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(54) Title: TOPICAL POLYMERIC ANTIMICROBIAL EMULSION

(57) Abstract: An emulsion composition for the topical application comprising: (a) A polymeric oily phase; (b) A polymeric emulsifier; (c) An aqueous phase; (d) A polymeric antimicrobial and optionally one or more components selected from polymeric film formers, inorganic and polymeric stabilizers, other inorganic or polymeric excipients and mixtures thereof.

TOPICAL POLYMERIC ANTIMICROBIAL EMULSION

FIELD OF THE INVENTION

The present invention relates to topical emulsion compositions and to methods
5 of preparing topical emulsion compositions.

BACKGROUND TO THE INVENTION

Topical preparations such as dermatologicals, pharmaceuticals, sunscreens,
cosmetics and topical biocides rely on a suitable a suitable carrier system to
10 deliver the active components into the skin. The carrier typically consists of a
mixture of one or more of the following ingredients: fats, oils, waxes and other
hydrophobic substances, plus water, glycerol, propylene glycol and other
hydrophilic substances, together with other pharmaceutically acceptable
excipients such as preservatives, fragrances and colouring agents. The nature
15 of the vehicle can play an important role in the efficacy or availability or rate and
extent of release of the active agent from the delivery system.

Topically applied products usually contain water and other components in
which microorganisms can grow. Such compositions generally contain
20 preservatives which may be in the form of a single or combination of
antimicrobial agents. Most antimicrobials are somewhat soluble in the
aqueous components since microorganisms generally grow in the
aqueous component. One group of antimicrobials which have been used
are esters of p-hydrobenzoic acid known as parabens and include methyl,
25 ethyl, propyl and butyl esters. Higher esters are also active but low
solubility makes them less desirable to use.

There is presently increasing concern with regard to the safety of long term use
of topical products. Possible adverse effects from transdermal absorption of
30 organic chemical components of the vehicle are also of particular concern. For
instance, the use of parabens as a preservative may lead to adverse reactions
following transdermal absorption in sensitive individuals. Furthermore
compounds used in combination with parabens such as imidazolidinyl urea or

diazolidinyl urea may cause skin irritation in some people. Further, aromatic amine derivatives used in many sunscreen preparations may cause irritation or allergy. It is difficult to maintain emulsion stability and effective dispersion of inorganic components in a composition.

5

It is one object of the present invention to provide a topical composition which substantially overcomes the abovementioned problems associated with the prior art, or at least provides a useful alternative thereto.

10 It is a further object of the present invention to provide a sunscreen composition with solid active agents such as titanium dioxide or zinc oxide or their derivatives whilst still maintaining the suncreening properties of the active agent.

15 It is a further objective to provide an antiseptic composition which is stable and of low irritancy.

The preceding discussion of the background art is intended to facilitate an understanding of the present invention only. It should be appreciated that the discussion is not an acknowledgement or admission that any of the material
20 referred to was part of the common general knowledge in Australia as at the priority date of this application.

Throughout the specification, unless the context requires otherwise, the word "comprise" or variations such as "comprises" or "comprising", will be understood
25 to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

SUMMARY OF THE INVENTION

In accordance with the present invention there is provided an emulsion
30 composition for the topical application comprising:

- (a) A polymeric oily phase;
- (b) A polymeric emulsifier component;
- (c) An aqueous phase; and
- (d) A polymeric antimicrobial.

Optionally, the composition further comprises one or more components selected from polymeric film formers, inorganic or polymeric stabilizers, other inorganic or polymeric excipients and mixtures thereof. Preferably substantially all the
5 organic components of the topical composition are polymeric.

The composition preferably comprises an active agent, which may be a therapeutic agent. The active agent may be a solid sunscreen agent such as a microfine particulate metal oxide. Zinc oxide and titanium dioxide and mixtures
10 thereof are preferred. The composition in an alternative embodiment comprises a sufficient amount of antimicrobial to provide antiseptic properties on the skin.

In accordance with the present invention there is further provided a method for the preparation of a topical emulsion composition, the method comprising the
15 steps of:

- (1) Dissolution of the polymeric preservative in aqueous solvent to provide an aqueous phase; and
- (2) Addition of a polymeric hydrophobic phase, with vigorous stirring, to the above aqueous phase.

20 Optionally, the aqueous solvent may contain one or more inorganic or polymeric stabilizers. Further, the aqueous phase may be warmed up to about 90°C.

