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(54) Abstract Title: **Skincare composition**

(57) A skincare composition in the form of an emulsion comprising:

- a) a sunscreen component comprising at least one organic sunscreen selected from the group consisting of bis-ethylhexyloxyphenol methoxyphenyl triazine and methylene bis-benzotriazolyl tetramethylbutylphenol;
- b) a moisturising system comprising starch or a derivative thereof and a polymeric quaternary compound salt having humectant properties; and
- c) an emulsifying system comprising at least one emulsifier comprising an anionic or non-ionic emulsifier.

The topical compositions have advantageous properties in protecting the skin against the effects of sunlight, especially UV radiation.

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Skincare Composition

The present invention relates to a composition for topical application which  
5 protects the skin from the effects of sunlight, in particular to a skincare composition  
in the form of an emulsion which provides a moisturising and sunscreen effect.

Radiation from the sun plays a major role in damaging one or more skin layers, for  
example the effect of the heat rays drying out the skin and the effect of UV rays in  
10 penetrating into the deeper levels of the skin. There are many different types of  
rays present in sunlight. UVB rays are responsible for causing sunburn where  
significant damage and dehydration of the skin occurs, and also may lead to skin  
cancers. UVA rays also contribute to skin cancer but additionally lead to a  
photoageing effect where the skin loses its healthy and youthful appearance. In  
15 the dermis, the collagen and elastin fibres which provide the skin with strength,  
structure and elasticity, are broken down by exposure to UV radiation, leading to  
wrinkles and sagging skin. The UV damage may occur at any time of year as the  
UVA rays, which penetrate more deeply into the skin than UVB rays, pass through  
glass.

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In addition, exposure to UV light may affect lipids in the outer layer of the skin  
causing the cells in the stratum corneum to adhere poorly to each other, providing  
that the new skin continuously being formed has an impaired skin barrier.

Furthermore, destruction of the lipids, which generally form a strong protective  
25 barrier acting to preserve the moisture in the body, may also cause the skin cells  
to lose the water they need to stay healthy and supple. A healthy stratum  
corneum comprises about 30% water, giving the skin resilience and elasticity.  
Accordingly, it is desired to moisturise skin exposed to UV light to retain its healthy  
function.

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Numerous products have been provided to protect the skin from the effect of  
exposure to the sun. These products include organic and/or inorganic

sunscreens. Many of the organic sunscreens which mop up the free radicals are unstable when formulated and do not provide protection for a prolonged period. In particular, great care must be taken to minimise the amount of ingredients to reduce the likelihood of the system being unstable. If the formulation does not provide adequate protection from the sun, the epidermis is a primary location at which damage occurs. Damage to the epidermis, including dehydration, increases the damage to the lower layers of the dermis and also the intercellular matrix between the layers.

- 10 The present invention seeks to provide an improved sun care formulation. It has now been found that by providing an effective sunscreen component in combination with a particular moisturising system, advantages in the protection and overall appearance of the skin are achieved.
- 15 Accordingly, the present invention provides a skincare composition in the form of an emulsion comprising:
- a) a sunscreen component comprising at least one organic sunscreen selected from the group consisting of bis-ethylhexyloxyphenol methoxyphenyl triazine and methylene bis-benzotriazolyl tetramethylbutylphenol;
  - 20 b) a moisturising system comprising starch or a derivative thereof and a polymeric quaternary compound salt having humectant properties; and
  - c) an emulsifying system comprising at least one emulsifier comprising an anionic or non-ionic emulsifier.
- 25

The present invention has allowed the formation of a stable sunscreen system in a formulation which is able to provide a continuous moisturisation effect. The moisturisation effect is maintained at continuous levels for a period of 12 hours or more. The continuous effect is particularly desirable as it significantly reduces the dehydration of the skin on exposure to sunlight and maximises the rehydration and moisturisation of the skin. A healthy skin with a properly functioning outer barrier

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layer exposed to the environment is better able to withstand the effects of exposure to sunlight than dehydrated, damaged skin. Advantages of the present invention include a stable and effective sunscreen formulation which not only reduces the effect of UV radiation on the skin from UV damage but also prevents it from drying out. In particular, not only do compositions according to the invention prevent substantial moisture loss, through the continuous addition of moisture over a period of 12 hours or more, the epidermal layer of the skin is healthier and is better able to withstand the effects of UV radiation. Accordingly, an advantageous UV protection effect may be obtained. The compositions are advantageously used daily to maximize their effect.

The sunscreen component useful in accordance with the present invention comprises at least one organic sunscreen selected from the group consisting of bis-ethylhexyloxyphenol methoxyphenyl triazine and methylene bis-benzotriazolyl tetramethylbutylphenol. Additional sunscreen agents may also be combined with said sunscreens, including p-aminobenzoic acids, esters and derivatives thereof, for example, 2-ethylhexyl p-dimethylaminobenzoate and the octyl ester of p-aminobenzoic acid; methoxycinnamate esters such as 2-ethylhexyl p-methoxycinnamate, 2-ethoxyethyl p-methoxycinnamate or  $\alpha,\beta$ -di-(p-methoxycinnamoyl)- $\alpha'$ -(2-ethylhexanoyl)-glycerin; benzophenones such as oxybenzone; 2-phenylbenzimidazole-5-sulfonic acid and disodium phenyl dibenzimidazole tetrasulfonate and terphthalylidene dicamphor sulfonic acid; alkyl- $\beta,\beta$ -diphenylacrylates for example alkyl  $\alpha$ -cyano- $\beta,\beta$ -diphenylacrylates such as octocrylene; triazines such as 2,4,6-trianilino-(p-carbo-2-ethylhexyl-1'-oxy)-1,3,5 triazine; camphor derivatives such as methylbenzylidene camphor; silicone derivatives such as drometrizole trisiloxane, benzylidene malonate polysiloxane and dimethicodiethyl benzal malonate and salicylates such as octyl salicylate.

