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(54) Title: WATER-BASED SKIN PRODUCTS

(57) Abstract: Water-based skin products that are free of alcohol may include a gel or a mousse for sanitising the skin or an ultrasound transmitting lubricating gel. The gel or mousse skin sanitiser may include a skin moisturiser, an antimicrobial agent and a foaming aid or a gelling agent. The ultrasound transmitting lubricating gel may include a skin moisturiser, a gelling agent and a lubricant.

WATER-BASED SKIN PRODUCTS

This application relates to water-based products for use on skin. In particular, it relates to a skin sanitiser and to a lubricating gel.

It is well known that in certain environments, such as in hospitals, cleanliness and disinfection are of paramount importance. Hospital staff are encouraged to wash and/or disinfect their hands between patients. Furthermore, hospital equipment should be sterilised between use on different patients.

Effective hand-washing is time-consuming. To speed up this process, hand sanitisers that can be simply rubbed into the skin without the need for rinsing have been developed. These generally involve the use of alcohol as an antimicrobial agent. As alcohol evaporates quickly at body temperature it is also quick-drying.

However, there are several disadvantages with alcohol-based skin sanitisers. Alcohol dries the skin, and so repeated use can lead to skin damage. Whilst its evaporation at body temperature leads to quick drying, it also means it can have evaporated before the user has been able to rub it into all parts of their hand. Alcohol is also highly flammable, which could have dangerous consequences in the case of a spill. Alcohol-containing products may also be problematic for strict members of religions such as Islam.

US 2003/0139307 discloses a sanitising hand cleanser intended to address some of the problems relating to high alcohol content. The disclosed cleanser nevertheless contains an effective amount of alcohol to produce a reduction in micro-organisms and is not water-based. The disclosed cleanser thus suffers from one or more of the above disadvantages associated with alcohol-containing sanitisers.

US 2004/0219227 relates to hydroalcoholic gel formulations for skin disinfection. The disclosed formulations generally include a high percentage of ethanol or propan-2-ol. Whilst this document discloses an antiseptic aqueous formulation, this still contains 2%

stearyl alcohol. The disclosed formulations thus suffer from at least one of the above problems associated with alcohol-containing skin sanitisers.

US 6,627,207 discloses a water-based gel-type skin sanitiser, having a low alcohol content. It discloses gel-type compositions containing from 5.9 to 31.1% by weight ethanol. Again, as the disclosed compositions contain ethanol, at least one of the above problems relating to alcohol-containing skin sanitisers applies.

US 6,977,082 relates to antibacterial compositions. Compositions including an active antibacterial agent, a surfactant, a hydrotrope, a hydric solvent (which may be an alcohol), at least one of a skin care agent, a foam stabiliser (which may be an alcohol) or a humectant, and water. The inventors found that cetyl alcohol provided the best results as a foam stabiliser.

US 7,192,601 discloses an antimicrobial and sporicidal composition that may be used as a topical skin care formulation. The composition may include ethanol or propan-2-ol as an antibacterial agent. Monohydric alcohols may also be used as emulsifiers/surfactants.

US 2007/0071537 discloses a sanitising wipe containing an antimicrobial liquid cleansing formulation. The formulation may be diluted with alcohol.

US 2003/0008791 discloses a liquid hand sanitiser. The sanitiser includes an antimicrobial agent, a spreading agent (or surfactant), a humectant, a thickener, a preservative, a fragrance and water. It is preferably substantially free of alcohol, but may contain up to 1% by weight of alcohol.

WO 2006/092581 discloses a lubricating composition prepared primarily from natural ingredients.

US 2006/0127316 discloses a lubricant ultrasound transmission medium that does not contain water. The medium may be prepared in alcohol.

WO 2007/038855 discloses an antimicrobial gel that may be used as an ultrasound transmission medium. The gel includes a solvent (which may be water), a thickener (which may be hydroxyethyl cellulose) and an antimicrobial agent. It may further include xamtham gum and/or propylene glycol.