Optionally, the polymeric hydrophobic phase may contain one or more active
25 agents. Further, the polymeric hydrophobic phase may be warmed up to about 90°C.

In accordance with the present invention there is still further provided the use of compositions as described hereinabove for purposes of topical or
30 dermatological application in humans or animals.

DETAILED DESCRIPTION OF THE INVENTION

The present invention provides an emulsion composition for the delivery of a range of active agents intended for topical application. The carrier components

of the composition are specifically chosen polymers. As such, the components of the carrier will be inhibited from being absorbed transdermally into the vascular circulatory system and consequently, higher safety will result.

- 5 Optionally, the composition further comprise one or more polymeric film formers and/or one or more inorganic or polymeric stabilizers and/or other inorganic or polymeric excipients.

10 The composition may comprise one or more active agents, which may be a therapeutic agent. The active agent may further be an inorganic sunscreen agent, including zinc oxide or titanium dioxide or derivatives or combinations thereof, or other inorganic solids capable of performing a sun-screening function.

- 15 In an alternative embodiment the emulsion composition comprises sufficient polymeric antimicrobial to provide antiseptic action on skin.

The emulsion compositions of the invention comprise a polymeric oil phase. The oil phase may for example include polyalkylene glycols, organosilane polymer (polycarbosilanes), polyvinyl alcohols, polyvinyl esters, polyvinylpyrrolidones, alkoxypolyethylene glycols, polysilanes, styrene-acrylate copolymers, polysaccharides, copolymers thereof and mixtures thereof. Preferred oil phase components are selected from the group consisting of polyorganosiloxanes.

25

Polyorganosiloxanes are particularly preferred as we have found them to provide emulsion stability in the polymeric compositions of the invention. The oil component is preferably free of fatty and paraffinic components. Polyorganosiloxanes include polyalkylsiloxanes and polyalkylaryl siloxanes.

30 Examples of polyalkylene glycols include polyethylene glycol, polypropylene glycol and copolymers of ethylene glycol and propylene glycol (ethylene oxide and propylene oxide).

The average molecular weight of the oil phase component or each of the oil phase components is preferably at least 500 and typically will be at least 1000.

Specific examples of the oil phase include cyclomethicone, imethicone, dimethicone copolyol and bis-phenylpropyl dimethicone. The concentration of the polymeric oily phase is typically 10% to 60% by weight of the composition with a preferred concentration of 15% to 50% by weight of the composition.

The polymeric emulsifier preferably comprises a polyoxyalkylene portion . Examples of emulsifiers include hexitan esters such as polysorbates, polyethoxylated alkyl phenols, polyethoxylated fatty alcohols, poloxamers, polyoxyethylene glycol monoethers, alkyl polyglucosides and ethoxylated polysiloxanes. The polymeric emulsifier is preferably from 1 to 15% by weight of the total composition and preferably from 1 to 11% by weight. The optimum surfactant composition will depend on the nature of the oil phase. It is particularly preferred that the emulsifier component comprise a primary emulsifier comprising one or more ethoxylated polysiloxanes and a secondary emulsifier comprising one or more emulsifiers selected from the group of polyoxyalkylene emulsifiers such as one or more selected from polysorbates, polyethoxylated alkylphenols, polyethoxylated fatty alcohols, poloxamers, polyalkylene glycol monoethers and alkyl polyglucosides.

The secondary emulsifier is most preferably selected from polyethylene glycol monoethers or mixture thereof. Polyethylene glycol monoether emulsifiers are commercially available as the "Brij" series and include polyoxyethylene lauryl ethers (Brij 30, 35) cetyl ethers (Brij 52, 56, 58), stearyl ethers (Brij 72, 76, 78) and oleyl ethers (Brij 92, 96, 98). The number average molecular of each of the emulsifier components is preferably at least 500 and more preferably at least 1000.

Specific examples of the most preferred polymeric primary emulsifier are ethoxylated polylaurylmethicone copolyol emulsifier, sodium PG propyldimethicone thiosulphate copolymer and cetyl dimethicone copolyol. The concentration of the primary emulsifier is typically 1% to 10% by weight of the

composition, preferably 2% to 8% by weight of the composition and most preferably 4% to 8% by weight of the composition.