In one embodiment, the sunscreen component comprises bis-ethylhexyloxyphenol methoxyphenyl triazine in combination with one or more of methylene bis-benzotriazolyl tetramethylbutylphenol, ethylhexyl methoxycinnamate, isoamyl p-methoxycinnamate and butyl methoxydibenzoylmethane. In another embodiment,

the sunscreen component comprises methylene bis-benzotriazolyl tetramethylbutylphenol in combination with one or more of bis-ethylhexyloxyphenol methoxyphenyl triazine, ethylhexylmethoxy cinnamate, isoamyl p-methoxycinnamate and butyl methoxydibenzoylmethane. Preferably, the

5 sunscreen component comprises a combination of bis-ethylhexyloxyphenol methoxyphenyl triazine, methylene bis-benzotriazolyl tetramethylbutylphenol and ethylhexylmethoxy cinnamate, optionally including isoamyl p-methoxycinnamate.

Preferably, a composition according to the invention comprises a sunscreen

10 component in an amount greater than 2.5% w/w, more preferably greater than 5% w/w and most preferably greater than 10% w/w. Further preferably, the sunscreen agent is present in the composition in an amount less than 25% w/w, more preferably less than 20% w/w and most preferably less than 10% w/w.

Accordingly, in particularly preferred compositions, the sunscreen component is

15 present in the composition in the range 2.5% to 25% w/w, more preferably in the range 5% to 20% w/w and most preferably in the range 10% to 18% w/w.

If desired, a composition according to the present invention may also comprise an inorganic sunscreen agent, preferably titanium dioxide. Said inorganic sunscreen

20 agent, if present, is preferably used in the range 1% to 10% w/w, more preferably in the range 2% to 8% w/w and most preferably in the range 3% to 7% w/w.

A composition according to the invention comprises a moisturising system comprising starch or a derivative thereof and a polymeric quaternary compound

25 salt having humectant properties. The starch or starch derivative is preferably a chemically or physically modified starch. Most preferably, the starch is modified so as to render it heat-stable and/or non-swelling.

A preferred form of starch derivative is a dimethyl imidazolidinone starch

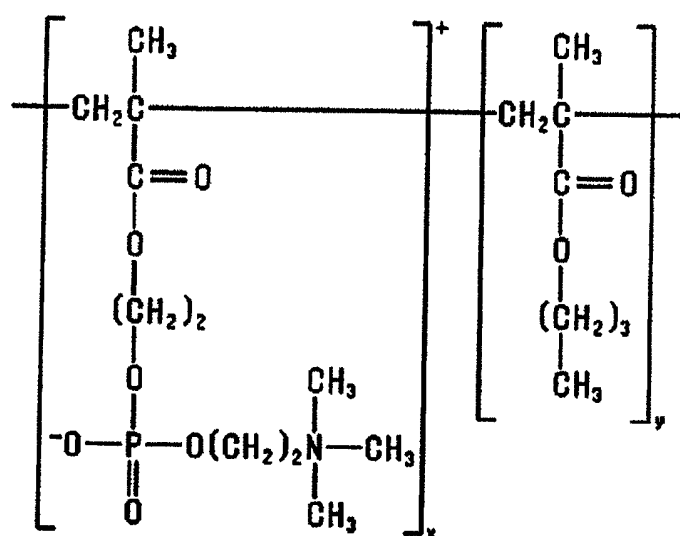
30 derivative, ie a product obtained by reaction of 1,3-dimethyl-4,5-dihydroxy-2-imidazolidinone (dimethyl imidazolidinone) with starch. Particular starches that may be used include corn starch but, more preferably, the starch is rice starch.

The dimethyl imidazolidinone starch derivative may thus be dimethylimidazolidinone corn starch or, more preferably, dimethylimidazolidinone rice starch.

- 5 A suitable form of dimethylimidazolidinone rice starch is available from Agrana u. Staerke AG, Conrathstr. 7, A-3950 Gmünd, Austria, under the trade name Rice NS. Another supplier is Dr Hauser, Reintalstrasse 8, D-82467 Garmisch-Partenkirchen, Germany.
- 10 The starch or starch derivative is preferably present in the composition according to the invention at a level of less than 15% w/w, preferably less than 10% w/w, and more preferably less than 5% w/w. The concentration of starch derivative is preferably greater than 0.1% w/w, and more preferably greater than 1% w/w. The concentration of starch derivative is therefore preferably in the range 0.1% to 15% w/w, and more preferably in the range 1% to 5% w/w, particularly in the range 2.25% to 3.75% w/w.
- 15

The polymeric quaternary ammonium salt is most preferably the material known as Polyquaternium-51, ie the polymeric quaternary ammonium salt that conforms

- 20 generally to the formula:



A suitable form of polyquaternium-51 is available from NOF Corporation, 4-20-3, Ebisu, Shibuya-ku, Tokyo 150, Japan, under the trade name Lipidure-PMB.

5 The ammonium salt is preferably present in the composition according to the invention at a level of less than 1% w/w, more preferably less than 0.1% w/w. The concentration of ammonium salt is preferably greater than 0.0001% w/w, and more preferably greater than 0.001% w/w. The concentration of ammonium salt is therefore preferably in the range 0.0001% to 1% w/w, and more preferably in the range 0.001% to 0.1% w/w.

