulation of claim 16, further comprising at least one skin protectant.
22. The formulation of claim 16, further comprising at least one insect repellent.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/017256

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61K7/42 A61K7/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61K C08G

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 02/092663 A (ARIZONA CHEMICAL COMPANY; PAVLIN, MARK, S) 21 November 2002 (2002-11-21) cited in the application page 6, line 9 - page 13, line 15 page 19, line 13 - line 22 page 20, line 13 - line 24 page 22, line 24 - line 28 page 24, line 3 - line 18 page 25, line 8 examples 1,2	1,2,4,7, 10,12, 14,16, 19,21
Y		1-22
Y	US 2003/223943 A1 (UANG YUH-JYE ET AL) 4 December 2003 (2003-12-04) paragraphs '0015!, '0017!, '0032!, '0033!, '0036! ----- -/--	1-22

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

8 September 2005

Date of mailing of the international search report

22/09/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Paloniemi Legland, R

INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/017256

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2003/198613 A1 (FENG SUE ET AL) 23 October 2003 (2003-10-23) paragraphs '0060! - '0063!, '0094!, '0119!, '0123! -----	1-22
Y	PATENT ABSTRACTS OF JAPAN vol. 1998, no. 02, 30 January 1998 (1998-01-30) & JP 09 263523 A (SHISEIDO CO LTD), 7 October 1997 (1997-10-07) abstract -----	1-22

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US2005/017256

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 02092663	A	21-11-2002	US 2002187170 A1	12-12-2002
			CA 2447107 A1	21-11-2002
			EP 1392759 A1	03-03-2004
			JP 2004532324 T	21-10-2004
			MX PA03010423 A	02-04-2004
			PL 367294 A1	21-02-2005
			WO 02092663 A1	21-11-2002
			US 2003236387 A1	25-12-2003
<hr/>				
US 2003223943	A1	04-12-2003	NONE	
<hr/>				
US 2003198613	A1	23-10-2003	US 2003086883 A1	08-05-2003
			US 2004091510 A1	13-05-2004
<hr/>				
JP 09263523	A	07-10-1997	NONE	
<hr/>				