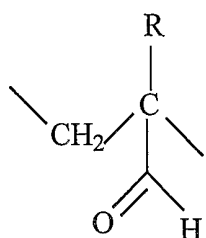
Specific examples of the most preferred polymeric secondary emulsifiers include polyethylene glycol ethers such as steareth 20 and polyethoxylated fatty alcohols such as laureth 23. The concentration of the secondary emulsifier is 0.05% to 5% by weight of the composition but preferably 0.2% to 1% by weight of the composition.

The concentration of the aqueous phase is 30% to 90% by weight of the composition, preferably 50% to 80% by weight of the composition.

The polymeric preservative is preferably selected from the group consisting of: Polymeric polyquaternary ammonium compounds such as poly[oxyethylene(dimethyliminio)ethylene(dimethyliminio)ethylene dichloride] (WSCP or Busan 77), polyquaternium 2 CTFA-adapted name (Mirapol-A15), and polyquaternium 1 CTFA-adapted name (Onamer M); biguanide polymers such as polyhexamethylene biguanide (PHMB) hydrochloride; polymers and copolymers of acrolein and mixtures thereof.

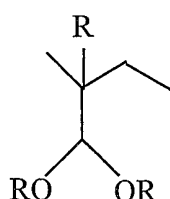
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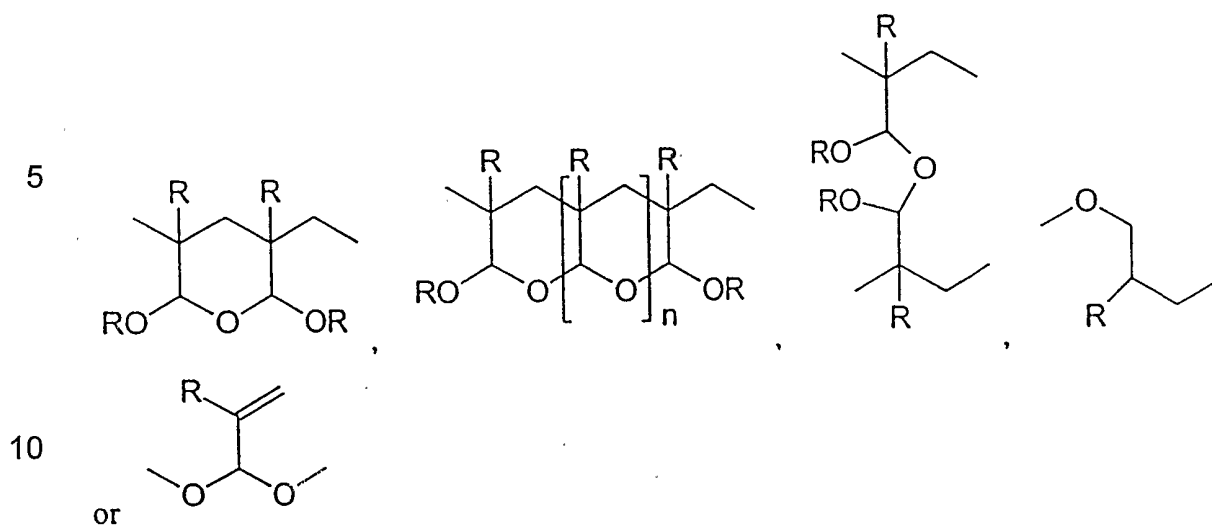
The preferred acrolein polymers and/or copolymers have the polymeric repeating unit:



wherein R is H or alkyl, usually C₁ to C₄ or this unit is hydrated, hemiacetal or acetal form and illustrated non-comprehensively of all possible structures, by the following formulae:

25





wherein n is one or more and R is as defined above or may be a polyether chain such as a polyethylene glycol. Examples of acrolein polymers and copolymers are described in US Patent 5290894 (Melrose et al) the contents of which are herein incorporated by reference.

15

Preferably the polymeric preservatives is an acrolein polymer of the type described in our International Applications PCT/AU96/00328 (WO 96/38186) and more preferably is a super activated acrolein polymer of the type described in PCT/AU00/00107 (WO 01/60874) the contents of which are herein incorporated by reference. Acrolein polymers of this type comprise poly(2-propenal, 2-propenoic acid) and are prepared by oxidation of solid polymer (poly-2-propenal) in air.