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The composition according to the invention may comprise one or more additional moisturising or humectant ingredients, ie moisturising or humectant ingredients that are additional to the starch derivative and the ammonium salt.

15 Most preferably, the additional moisturising or humectant ingredient is a relatively low molecular weight polyalcohol, eg a C<sub>2-6</sub> aliphatic polyalcohol. Examples of such polyalcohols include glycerin (1,2,3-trihydroxypropane), 1,3-butylene glycol and propylene glycol. The most preferred additional moisturising or humectant ingredient is glycerin.

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The additional moisturising or humectant ingredient(s) are preferably present in the composition at a level of up to 25% w/w or more, more preferably up to 20% w/w. The concentration of additional moisturising or humectant ingredient(s) is preferably greater than 1% w/w, more preferably greater than 5% w/w, and most  
25 preferably greater than 10% w/w. The concentration of additional moisturising or humectant ingredient(s) is therefore preferably in the range 1% to 25% w/w, and more preferably in the range 5% to 20% w/w.

Where glycerin is present in the composition, the concentration of glycerin is  
30 preferably in the range 1% to 20% w/w, more preferably in the range 10% to 20% w/w, and in particular in the range 10% to 15% w/w.

The composition may comprise more than one aliphatic polyalcohol. In some embodiments, the composition comprises both glycerin and propylene glycol.

5 Compositions comprising one or more aliphatic polyalcohols have been found to be particularly beneficial. In a more specific aspect, the invention thus provides a composition for topical application to the skin, which composition comprises a starch or starch derivative, a polymeric quaternary ammonium salt having humectant properties, and from 10% to 20% w/w of one or more aliphatic polyalcohols. The polyalcohols are preferably C<sub>2-6</sub> aliphatic polyalcohols, most  
10 preferably selected from the group consisting of glycerin (1,2,3-trihydroxypropane), 1,3-butylene glycol and propylene glycol. Preferably, the composition comprises glycerin.

15 In preferred embodiments, the composition is free of any additional moisturising agents other than the low molecular weight polyalcohols. In particular, the composition is preferably free of sodium PCA, urea, trehalose and sodium hyaluronate.

In preferred composition according to the present invention, the ratio of  
20 moisturising system to sunscreen component is in the range 1:1 to 1:20 parts by weight, more preferably 1:2 to 1:10 parts by weight, most preferably 1:4 to 1:6 parts by weight.

A composition according to the present invention is in the form of an emulsion,  
25 preferably a water-in-oil emulsion. Preferably, the oil component comprises: hydrocarbons, silicone oils, triglycerides, waxes, glycerin, fatty acids, fatty acid alcohols and esters thereof, mineral oils, vegetable oils and hydrogenated vegetable oils, lanolin or mixtures thereof. Examples of hydrocarbons include paraffins (for example paraffinum liquidum and white soft paraffin), petrolatum,  
30 hydrogenated polyisobutene, alkyl benzoates, isohexadecane, isododecane, isononyl isonanoate, diisopropylcyclohexane; examples of silicone oils include dimethicone, cyclomethicone, cetyldimethicone or stearyl dimethicone, examples of



triglycerides include natural triglycerides and synthetic or semi-synthetic triglycerides including caprylic/capric triglyceride ; examples of waxes include vegetable waxes such as carnauba wax, animal waxes such as beeswax, and mineral waxes such as paraffin wax, ozokerite; examples of esters of fatty acids or  
 5 alcohols include isopropyl palmitate, isopropyl myristate, dioctylmaleate, glyceryl oleate and cetostearyl isononanoate, octyl palmitate, cetearyl alcohol, stearyl alcohol, cetyl alcohol, glyceryl Myristate, decyl cocoate: examples of mineral oils include Vaseline oil; examples of vegetable oils include jojoba oil, soy bean oil, coconut oil, sunflower seed oil, apricot kernel oil, shea butter, avocado oil and  
 10 examples of hydrogenated vegetable oils include hydrogenated palm oil.

The cosmetically oil chosen for any composition may depend on the type of composition desired. Preferred classes of oils include silicone oils, mineral oils, vegetable oils and triglycerides, especially mineral oils and vegetable oils.  
 15 Particularly preferred oils are butyrospermum parkii, caprylic/capric triglyceride, C12-15 alkyl benzoate, isohexadecane, triethylhexanoin, cyclomethicone, dimethicone, glycerin, cetearyl alcohol, isopropylpalmitate, stearyl alcohol, cetyl alcohol, stearyl dimethicone, glyceryl myristate, paraffinum liquidum, acrylates copolymer and decyl cocoate or mixtures thereof. Especially preferred is a  
 20 combination of glycerin, C12-15 alkyl benzoate, caprylic/capric triglyceride, cyclomethicone and stearyl alcohol, optionally in combination with one or more oils identified above.

Preferably, said oil is present in an amount in the range 4% to 50% w/w, more  
 25 preferably in the range 6% to 30% w/w and most preferably in the range 8% to 20% w/w.

Preferably, water is present in the composition in the range 20% to 80% w/w, more preferably in the range 25% to 75% w/w and most preferably in the range 35% to  
 30 55% w/w.

An emulsifying system useful in accordance with the present invention comprises at least one emulsifier comprising an anionic or non-ionic emulsifier. Typical classes of these emulsifiers are known to those skilled in the art. Optionally, the emulsifier may be combined with a thickening agent.