According to a first aspect of the present invention, there is provided a water-based skin sanitiser that is free of alcohol, wherein the skin sanitiser is a gel or a mousse.

The skin sanitiser preferably includes: a skin moisturiser; an antimicrobial agent; and a foaming aid or a gelling ingredient.

Preferably, the skin moisturiser is a skin humectant and/or a skin soothant and/or a skin softener.

The skin sanitiser may further include any or all of: a surfactant, a pH adjuster, a pH balancer, a colorant, a preservative.

In an embodiment, the skin sanitiser may include a plant-based ingredient such as aloe vera; a diol such as propylene glycol or ethylene glycol; PEG-8 dimethicone, PEG-8 ricinoleate, polyquaternium 57; and/or a polysorbate such as polysorbate 20.

In an embodiment, the antimicrobial agent may be an antibacterial agent such as cetrimide, chlorhexidine digluconate, benzalkonium chloride, and/or triclosan.

The antimicrobial agent may be provided in an amount of about 0.495-0.88%. In certain embodiments it is provided in an amount of about 0.495-0.605% or about 0.72%-0.88%.

When the skin sanitiser is a sanitising gel the gelling agent may be an acrylates/C10-30 alkyl acrylates crosspolymer.

In a preferred embodiment the skin sanitiser is a gel and includes a skin soothant, a skin humectant, a gelling agent, an antimicrobial agent, a surfactant, a pH adjuster, a pH balancer and a colourant.

Preferably the gel includes about 3.6-4.4% skin soothant, about 18-22% skin humectant, about 0.45-0.55% gelling ingredient, about 0.495-0.88% antimicrobial agent, about 1.35-1.65% surfactant, about 0.027-0.033% pH adjuster, about 0.72-0.88% triethanolamine, and/or about 0.0009-0.0011% colourant.

In a particularly preferred embodiment, the gel includes about 4% skin soothant about 20% skin humectant, about 0.5% gelling ingredient, about 0.8% antimicrobial agent, about 1.5% surfactant, about 0.03% pH adjuster; about 0.8% pH balancer and/or about 0.001% colourant.

When the skin sanitiser is a sanitising mousse, it may include a foaming aid, which may also act as an antimicrobial agent, such as cetrimide and/or chlorhexidine digluconate.

In a preferred embodiment, the skin sanitiser is a mousse and includes a skin soothant, a skin humectant, a skin moisturiser or softener, an antimicrobial agent, a foaming aid, a preservative and a pH adjuster.

Preferably the mousse includes about 1.8-2.2% skin soothant, about 4.5-5.5% skin humectant, about 0.63-0.77% skin moisturiser or softener; about 0.405-0.495% foaming aid/antimicrobial agent; about 0.18-0.22% preservative; about 0.18-0.22% pH adjuster, and/or about 0.09-0.11% antimicrobial agent.

In a particularly preferred embodiment, the mousse includes about 2% skin soothant, about 5% skin humectant, about 0.7% skin moisturiser or softener, about 0.25% foaming aid/antimicrobial agent, about 0.2% preservative, about 0.2% pH adjuster, and/or about 0.1% antimicrobial agent.

According to a second aspect of the present invention, there is provided a water-based ultrasound transmitting lubricating gel that is free of alcohol.

The lubricating gel preferably includes: a skin moisturiser; a gelling agent; and a lubricant.

Preferably the skin moisturiser is a skin humectant.

The lubricating gel may further include any or all of a thickening agent, a preservative, a pH adjuster.

Preferably, the lubricant also acts as a thickening agent.

In an embodiment the lubricating gel may include a diol such as propylene glycol or ethylene glycol; a cellulose ether such as hydroxyethylcellulose; a polysaccharide such as xantham gum, a paraben such as methylparaben, ethylparaben, propylparaben or butylparaben; and/or disodium EDTA.

Preferably the lubricating gel includes about 18-22% skin humectant, about 0.9-1.1% lubricant; about 0.09-0.11% gelling agent, about 0.36-0.44% preservative; and/or about 0.09-0.11% pH adjuster.