20

The activated acrolein polymers described in WO 96/38186 and WO 01/60874 are particularly suited to use in the compositions of the invention as they are generally stable in the formulation and are sufficiently water soluble to provide preservative and antiseptic properties. They are also safe as the polymers are not absorbed across the skin barrier. The polymers of WO 01/60874 exhibit enhanced microbial activity as a result of heating of poly(2-propenal, 2-propenoic) acid in a solution of polyethylene glycol, polyol or alkanol containing water. Super-activation is facilitated by the presence of polyethylene glycols or polyols or alkanols. We believe that the presence of the polyethylene glycol or polyol or alkanol protects and stabilizes the carbonyl groups of the polymers,

25

30

possibly by formation of acetals, from alkaline degradation by the Cannizarro reaction.

5 An added advantage of super-activation is that it reduces significantly the presence of contaminant acrolein which is a source of tissue and dermal irritation.

10 Suitable acrolein polymers are available from Chemeq Limited under the trade mark CHEMYDE. The average molecular weight of each of the preservative components is preferably at least 500 and more preferably at least 1000. The concentration of the polymeric preservative is at least 0.005% by weight of the composition, preferably 0.01% to 1.0% by weight of the composition, and more preferably 0.05% to 0.4% by weight of the composition.

15 Examples of the polymeric film former include but are not restricted to PVP/Polycarbamylpolyglycol ester, PVP/eicosene copolymer, PVP/dimethiconylacrylate/polycarbamyl/polyglycol ester. The concentration of the film former is 0.5% to 5% by weight, preferably 1% to 3% by weight of the emulsion composition.

20

In one embodiment of the invention the composition is a sunscreen composition containing a sunscreen agent such as a particulate metal oxide. Titanium dioxide and zinc oxide are particularly preferred. The concentration of metal oxide in the composition will typically be in the range of from 0.5 to 50% by weight and preferably from 1 to 40% by weight of the composition.

25

In an alternative preferred embodiment the composition of the invention is a topical antiseptic. In the composition for use as an antiseptic the concentration of polymeric preservative will be sufficient to provide an antiseptic activity when applied to skin.

30

When the polymeric preservative is an acrolein polymer or copolymer such as the CHEMYDE brand antimicrobial the concentrations for use in an antiseptic is typically at least 1% by weight and more preferably at least 2% by weight.

Preferably at least 95% by weight of the organic components of the emulsion composition have a number average molecular weight of at least 1000 and more preferably at least 98% of the organic components have a number average molecular weight of at least 1000. Most preferably 100% of the organic components have a number average molecular weight of at least 1000.

The use of organic components of molecular weight of over 1000 reduces significantly the problem of irritation and transdermal transmission associated with the prior art. This is especially so when the proportion of the total organic components of molecular weight over 1000 is very high. Furthermore it also produces an emulsion of high stability particularly when the preferred polymeric components described above are used.

The composition of the invention may be in the form of a water in oil emulsion or an oil in water emulsion. Oil in water emulsions are generally preferred.

In the process according to the invention the polymeric preservative is dissolved in aqueous solvent to provide an aqueous phase. When the polymeric preservative is an acrolein polymer or copolymer, particularly a super activated poly(2-propenal, 2-propenoic acid), it is generally more convenient to dissolve the polymer in mildly alkaline solution (such as dilute aqueous carbonate solution) as dissolution occurs more readily in alkaline solution. The pH of the aqueous phase may then be adjusted by addition of acid if desired.

The poly(2-Propenal, 2-propenoic acid) polymer is typically soluble in water in an amount of from 0.5 to 5% at a pH of from 6 to 8 at 25°C. The solubility of the polymer typically increases with an increasing pH above 7. The pH of the aqueous phase is typically in the range of from 6 to 8.

The aqueous phase is combined with the oil phase with vigorous mixing in the presence of the emulsifier to provide an emulsion. Additional components may be present during formation of the emulsion or may be subsequently added.

The present invention will now be described with reference to the following examples which are not to be interpreted to limit the scope of the present invention.

5 Example 1

An example of the composition of the invention when used as a sunscreen emulsion is shown below. Super activated polyacrolein polymer was prepared in accordance with Example 1 of International Application PCT/AU00/00107
 10 (WO 01/60874). The resulting polymer is a poly(2-propenal, 2-propenoic acid) polymer super activated by heating in aqueous polyol solution such as PEG. The PEG is believed to provide a derivative with protected carbonyl groups possibly by formation of acetals by a Cannizarro reaction. The polymer was dissolved in the aqueous phase.