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Preferably, the emulsifying system comprises a combination of emulsifiers with different HLB values, more preferably at least one emulsifier with a high HLB value and at least one emulsifier with a low-medium HLB value, especially preferably at least one emulsifier with a high HLB value and at least one emulsifier with a low

10 HLB value. In one embodiment, the mixture of emulsifiers may comprise a combination of one or more anionic emulsifiers with one or more non-ionic emulsifiers. In another embodiment, the mixture may comprise a combination of anionic emulsifiers. In another embodiment, the mixture may comprise a combination of non-ionic emulsifiers.

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The emulsifying system is preferably present in the composition in an amount in the range 0.01% to 20% w/w, preferably 0.1% to 15% w/w, most preferably 1-10% w/w.

20 In preferred composition according to the present invention, the emulsifying system comprises a liquid crystal forming system, preferably a high level of liquid crystals. Suitably, the emulsifying system comprises at least one high HLB emulsifier and at least one low-medium HLB emulsifier. Examples of high HLB emulsifiers include: methylglucose sesquistearate, sucrose cocoate, decyl

25 glucoside, potassium stearate, isolaureth-4 phosphate, steareth-21, stearete-10, cetareth-12, cetareth-20, oleth-10, polyglyceryl-3 methylglucose distearate, sodium cetearyl sulphate, PEG-12 oleate, PEG-12 stearate or PEG-80 sorbitan. Typically, the high HLB emulsifier is present in an amount in the range 0.01% to 10% w/w, more preferably in the range 0.1% to 5% w/w.

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Examples of low-medium HLB emulsifiers include stearyl alcohol, sorbitan stearate, cetearyl alcohol, glyceryl stearate, stearate-2, cetareth-5, polyglyceryl-3

oleate, PEG-2 stearate, sorbitan oleate sorbitan palmitate or cetyl PEG/PPG/-19/1 dimethicone. Typically, a low-medium HLB emulsifier may be present in the composition in an amount in the range 0.1% to 10% w/w, more preferably in the range 0.5% to 5% w/w.

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Conveniently, the emulsifiers used may be selected from one or more of sorbitan stearate, sucrose cocoate, methyl glucose desquistearate, cetyl phosphate, dicetylphosphate, ceteth-10 phosphate, cetearyl alcohol, glyceryl stearate, cetearyl glucoside, especially methylglucose sesquistearate, stearyl alcohol, sucrose

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cocoate and sorbitan stearate. The combinations of methylglucose sesquistearate/stearyl alcohol or sucrose cocoate/ sorbitan stearate are particularly preferred.

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Optionally other emulsifiers may also be incorporated in compositions according to the invention including steareth-2, steareth-21, steareth-10, cetareth-5, cetareth-12, cetareth-20, oleth-10, polyglyceryl-3 oleate, polyglyceryl-3 methylglucose distearate, sodium cetearyl sulphate, sodium stearate, PEG-12 Oleate, PEG-2 stearate, PEG-12 stearate, sorbitan oleate, sorbitan palmitate and cetyl PEG/PPG-10/1 dimethicone.

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Suitably, thickeners include hydrophilic polymers and derivatives thereof, eg agarose, carbomer, polyacrylamide, alkyl acrylate crosspolymer, carboxymethyl hydroxyethylcellulose, hydroxyethyl cellulose, xanthan gum, cellulose gum, and hydroxypropyl starch.

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Compositions in accordance with the invention may be formulated in any one of numerous different forms. Suitable types of composition, and methods by which they may be prepared, will generally be evident to those skilled in the art.

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Compositions according to the invention are formulated as emulsions. The emulsions may be o/w, w/o, o/w/o or w/o/w emulsions. Preferred emulsion compositions are o/w emulsions. Such emulsion-type compositions may be

described *inter alia* as creams or lotions. Other emulsion compositions are w/o emulsions.

As moisturisation of the skin is an important benefit of the compositions according to the invention, additional ingredients that contribute to improved skin-feel are preferably present. Such additional ingredients may include skin conditioning agents.

Suitable skin conditioning agents that may be present include ingredients having emollient properties, ie ingredients which help to maintain the soft, smooth and pliable appearance of the skin, and which function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking and to improve the skin's appearance. Suitable skin conditioning ingredients will be evident to those skilled in the art, but examples include PPG-15 stearyl ether, ethylhexyl stearate, cetyl dimethicone, octyldodecanol, PPG-20 methyl glucose ether, isopropyl myristate isopropyl palmitate, isopropyl laurate isodecyl laurate, isodecyl neopentanoate, isohexadecane, pentaerythrityl tetraisostearate, caprylic/capric triglyceride, canola oil, sunflower oil (*Helianthus annuus*), olive oil (*Olea europea*), cottonseed oil (*Gossypium herbaceum*), jojoba oil (*Simmondsia chinensis*), shea butter (*Butyrospermum parkii*), cocoa butter (*Theobroma cacao*), cupuacu butter (*Theobroma grandiflorum*), avocado oil (*Persea gratissima*), evening primrose oil (*Oenothera biennis*), mineral oil, liquid paraffin, squalane, dimethicone, phenyl trimethicone, cyclomethicone, cyclopentasiloxane, dimethiconol and petrolatum.