In a particularly preferred embodiment the lubricating gel includes about 20% skin humectant; about 1% lubricant; about 0.1% gelling agent; about 0.4% preservative, and/or about 0.1% pH adjuster.

The applicant has developed water-based sanitising products and conductance/lubricating gels that contain no alcohol. The products are highly effective and also contain ingredients to improve the condition of the skin. The following Examples are illustrative and are in no way limiting.

Example 1: Sanitising Gel

A preferred sanitising gel includes the following ingredients 4.00% aloe barbadensis (10x strength) (obtainable as USA Best 10-1 Aloe Vera™ from Paroxite), 20.00% propylene glycol; 0.50% acrylates/C10-30 alkyl acrylates cross polymer (CARBOPOL® Ultrez 20 polymer from Noveon); 0.25% cetrimide (Surfac Cetrimide BP Powder obtainable from Surfachem); 0.30% chlorhexidine digluconate (Surfac CHX20 obtainable from Surfachem); 1.50% polysorbate 20 (Surfacare T20 available from Surfachem Group Limited); 0.03% disodium EDTA; 0.80% triethanolamine (Surfac Triethanolamine standard available from Surfachem Group Limited); and 0.001% CI 42090 (FDC Blue No. 1) (from Simpsons (UK) Ltd) dissolved in UV irradiated water.

The gel is made by mixing 95% of the water and the disodium EDTA in a suitable first vessel until the disodium EDTA has dissolved. Subsequently, whilst mixing, the acrylates/C10-30 alkyl acrylates crosspolymer is added. Mixing is continued until fully wetted. The next step is to add (with mixing) the aloe barbadensis, the propylene glycol, and the CI 42090 and mix well. In a separate second vessel, a premix of the cetrimide, and 5% of the total required water is formed. This is mixed until there is no visible solid. The chlorhexidine digluconate is then added to the second vessel and mixed well, followed by the polysorbate 20, which is mixed well. The mixer in the main vessel is turned off, thereby allowing the mixture therein to stand for 30 minutes. After this time, the triethanolamine is added to the first vessel and mixed until fully gelled. The pH should be adjusted to approximately 8. With slow stirring, the premix in the second vessel is added to the first vessel by slowly pouring over a period of 10 to 20 minutes.

The resulting gel is a clear pale blue viscous gel having no characteristic odour. Its specific gravity is 1.01± 0.15 at 25°C and its viscosity is 20,000 cps ± 3,000 cps. The pH at 25°C is between 7.70 and 8.50. Fewer than 100 cfu/ml were identified in microbiological tests, with a complete absence of pathogens.

The gel is subsequently packaged in a 50ml PVC inverted bottle that can clip onto a pocket or belt.

The sanitising gel can be used in any environment where quick and effective skin sanitisation is required. The user simply squirts some of the gel onto their hands and rubs it all over. Within 30 seconds to one minute the gel is absorbed; there is therefore no need to rinse.

There are several advantages to the above-described embodiment

The sanitising gel has excellent sanitisation properties by inclusion of the antibacterial agents cetrimide and chlorhexidine digluconate. Furthermore, it is beneficial to the skin of the user by inclusion of moisturisation ingredients and skin softening ingredients.

Aloe barbadensis is a plant extract having beneficial skin soothing properties. Propylene glycol acts as a skin humectant, and advantageously allows the product to have a longer lasting effect.

Polysorbate 20 acts as a surfactant. Advantageously, it also acts as a fragrance solubiliser and stabiliser, it acts as a lubricator and has a soothing effect on the skin.

Disodium EDTA allows the pH of the product to be adjusted to the pH of the skin (approximately 6). Triethanolamine acts as a pH balancer.

This product fulfils the requirements of BS EN 1276:1997 (suspension test) and BS EN 1500:1997 (human volunteer) despite the absence of alcohol.

In a modification, the amount of cetrimide is 0.5%. In another modification, benzalkonium chloride is used as an antibacterial agent instead of cetrimide. Preferably, the amount of benzalkonium chloride is 0.5%.