15

	Raw Material	Function	% w/w
	Purified water	Aqueous phase	49.5
	VEEGUM Ultra	Inorganic stabilizer (magnesium aluminium silicate)	1.0
20	Sodium Chloride	Inorganic stabilizer	2.0
	CHEMYDE ^{RTM} antimicrobial	Polymeric preservative	0.2
	Antaron V220	Polymeric film former	2.0
	BRIJ 78	Polymeric secondary emulsifier	0.3
	DCQ2-5200	Polymeric primary emulsifier	5.0
25	GE SF 1555		
	Bis phenylpropyl dimethicone	Polymeric hydrophobic component	15.0
	Titanium Dioxide	Inorganic sunscreen	13.0
	Zinc Oxide	Inorganic sunscreen	2.0
	DC silicone 1401	Polymeric excipient (emollient)	5.0
30	SUNSPHERES	Styrene-acrylate copolymer (polymeric hydrophobic component)	5.0

Samples of the sunscreen, after accelerated ageing at 80°C for 4 months maintained emulsion stability and a sun protection factor of 15, and were

inoculated after storage with different bacteria in accordance with the Preservative efficiency test BP Topical (EP 2000; Method TM107). The bacterial population after storage at 20°C for various periods is shown in Table 1 below:

5

Table 1

Time Point	<i>S. aureus</i> AMS 027 (ATCC6538)	<i>P. aeruginosa</i> AMS 017 (ATCC9027)
Inoculum CFU/ml	3.8×10^5	5.2×10^5
0 hr	5.9×10^5	1.4×10^5
48 hr	<100	<100
7 Days	<100	<100
14 Days	<100	<100
28 Days	<100	<100

All results are expressed as CRU Colony Forming Unit) per g.

< less than

10

The method used in the preparation of the above composition was as follows:

1. Prepare the aqueous phase
 - 1.1 Disperse the VEEGUM magnesium aluminium silicate (inorganic stabilizer) in de-ionized water by stirring for 20 minutes, and then add the sodium chloride, stirring until dissolved;
 - 1.2 Adjust the pH to slightly basic (pH 7.5) and then add the CHEMYDE^{RTM} antimicrobial polymer (polymeric preservative) with stirring, until dissolved;
 - 1.3 Heat to 70°C.
2. Separately, prepare the polymeric oily phase:
 - 2.1 Heat a mixture of the ANTARON PVP/Eicosene copolymer (polymeric film former), BRIJ78 steareth-20 (polymeric secondary emulsifier), DCO2-5200 laurylmethicone copolymer (polymeric

25

primary emulsifier), and bis phenylpropyl dimethicone (polymeric hydrophobic component), with stirring, to 70°C,

5 2.2 Add the titanium dioxide and zinc oxide, with stirring, to disperse in the above oily phases, whilst maintaining the temperature at 70°C.

3. Mix to emulsify the aqueous and polymeric oily phases:

10 3.1 Very slowly add the oily phase (from 2.2) to the aqueous phase (from 1.3) whilst stirring with a Silverson mixer at 5,000 rpm, until emulsified.

4. Whilst continuing to stir, add the DC SILICONE FLUID 1401 cyclomethicone and dimethiconol (polymeric emollient).

15 5. Allow to cool to 50°C, then add the "Sunspheres" using slow speed stirring.

Example 2

20 The following formulation of an emollient hand cream is prepared by the same method as Example 1:

Raw Material	Function	% w/w
Purified water	Aqueous Phase	69.5
VEEGUM Ultra	Inorganic stabilizer	1.0
25 Sodium Chloride	Inorganic stabilizer	2.0
CHEMYDE ^{RTM} antimicrobial	Polymeric preservative	0.2
Antaron V 200	Polymeric film former	2.0
BRIJ 78	Polymeric secondary emulsifier	0.3
DCQ2-5200	polymeric primary emulsifier	5.0
30 GE Silicone fluid SF1555	Polymeric hydrophobic component and emollient	15.0
DC Silicone fluid 1401	Polymeric emollient	5.0

The produce was aged at 40°C for 4 months after which it was stable and passed the BP challenge by bacteria as described in Example 1.