25

The composition will generally also comprise other ingredients or excipients which constitute or form part of a dermatologically acceptable carrier and will be well known to those skilled in the art. These include, for example:

- 30 a) Chelating agents or sequestering agents (sequestrants) – ingredients that have the ability to complex with and inactivate metallic ions in order to prevent their adverse effects on the stability or appearance of the

composition. Examples of chelating agents are ethylenediamine tetraacetic acid and its salts, notably the dipotassium and especially the disodium or tetrasodium salt.

- 5    b)    Preservatives – ingredients which prevent or retard microbial growth and thus protect the composition from spoilage. Examples of preservatives include DMDM hydantoin, propylparaben, methylparaben, phenoxyethanol, sodium benzoate, bronopol, sodium dehydroacetate, polyhexamethylenebiguanide hydrochloride, isothiazolone and  
10        diazolidinylurea.
- c)    Perfumes and colourings.
- d)    pH adjusting agents; and  
15        e)    Anti-oxidants.

As described above, the compositions according to the invention are useful in that they enhance the moisturisation of the skin. Accordingly, in another aspect the  
20    invention provides methods for protecting the skin or for regulating the condition of the skin, which method comprises the topical application to the skin of a composition as herein described. In particular, the above methods protect the skin from the effects of sunlight and/or improve the appearance of the skin following exposure to sunlight. The skin to which the composition is applied will most  
25    commonly be human skin, the composition generally being applied by the user to his or her own skin. Usually, the composition will be applied to areas of skin that are normally exposed, eg the face and/or neck, the arms, hands or legs. A composition according to the invention is applied to the skin for example by rubbing or massaging into the skin, preferably before exposure to the sun for example  
30    minutes before sun exposure. .

In a yet further aspect of the invention, there is provided the use of a moisturising system comprising starch or a derivative thereof and a polymeric quaternary compound salt having humectant properties in the preparation of a skincare composition in the form of an emulsion having an emulsifying system comprising  
 5 an anionic or non-ionic emulsifier and a sunscreen component comprising at least one organic sunscreen selected from the group consisting of bis-ethylhexyloxyphenol methoxyphenyl triazine and methylene bis-benzotriazolyl tetramethylbutylphenol.

10 The present invention also provides a process to prepare a composition as previously described comprising combining said sunscreen component with an oily phase and homogenously mixing with an aqueous phase. In the process, further ingredients may be incorporated into the oil phase/ aqueous phase before and/or after mixing with said active ingredient. One or more active ingredients may be  
 15 added at different stages of the process. Either or both the oil and aqueous phases may be heated before being combined, for example to a temperature in the range 50-100°C.

In the following examples, there are described several preferred embodiments to  
 20 illustrate the invention. However, it is to be understood that the invention is not to be limited to the specific embodiments.

In the examples, Methylene Bis-benzotriazolyl Tetramethylbutylphenol and Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine are available from Ciba Speciality  
 25 Chemicals, D-79630 Grenzach-Wyhlen, Germany, under the trade names Tinosorb M and Tinosorb S respectively; Ethylhexyl Methoxycinnamate and Isoamyl p-Methoxycinnamate are available from Symrise, D20354 Hamburg, Germany under the trade names Parsol MCX and Neo Heliopan E 1000, respectively.

Example 1 : Cream

	<u>Ingredient</u>	<u>% w/w</u>
5	Glycerin	12.0
	Isopropylpalmitate	5.0
	C12-15 Alkyl Benzoate	4.0
	Isoamyl p-Methoxycinnamate	3.75
10	Ethylhexyl Methoxycinnamate	3.716
	Caprylic/Capric Triglyceride	3.5
	Aluminium Starch Octenylsuccinate	3.0
	Dimethylimidazolidinone Rice Starch	2.5
	Methylene Bis-benzotriazolyl Tetramethylbutylphenol	2.5
15	Cyclomethicone	2.0
	Methyl Glucose Sesquistearate	2.0
	Stearylalcohol	2.0
	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	1.9
	Phenoxyethanol	1.0
20	Parfum	0.5
	Decyl Glucoside	0.45
	Sodium Hydroxide	0.05
	Carbomer	0.12
	Propylene Glycol	0.025
25	Xanthan Gum	0.025
	Polyquaternium-51	0.01
	BHT	0.003
	Water	to 100%

30

Method

- 35 The sunscreens, excepting Methylene Bis-benzotriazolyl Tetramethylbutylphenol, the emulsifiers and other oily ingredients were combined to form the oil phase.

The moisturising system was combined with the water and water-soluble ingredients to form the aqueous phase. The oil and water phases were independently heated to 70 -80°C and the oil phase admixed with the water phase. The two phases were homogenised and cooled with careful stirring. Ingredients

- 5 sensitive on temperature, including Methylene Bis-benzotriazolyl Tetramethylbutylphenol, were then added to the emulsion at room temperature and the pH adjusted.

#### Example 2 : Cream

10	<u>Ingredient</u>	<u>% w/w</u>
	Glycerin	12.0
	Sorbitan Stearate	5.09
15	C12-15 Alkyl Benzoate	5.0
	Ethylhexyl Methoxycinnamate	7.433
	Caprylic/Capric Triglyceride	3.0
	Aluminium Starch Octenylsuccinate	3.0
	Isohexadecane	3.0
20	Dimethylimidazolidinone Rice Starch	2.5
	Methylene Bis-benzotriazolyl Tetramethylbutylphenol	2.5
	Cyclomethicone	2.0
	Cetearyl Alcohol	1.0
	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	1.9
25	Butyrospermum parkii	1.0
	Phenoxyethanol	1.0
	Parfum	0.5
	Decyl Glucoside	0.45
	Sucrose Cocoate	0.41
30	Xanthan Gum	0.125
	Tocopherol	0.1
	Carbomer	0.120
	EDTA	0.05
	Sodium Hydroxide	0.04