Example 2: Sanitising Mousse

A preferred sanitising mousse contains 2.00% aloe barbadensis (10x strength) (for example, obtainable as USA Best 10-1 Aloe Vera™ from Paroxite); 5.00% propylene glycol; 0.70% PEG-8 dimethicone, PEG-8 ricinoleate, polyquaternium 57 (available as Zenicone XQ™ from Zenitech®), 0.25% cetrimide (available from Surfachem Group Ltd as Surfac Cetrimide BP Powder), 0.20% chlorhexidine digluconate (available as Surfac CHX20 from Surfachem Group Ltd); 0.20% citric acid; 0.20% disodium EDTA and; 0.10% triclosan in UV irradiated water.

The mousse is made by, in a suitable first vessel, premixing 10% of the water with the disodium EDTA and warming the mixture until the disodium EDTA has dissolved. The remainder of the water is added to a second suitable vessel, then, with mixing, the disodium EDTA solution, the aloe vera (10x), the cetrimide, the chlorhexidine digluconate, the PEG-8 dimethicone, PEG-8 ricinoleate polyquaternium 57 and the citric acid are added and mixed until all of the solids have been solubilised. In a third suitable vessel, the propylene glycol and the triclosan are warmed and mixed until solubilised. The propylene glycol/triclosan mix is then slowly poured into the main mixture in the second vessel whilst mixing.

The result is a clear liquid having no characteristic odour. Its specific gravity is 1.01 ± 0.15 at 25°C. The pH at 25°C is 6.00 ± 0.60. Fewer than a hundred cfu/ml were found in microbiological tests with a complete absence of pathogens.

The liquid is packaged in a 50ml cylindrical bottle having a pump-action dispenser.

As with the above-described sanitising gel, the user squirts an appropriate amount of mousse onto their hands and rubs it in to provide effective sanitization. The mousse dries; there is therefore no requirement for rising.

The sanitising mousse has excellent sanitisation properties due to the inclusion of the antibacterial agents cetrimide, chlorhexidine digluconate and triclosan. Advantageously, cetrimide and chlorohexidine digluconate also act as foaming aids.

The mousse also contains ingredients beneficial to the user's skin. Aloe barbadensis is a plant extract having skin soothing properties. Propylene glycol is not only a skin humectant, but advantageously allows the product to have a longer lasting effect. PEG-8 dimethicone, PEG-8 ricinoleate, polyquaternium 57 is a high density polymer with excellent moisturisation and skin softening properties, which softens and moisturises the skin on use.

The disodium EDTA can be used to adjust the pH of the product to the pH of the skin (approximately 6). The citric acid acts as a cleaning agent, a preservative and an antioxidant.

Furthermore, the mousse is not an aerosol and so there is no risk of any aerosol propellant interfering with remaining ingredients.

The mouse has undergone microbiological testing and this product fulfils the requirements of BS EN 1276:1997 (suspension test) and BS EN 1500:1997 (human volunteer) despite the absence of alcohol.

In a modification, the amount of cetrimide is 0.5%. In another modification, benzalkonium chloride is used as an antibacterial agent instead of cetrimide. Preferably, the amount of benzalkonium chloride is 0.5%.

Example 3: Lubricating Gel

A lubricating gel that can be used for ultrasound transmission preferably contains 20.0% propylene glycol; 1.0% hydroxyethylcellulose (for example, that can be obtained as Natrosol® 250 HHR from Crestchem); 0.1% xanthan gum (such as can be obtained as Keltrol® CGRD from CPKelco); 0.2% methylparaben; 0.2% imidazolidinyl urea (such

that as that which can be obtained as Surfacare PC GM115 from Surfachem); and 0.1% disodium EDTA in UV irradiated water.