Example 3

5

This example demonstrates a composition of the invention in the form of an antimicrobial antiseptic lotion which may be used to sanitize and protect skin from undesirable bacterial levels:

10	Raw Material	Function	% w/w
	Purified water	Aqueous Phase	67.7
	VEEGUM Ultra	Inorganic stabilizer	1.0
	Sodium Chloride	Inorganic stabilizer	2.0
	CHEMYDE ^{RTM} antimicrobial	Polymeric preservative and	
15		sanitizing agent	2.0
	Antaron V200	Polymeric film former	2.0
	BRIJ 78	Polymeric secondary emulsifier	0.3
	DCQ2-5200	polymeric primary emulsifier	5.0
	Bis phenylpropyl dimethicone	Polymeric hydrophobic component	15.0
20	DC silicone 1401	Polymeric excipient (emollient)	5.0

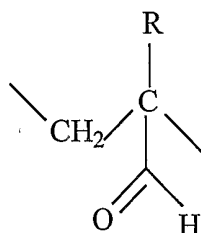
The produce was aged at 40°C for 4 months after which it was stable and passed the BP challenge by bacteria as described in Example 1.

25 The compositions of the present invention provide a vehicle for the topical delivery of a range of active agents which substantially overcome the problems associated with the prior art, or at least provides a useful alternative thereto. Further, the vehicle is safe, since the vehicle, in having all or substantially all organic components, polymeric, is not significantly absorbed through the skin

30 via the transdermal route.

Claims:

1. An emulsion composition for the topical application comprising:
- (a) A polymeric oily phase;
 - (b) A polymeric emulsifier;
 - 5 (c) An aqueous phase;
 - (d) A polymeric antimicrobial and
- optionally one or more components selected from polymeric film formers, inorganic and polymeric stabilizers, other inorganic or polymeric excipients and mixtures thereof.
- 10
2. An emulsion composition according to claim 1 comprising:
- (a) 10 to 60% by weight of said polymeric oil phase;
 - (b) 1 to 15% by weight of said polymeric emulsifier;
 - (c) 30 to 90% by weight of said aqueous phase; and
 - 15 (d) at least 0.005% by weight of said polymeric preservative.
3. An emulsion composition according to claim 1 wherein the polymeric preservative comprises one or more polymers selected from the group consisting of polyquaternary ammonium compounds, biguanide polymers and
- 20 polymers and copolymers of acrolein.
4. An emulsion composition according to claim 3 wherein the average molecular weight of each of the one or more polymers is at least 1000.
- 25 5. An emulsion composition according to claim 1 wherein the polymeric preservative comprises one or more polymers selected from the group consisting of acrolein polymers having the repeating unit of formula:



- wherein R is H or alkyl, usually C₁ to C₄ or this unit is hydrated, hemiacetal or
- 30 acetal form.

6. An emulsion composition according to claim 5 wherein the acrolein polymer is poly(2-propenal, 2-propenoic acid).
- 5 7. An emulsion composition according to claim 6 wherein the acrolein polymer has been activated by heating in an aqueous solution of one or more polyethylene glycols, polyols and alkanols.
8. An emulsion composition according to claim 1 wherein the polymeric oil
10 phase comprises one or more polymers selected from the group consisting of polyalkylene glycols, organosilane polymer (polycarbosilanes), polyvinyl alcohols, polyvinyl esters, polyvinylpyrrolidones, alkoxy polyethylene glycols, polysilanes, styrene-acrylate copolymer, polysaccharides, copolymers thereof and mixtures thereof.
- 15 9. An emulsion composition according to claim 1 wherein the polymeric oil phase comprises one or more polymers selected from the group consisting of polyorganosiloxanes.
- 20 10. An emulsion composition according to claim 1 wherein the average molecular weight of each of the one or more said polymers is at least 1000.
11. An emulsion composition according to claim 1 wherein the polymeric emulsifier includes one or more emulsifiers selected from the group of
25 polyoxyalkylene emulsifiers and ethoxylated polysiloxane emulsifiers.
12. An emulsion composition according to claim 11 wherein the polymeric emulsifier comprises a primary emulsifier comprising one or more ethoxylated polysiloxane emulsifiers and a secondary emulsifier comprising one or more
30 polyoxyalkylene emulsifiers.
13. An emulsion composition according to claim 11 wherein the primary emulsifier comprises one or more emulsifiers selected from the group consisting

of ethoxylated polyacrylmethicone copolymer, sodium PG propyldimethicone thiosulphate copolymer and cetyl dimethicone copolyol.