Propylene Glycol	0.025
Polyquaternium-51	0.01
BHT	0.007
Water	to 100%

5

Method

10 The composition of Example 2 was prepared in a similar manner to that described in Example 1.

Example 3 : Cream

15	<u>Ingredient</u>	<u>% w/w</u>
	Glycerin	10.53
	C12-15 Alkyl Benzoate	8.0
	Ethylhexyl Methoxycinnamate	4.96
20	Propylene Glycol	4.0
	Cyclomethicone	4.0
	Caprylic/Capric Triglyceride	3.5
	Aluminium Starch Octenylsuccinate	3.0
	Triethylhexanoin	3.0
25	Cetearyl Alcohol	3.0
	Dimethylimidazolidinone Rice Starch	2.5
	Isohexadecane	2.5
	Glyceryl Stearate SE	2.0
	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	1.7
30	Titanium Dioxide	2.4
	Methylene Bis-benzotriazolyl Tetramethylbutylphenol	1.4
	Cetearyl Glucoside	1.25
	Butyrospermum parkii	1.0
	Phenoxyethanol	1.0
35	Parfum	0.5
	Decyl Glucoside	0.25

	Isolaureth-4 Phosphate	0.3
	PEG-25 Butyl Vinylether / Sodium Maleate Copolymer	0.3
	Carbomer	0.12
	Tocopherol	0.1
5	Sodium Hydroxide	0.06
	EDTA	0.05
	Xanthan Gum	0.014
	Polyquaternium-51	0.01
	BHT	0.005
10	Butylmethoxydibenzoyl methane	1.5
	Water	to 100%

#### Method

- 15 The composition of Example 3 was prepared in a similar manner to that described in Example 1.

#### Example 4 : Cream

20	<u>Ingredient</u>	<u>% w/w</u>
	Glycerin	12.0
	C12-15 Alkyl Benzoate	6.0
25	Ethylhexyl Methoxycinnamate	4.459
	Caprylic/Capric Triglyceride	3.5
	Aluminium Starch Octenylsuccinate	3.0
	Dimethylimidazolidinone Rice Starch	2.5
	Isohexadecane	2.5
30	Cyclomethicone	2.0
	Triethylhexanoin	2.0
	Methylene Bis-benzotriazolyl Tetramethylbutylphenol	2.0
	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	1.9
	Butyrospermum parkii	1.0
35	Phenoxyethanol	1.0

	Parfum	0.5
	Decyl Glucoside	0.36
	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0.2
	Carbomer	0.2
5	Tocopherol	0.1
	EDTA	0.05
	Sodium Hydroxide	0.03
	Propylene Glycol	0.025
	Xanthan Gum	0.02
10	Polyquaternium-51	0.01
	BHT	0.005
	Water	to 100%

#### Method

- 15 The composition of Example 4 was prepared in a similar manner to that described in Example 1.

#### 20 Example 5 : Cream

	<u>Ingredient</u>	<u>% w/w</u>
	Glycerin	12.0
25	C12-15 Alkyl Benzoate	6.0
	Ethylhexyl Methoxycinnamate	3.996
	Caprylic/Capric Triglyceride	3.5
	Aluminium Starch Octenylsuccinate	3.0
	Dimethylimidazolidinone Rice Starch	2.5
30	Cyclomethicone	2.0
	Triethylhexanoin	2.0
	Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine	1.7
	Methylene Bis-benzotriazolyl Tetramethylbutylphenol	1.4
	Butyrospermum parkii	1.0
35	Phenoxyethanol	1.0

	Parfum	0.5
	Decyl Glucoside	0.25
	Acrylates/C10-30 Alkyl Acrylate Crosspolymer	0.2
	Isolaureth-4 Phosphate	0.1875
5	PEG-25 Butyl Vinylether / Sodium Maleate Copolymer	0.1875
	Carbomer	0.18
	Tocopherol	0.1
	EDTA	0.05
	Sodium Hydroxide	0.04
10	Propylene Glycol	0.014
	Xanthan Gum	0.014
	Polyquaternium-51	0.01
	BHT	0.004
	Water	to 100%

15

Method

The composition of Example 5 was prepared in a similar manner to that described in Example 1.

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Clinical Trial

25 The continuous moisturisation effect of Examples 1 and 2 was measured using a standard Corneometer CM 825. The method by which moisturisation is measured is based on the dielectric constant of water. Due to the high dielectric constant of water, the dielectric characteristics of the stratum corneum are related to the water content. Assuming constant frequency, temperature and structure of the skin  
30 surface, an increase of capacitance correlates with an increase in skin hydration.

The study was conducted double blind on 30 female volunteers with dry skin. The investigation sites were localised at the inner sides of both forearms. The skin hydration was measured immediately before product application (t zero), after 2  
35 hours , 4 hours, 6 hours , 8 hours and 12 hours .

The results below represent the skin hydration relative to t zero (=1) and how it changes over time.

Times of control	2 hrs	4 hrs	6 hrs	8 hrs	10 hrs	12 hrs
Example 1	1,50	1,50	1,46	1,41	1,40	1,39
Example 2	1,47	1,43	1,43	1,39	1,38	1,37

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It can be seen that both formulations exhibited an advantageous continuous moisturisation profile. In addition, both formulations were deemed to provide valuable sunscreen profiles.