To manufacture the gel, the water is added to a first suitable vessel, and with a mixer the imidazolidinyl urea, disodium EDTA are added and mixed until there are no visible solids (this takes approximately 30 minutes). In a separate second suitable vessel the methylparaben is dissolved in the propylene glycol by gently warming to increase the rate of solubility. The methylparaben/propylene glycol mixture is then added to the imidazolidinyl urea/disodium EDTA solution and mixed well. Then, the hydroxyethylcellulose and xanthan gum are added with mixing; mixing is continued until the gum and the cellulose are fully hydrated (this takes at least three hours).

The resulting product is a clear, colourless, flowable gel having no characteristic odour. Its specific gravity is 1.01 ± 0.15 at 25°C and it has a viscosity of 25,000 cps ± 3,000 cps at 25°C. The pH of the gel at 25°C is 6.00 ± 0.60. Fewer than 100 cfu/ml were found in microbiological tests, and there was a complete absence of pathogens.

The gel is packaged into 8ml single use sachets.

A microbiological challenge test has shown this conductance gel to fulfil the requirements of the BP (1999). The results are shown in Table 1:

Organism	Innoculum level cfu g/ml product	Recovery cfu g or ml				
		0	2 days	7 days	14 days	28 days
Pseudomonas aeruginosa ATCC 9987	8.7 x 10e6	2.0 x 10e6	<100	<10	<10	<10
Staphylococcus aureus ATCC 6538	6.0 x10e6	9.8 x 10e5	<100	<10	<10	<10
Escherichia coli HCTC 8545	1.0 x 10e6	9.8 x 10e5	<100	<10	<10	<10
Aspergillus niger ATCC 16404	3.9 x 10e5	3.4 x 10e5	NT	3.0 x 10e3	4.0 x 10e2	10
Candida albicans HCTC NDFF 3153	1.1 x 10e6	9.3 x 10e5	NT	<100	<10	<10

In use, the desired amount of product is applied onto the area required and is gently massaged over the area. It is particularly envisaged for use during ultrasound examination (both external and internal).

There are several advantages to the above lubricating gel. It can be used during ultrasound examination and it has high lubricity. It contains no alcohol or fragrance thereby reducing the risk of irritating the skin of the person undergoing the procedure. The gel does not dry the skin, and it is also oil free.

Hydroxyethylcellulose is the main thickening agent, which advantageously has lubricating properties. Furthermore xanthan gum is a naturally derived gelling agent, which also improves the lubricity of the product. Propylene glycol acts as a skin humectant, and advantageously allows the product to have a longer lasting effect.

Methylparaben and imidazolidinyl urea contribute to the preservative properties of the product. Disodium EDTA allows the pH of product to be adjusted to that of the skin (approximately 6.0). It also has sequestering properties.

A skilled person will appreciate that modifications may be made to the above preferred embodiments without departing from the scope of this invention. For example, it is clear that certain preferred ingredients, such as the colourant, could be omitted whilst still retaining the advantages of the products described herein. Furthermore, preferred ingredients may be substituted by other ingredients having similar properties.

The disclosures in United Kingdom patent application no. 0720574.3, from which this application claims priority, and in the abstract accompanying this application are incorporated herein by reference.

CLAIMS

1. A water-based skin sanitiser that is free of alcohol, wherein the skin sanitiser is a gel or a mousse.

2. A skin sanitiser as claimed in claim 1, including a skin moisturiser; an antimicrobial agent; and a foaming aid or a gelling ingredient.

3. A skin sanitiser as claimed in claim 2, wherein the skin moisturiser is a skin humectant and/or a skin soothant and/or a skin softener.

4. A skin sanitiser as claimed in claim 1, 2 or 3, including any or all of: a surfactant, a pH adjuster, a pH balancer, a colorant, a preservative.

5. A skin sanitiser as claimed in any preceding claim, including a plant-based ingredient; a diol; PEG-8 dimethicone, PEG-8 ricinoleate, polyquaternium 57; and/or a polysorbate.