14. An emulsion composition according to claim 11 wherein the secondary
5 emulsifier comprises one or more emulsifiers selected from the group consisting of polyethylene glycol ethers and polyethoxylated fatty alcohols.
15. An emulsion composition according to claim 11 wherein the primary
10 emulsifier is present in an amount of from 1 to 10% by weight of the composition and the secondary emulsifier is present in an amount of from 0.5 to 5% by weight of the composition.
16. An emulsion composition according to claim 11 wherein the number
15 average molecular weight of each emulsifier is at least 500.
17. An emulsion composition according to claim 1 wherein the composition
includes from 0.5 to 5% of a polymeric film former.
18. An emulsion composition according to claim 1 wherein the polymeric film
20 former is selected from the group consisting of PVP/Polycarbomoylpolyglycol ester, PVP/eicosene copolymer, PVP/dimethiconylacrylate/polycarbamyl/polyglycol ester, and mixtures thereof.
19. An emulsion composition according to claim 1 wherein the vehicle
25 comprises an inorganic or polymeric stabiliser.
20. An emulsion composition according to claim 19 wherein the stabilizer is
magnesium aluminium silicate.
- 30 21. An emulsion composition according to claim 1 for use as a sunscreen comprising at least one particulate sunscreen agent selected from zinc oxide and titanium dioxide.

22. An emulsion composition according to claim 21 wherein the particulate sunscreen agent is present in an amount of from 0.5% to 50% by weight of the composition.
- 5 23. An emulsion composition according to claim 21 wherein the composition comprises a polymeric preservative which is an acrolein polymer or copolymer in an amount of from 0.005 to 2% by weight.
- 10 24. An emulsion composition according to claim 1 for use as a skin antiseptic comprising an acrolein polymer or copolymer in an amount of at least 0.5% by weight of the composition.
- 15 25. An emulsion composition according to claim 24 wherein the acrolein polymer or copolymer is present in an amount of from 0.5 to 5% by weight of the composition.
- 20 26. An emulsion composition according to claim 1 wherein at least 95% by weight of the organic components of the composition have a number average molecular weight of at least 1000.
- 25 27. A process for preparing an emulsion composition comprising dissolving a polymeric antimicrobial comprising an acrolein polymer or copolymer in an aqueous solution, mixing the aqueous phase with a polymeric oil phase in the presence of a polymeric emulsifier to provide an emulsion composition according to claim 1.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU01/01212

A. CLASSIFICATION OF SUBJECT MATTER																	
Int. Cl. ⁷ : A61K 9/107; A01N 25/10, 25/02; A61P 31/04																	
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) File WPAT and keywords																	
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched File MEDLINE and keywords																	
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) WPAT, Medline: Polymer, oil, emulsion, Polyalkylene glycol, PEG, silane, siloxane, polysaccharide, antimicrob, preservative, polyquatarnary, biguanide, acrolein, propenal, polypropenoic																	
C. DOCUMENTS CONSIDERED TO BE RELEVANT																	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.															
A	WO 200003723 A (Chemeq Limited) 27 January 2000 Whole document	1-27															
A	WO 200061113 A (Phares Pharmaceuticals Research N.V.) 19 October 2000 Whole document	1-27															
A	EP 771525 A (Rohm and Haas Company) 7 May 1997 Whole document	1-27															
A	EP 492843 A (Rohm and Haas Company) 1 July 1992 Whole document	1-27															
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex																	
* Special categories of cited documents: <table border="0" style="width: 100%;"> <tr> <td style="width: 33%;">"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td style="width: 33%;">"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</td> <td style="width: 33%;"></td> </tr> <tr> <td>"E" earlier application or patent but published on or after the international filing date</td> <td>"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</td> <td></td> </tr> <tr> <td>"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)</td> <td>"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</td> <td></td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> <td></td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"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		"E" earlier application or patent but published on or after the international filing date	"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		"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)	"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		"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family		"P" document published prior to the international filing date but later than the priority date claimed		
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Date of the actual completion of the international search 31 October 2001	Date of mailing of the international search report 19 NOV 2001																
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized officer G.J. McNEICE Telephone No : (02) 6283 2055																

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU01/01212

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	200003723	AU	51404/99	BR	9908386	EP	1112076
WO	200061113	AU	200039804				
EP	771525	CN	1154202	BR	9605332	CA	2188221
		JP	9124404				
EP	492843	AU	88891/91	BR	9105131	CA	2055380
		CN	1064985	FI	915784	HU	60100
		IE	914270	IL	100291	JP	5058814
		MX	9102485	NO	914754	NZ	240893
		PT	99734	US	5648086	US	5703105
							END OF ANNEX