## Claims

1. A skincare composition in the form of an emulsion comprising:
  - 5 a) a sunscreen component comprising at least one organic sunscreen selected from the group consisting of bis-ethylhexyloxyphenol methoxyphenyl triazine and methylene bis-benzotriazolyl tetramethylbutylphenol;
  - 10 b) a moisturising system comprising starch or a derivative thereof and a polymeric quaternary compound salt having humectant properties; and
  - c) an emulsifying system comprising at least one emulsifier comprising an anionic or non-ionic emulsifier.
- 15 2. A composition as claimed in Claim 1 wherein the sunscreen component comprises bis-ethylhexyloxyphenol methoxyphenyl triazine in combination with one or more of methylene bis-benzotriazolyl tetramethylbutylphenol, ethylhexyl methoxycinnamate, isoamyl p-methoxycinnamate and butyl methoxydibenzoylmethane.
- 20 3. A composition as claimed in Claim 1 wherein the sunscreen component comprises methylene bis-benzotriazolyl tetramethylbutylphenol in combination with one or more of bis-ethylhexyloxyphenol methoxyphenyl triazine, ethylhexylmethoxy cinnamate, isoamyl p-methoxycinnamate and butyl
  - 25 methoxydibenzoylmethane.
4. A composition as claimed in any preceding claim wherein the sunscreen component comprises a combination of bis-ethylhexyloxyphenol methoxyphenyl triazine, methylene bis-benzotriazolyl tetramethylbutylphenol and
  - 30 ethylhexylmethoxy cinnamate, optionally including isoamyl p-methoxycinnamate.

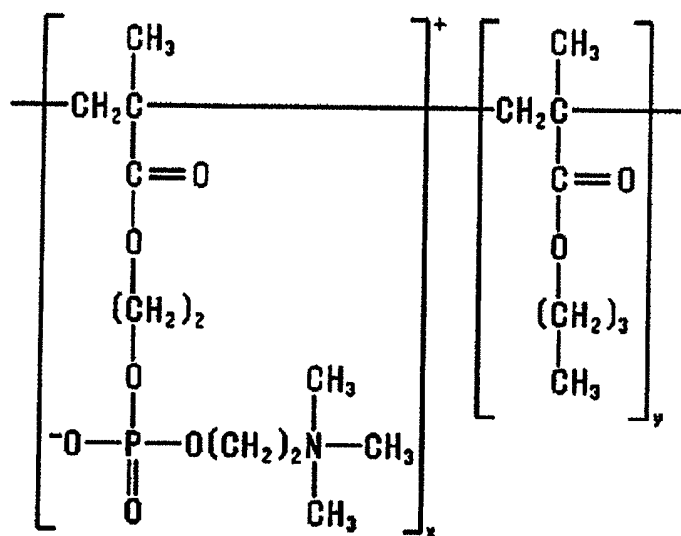
5. A composition as claimed in any preceding claim comprising said sunscreen component in an amount greater than 2.5% w/w, more preferably greater than 5% w/w and most preferably greater than 10% w/w.
- 5 6. A composition as claimed in any preceding claim comprising said sunscreen component in an amount less than 25% w/w, more preferably less than 20% w/w, more preferably less than 10% w/w.
7. A composition as claimed in any preceding claim wherein the sunscreen  
10 component is present in the range 2.5% to 25% w/w, more preferably in the range 5% to 20% w/w and most preferably in the range 10% to 18% w/w.
8. A composition according to any preceding claim further comprising an inorganic sunscreen agent, preferably titanium dioxide.  
15
9. A composition according to Claim 8 wherein said inorganic sunscreen agent is present in the range 1% to 10% w/w, more preferably in the range 2% to 8% w/w and most preferably in the range 3% to 7% w/w.
- 20 10. A composition as claimed in any preceding claim, wherein the starch or starch derivative is a chemically or physically modified starch.
11. A composition as claimed in any preceding claim, wherein the starch derivative is a product obtained by reaction of 1,3-dimethyl-4,5-dihydroxy-2-  
25 imidazolidinone (dimethyl imidazolidinone) with starch.
12. A composition as claimed in any preceding claim, wherein the starch derivative is dimethylimidazolidinone rice starch.
- 30 13. A composition as claimed in any preceding claim, wherein the starch or starch derivative is present in the composition at a level of less than 15% w/w, preferably less than 10% w/w, and more preferably less than 5% w/w.

14. A composition as claimed in any preceding claim, wherein the starch derivative is present in the composition at a level of greater than 0.1% w/w, and more preferably greater than 1% w/w.

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15. A composition as claimed in any preceding claim, wherein the concentration of starch derivative is in the range 0.1% to 15% w/w, and more preferably in the range 1% to 5% w/w, particularly 2.25% to 3.75% w/w.

10 16. A composition as claimed in any preceding claim, wherein the polymeric quaternary ammonium salt is Polyquaternium-51, ie the polymeric quaternary ammonium salt that conforms generally to the formula:



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17. A composition as claimed in any preceding claim, wherein the ammonium salt is present in the composition at a level of less than 1% w/w, more preferably less than 0.1% w/w.

20 18. A composition as claimed in any preceding claim, wherein the ammonium salt is present in the composition at a level greater than 0.0001% w/w, and more preferably greater than 0.001% w/w.



19. A composition as claimed in any preceding claim, wherein the concentration of ammonium salt is in the range 0.0001% to 1% w/w, and more preferably in the range 0.001% to 0.1% w/w.