6. A skin sanitiser as claimed in any preceding claim, including an antimicrobial agent.

7. A skin sanitiser as claimed in claim 6, wherein the antimicrobial agent is an antibacterial agent.

8. A skin sanitiser as claimed in claim 6 or 7, wherein the amount of antimicrobial agent is about 0.495%-0.88%.

9. A skin sanitiser as claimed in claim 8, wherein the amount of antimicrobial agent is about 0.495-0.605%.

10. A skin sanitiser as claimed in claim 8, wherein the amount of antimicrobial agent is about 0.72-0.88%.

11. A skin sanitiser as claimed in claim 7, wherein the antibacterial agent is cetrimide, chlorhexidine digluconate, benzalkonium chloride, and/or triclosan.

12. A skin sanitiser as claimed in any preceding claim, wherein the skin sanitiser is a gel, and wherein the gelling agent is an acrylates/C10-30 alkyl acrylates crosspolymer.

13. A skin sanitiser as claimed in any preceding claim, wherein the skin sanitiser is a gel and includes a skin soothant, a skin humectant, a gelling agent, an antimicrobial agent, a surfactant, a pH adjuster, a pH balancer and a colourant.

14. A skin sanitiser as claimed in any preceding claim, wherein the gel includes about 3.6-4.4% skin soothant, about 18-22% skin humectant, about 0.45-0.55% gelling ingredient, about 0.495-0.88% antimicrobial agent, about 1.35-1.65% surfactant, about 0.027-0.033% pH adjuster, about 0.72-0.88% triethanolamine, and/or about 0.0009-0.0011% colourant.

15. A skin sanitiser as claimed in claim 14, wherein the gel includes about 4% skin soothant about 20% skin humectant, about 0.5% gelling ingredient, about 0.8% antimicrobial agent, about 1.5% surfactant, about 0.03% pH adjuster; about 0.8% pH balancer and/or about 0.001% colourant.

16. A skin sanitiser as claimed in any of claims 1 to 11 wherein the skin sanitiser is a mousse containing a foaming aid.

17. A skin sanitiser as claimed in claim 16, wherein the foaming aid also acts as an antimicrobial agent.

18. A skin sanitiser as claimed in claim 16 or 17, including a skin soothant, a skin humectant, a skin moisturiser or softener, an antimicrobial agent, a foaming aid, a preservative and a pH adjuster.

19. A skin sanitiser as claimed in claim 16, 17 or 18, including about 1.8-2.2% skin soothant, about 4.5-5.5% skin humectant, about 0.63-0.77% skin moisturiser or softener;

about 0.405-0.495% foaming aid/antimicrobial agent; about 0.18-0.22% preservative; about 0.18-0.22% pH adjuster and/or about 0.09-0.11% antimicrobial agent.

20. A skin sanitiser as claimed in claim 19, including about 2% skin soothant, about 5% skin humectant, about 0.7% skin moisturiser or softener, about 0.25% foaming aid/antimicrobial agent, about 0.2% preservative, about 0.2% pH adjuster, and/or about 0.1% antimicrobial agent.

21. A water-based ultrasound transmitting lubricating gel that is free of alcohol.

22. A lubricating gel as claimed in claim 21, including a skin moisturiser; a gelling agent; and a lubricant.

23. A lubricating gel as claimed in claim 22, wherein skin moisturiser is a skin humectant.

24. A lubricating gel as claimed in claim 21, 22 or 23, including any or all of a thickening agent, a preservative, a pH adjuster.

25. A lubricating gel as claimed in any of claims 21 to 24, wherein the gel includes a lubricant that also acts as a thickening agent.

26. A lubricating gel as claimed in any of claims 21 to 25, including a diol; a cellulose ether; a polysaccharide; a paraben; and/or disodium EDTA.

27. A lubricating gel as claimed in any of claims 21 to 26, including about 18-22% skin humectant, about 0.9-1.1% lubricant; about 0.09-0.11% gelling agent, about 0.36-0.44% preservative; and/or about 0.09-0.11% pH adjuster.

28. A lubricating gel as claimed in 27, including about 20% skin humectant; about 1% lubricant; about 0.1% gelling agent; about 0.4% preservative, and/or about 0.1% pH adjuster.