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20. A composition as claimed in any preceding claim, wherein the ratio of moisturising system to sunscreen component is in the range 1:1 to 1:20 parts by weight, more preferably 1:2 to 1:10 parts by weight, most preferably 1:4 to 1:6 parts by weight.

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21. A composition as claimed in any preceding claim, which further comprises one or more additional moisturising or humectant ingredients.

22. A composition as claimed in Claim 21, wherein the additional moisturising or humectant ingredient is a relatively low molecular weight polyalcohol, eg a C<sub>2-6</sub> aliphatic polyalcohol.

23. A composition as claimed in Claim 22, wherein the polyalcohol is selected from the group consisting of glycerin (1,2,3-trihydroxypropane), 1,3-butylene glycol and propylene glycol.

24. A composition as claimed in any one of Claims 21 to 23, wherein the additional moisturising or humectant ingredients are present in the composition at a concentration of up to 25% w/w or more, more preferably up to 20% w/w.

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25. A composition as claimed in any one of Claims 21 to 24, wherein the additional moisturising or humectant ingredient(s) are present in the composition at a level of greater than 1% w/w, more preferably greater than 5% w/w, and most preferably greater than 10% w/w.

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26. A composition as claimed in any one of Claims 21 to 25, wherein the concentration of additional moisturising or humectant ingredient(s) is in the range

1% to 25% w/w, and more preferably in the range 10% to 20% w/w, and in particular in the range 10% to 15% w/w.

27. A composition as claimed in any preceding claim, which comprises glycerin.

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28. A composition as claimed in any preceding claim wherein the oil comprises one or more of silicone oils, mineral oils, vegetable oils and triglycerides, especially mineral oils and vegetable oils, preferably butyrospermum parkii, caprylic/capric triglyceride, C12-15 alkyl benzoate, isohexadecane, triethylhexanoin, cyclomethicone, dimethicone, glycerin, cetearyl alcohol, isopropylpalmitate, stearyl alcohol, cetyl alcohol, stearyl dimethicone, glyceryl myristate, paraffinum liquidum, acrylates copolymer and decyl cocoate or mixtures thereof and most preferably a combination of glycerin, C12-15 alkyl benzoate, caprylic/capric triglyceride, cyclomethicone and stearyl alcohol, optionally in combination with one or more further oils.

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29. A composition as claimed in any preceding claim wherein said oil is present in an amount in the range 4% to 50% w/w, more preferably in the range 6% to 30% w/w and most preferably in the range 8% to 20% w/w.

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30. A composition as claimed in any preceding claim wherein said water is present in an amount in the range 20% to 80% w/w, more preferably in the range 25% to 75% w/w and most preferably in the range 35% to 55% w/w.

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31. A composition as claimed in any preceding claim, wherein the emulsifying system comprises a liquid crystal forming system.

32. A composition as claimed in any preceding claim, wherein the emulsifying system comprises at least one high HLB emulsifier and at least one low-medium HLB emulsifier.

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33. A composition as claimed in Claim 32 wherein the high HLB emulsifier comprises one or more of methylglucose sesquistearate, sucrose cocoate, decyl glucoside, potassium stearate, isolaureth-4 phosphate, steareth-21, stearete-10, cetareth-12, cetareth-20, oleth-10, polyglyceryl-3 methylglucose distearate,  
 5 sodium cetearyl sulphate, PEG-12 oleate, PEG-12 stearate or PEG-80 sorbitan.

34. A composition as claimed in either one of Claims 32 or 33 wherein the high HLB emulsifier is present in an amount in the range 0.01% to 10% w/w, more preferably in the range 0.1% to 5% w/w.

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35. A composition as claimed in Claim 32 wherein the low-medium HLB emulsifier comprises stearyl alcohol, sorbitan stearate, cetearyl alcohol, glyceryl stearate, stearate-2, cetareth-5, polyglyceryl-3 oleate, PEG-2 stearate, sorbitan oleate sorbitan palmitate or cetyl PEG/PPG/-19/1 dimethicone.

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36. A composition as claimed in Claim 35 wherein the low-medium emulsifier is present in the composition in an amount in the range 0.1% to 10% w/w, more preferably in the range 0.5% to 5% w/w.

20 37. A composition as claimed in any preceding claim, which further comprises one or more emollients and/or thickeners.

38. A composition as claimed in any preceding claim, which further comprises one or more ingredients selected from the group consisting of:

- 25 a) skin conditioners;  
 b) stabilizers;  
 c) chelating agents;  
 d) anti-oxidants;  
 e) preservatives;  
 30 f) perfumes and colourings;  
 g) pH adjusting agents; and  
 h) anti-oxidants.

39. A method for moisturising skin, which method comprises the topical application to the skin of a composition as claimed in any preceding claim.



For Innovation

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**Application No:** GB0611743.6

**Examiner:** Dr Jim Houlihan

**Claims searched:** 1-39

**Date of search:** 9 October 2006

## Patents Act 1977: Search Report under Section 17

### Documents considered to be relevant:

Category	Relevant to claims	Identity of document and passage or figure of particular relevance
A	1, at least	US2005/0266055 A (Stiller S et.al.) page 15, Table
A	1, at least	EP1371359 A (Belersdorf AG) page 31-33, "O/W Emulsionen"

### Categories:

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category	P	Document published on or after the declared priority date but before the filing date of this invention
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application

### Field of Search:

Search of GB, EP, WO & US patent documents classified in the following areas of the UKC<sup>X</sup> :

Worldwide search of patent documents classified in the following areas of the IPC

A61K

The following online and other databases have been used in the preparation of this search report

Caplus, EPODOC, WPI