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NOTICE OF ENTITLEMENT

We SETON HEALTHCARE GROUP PLC
of Tubiton House, Medlock Street, Oldham OL1 3HS, United
Kingdom

being the applicant in respect of Application No 47219/93,
state the following:-

1. The person nominated for the grant of the patent:
has entitlement from the actual inventor. The applicant is
the assignee of the actual inventor.
2. The person nominated for the grant of the patent:
is the applicant of the basic application listed in the
declaration lodged under Article 8 of the PCT.

The basic application listed in the declaration made under
Article 8 of the PCT is the first application made in a
Convention country in respect of the invention.

DATED this 7th day of February 1995.

SETON HEALTHCARE GROUP PLC
By its Patent Attorneys
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TOPICAL COMPOSITION
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- (56) Prior Art Documents
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CH 667010
- (57) Claim

1. A topical paste for impregnating a bandage comprising zinc oxide in a stable emulsion comprising from 0.2 to 16% wt of at least one fat and/or oil, at least one emulsifying agent, at least one inorganic suspending agent, at least one water soluble viscosity improver and water, in the absence of a preservative.

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<p>(51) International Patent Classification ⁵ : A61K 33/30, A61L 15/44 A61K 9/06</p>	<p>A1</p>	<p>(11) International Publication Number: WO 94/03190 (43) International Publication Date: 17 February 1994 (17.02.94)</p>
<p>(21) International Application Number: PCT/GB93/01662 (22) International Filing Date: 5 August 1993 (05.08.93) (30) Priority data: 9216879.8 8 August 1992 (08.08.92) GB (71) Applicant (for all designated States except US): SETON HEALTHCARE GROUP PLC [GB/GB]; Tubiton House, Medlock Street, Oldham OL1 3HS (GB). (72) Inventor; and (75) Inventor/Applicant (for US only): NESBIT, Michael, Robert [GB/GB]; 168 Eastgate, Louth, Lincolnshire LN11 9AB (GB). (74) Agents: GOODWIN, Mark et al.; M'Caw & Co., 41-51 Royal Exchange, Cross Street, Manchester M2 7BD (GB).</p>	<p>(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, US, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published With international search: report.</p> <p>668986</p>	
<p>(54) Title: TOPICAL COMPOSITION</p>		
<p>(57) Abstract</p> <p>A topical composition for impregnating a bandage comprises zinc oxide in a stable oil in water emulsion. The emulsion comprises one or more fats or oils, one or more emulsifying agents, at least one water soluble gum and water. No preservative is required.</p>		

TOPICAL COMPOSITION

This invention relates to a topical composition comprising zinc oxide particularly, but not exclusively for impregnating a bandage.

5 Bandages impregnated with pastes containing zinc oxide are commonly used for the treatment of skin complaints such as leg ulcers, varicose eczemas and chronic dermatitis. These known pastes are not sufficiently emulsified and are therefore unstable, particularly when subjected to sterilisation processes such as heating and irradiation. As 10 these known pastes cannot be properly sterilised it is conventional to include "preservatives" which include antibacterial agents, such as alkyl p-hydroxybenzoates, in order to irradiate any bacteria that are not eliminated by other sterilisation techniques. These preservatives cause 15 hyposensitivity when the bandage comprising the paste is applied to the wound.

20 The present invention has been made from a consideration of this problem.

25 According to the present invention there is provided a topical paste for impregnating a bandage comprising zinc oxide in a stable emulsion comprising from 0.2 to 16% wt of at least one fat and/or oil, at least one emulsifying agent, at least one inorganic suspending agent, at least one water soluble viscosity improver and water, in the absence of a preservative.

The stable emulsions of the compositions of the present invention eliminate the need for a preservative. Thus topical



zinc oxide containing compositions can be made which do not suffer from the drawback of sensitivity.

The compositions of the invention are primarily intended for impregnating bandages for use in the treatment of skin diseases.

The zinc oxide is the active agent. The composition preferably comprises from 0.5% to 40.0% wt of zinc oxide and more preferably substantially 15% wt of zinc oxide. The composition may comprise additional active ingredients such as calamine, ichthammol, clioquinol and coal tar. The composition preferably comprises from 0 to 40% wt of additional actives.

In a preferred embodiment of the invention the fats and/or oils comprise fractionated coconut oil and/or synthetic spermacetti, combinations of cetyl alcohol; stearyl alcohol; other alcohols (C_8 to C_{24}); triglyceride oils or fats; esters such as cetyl palmitate, myristyl myristate; liquid and solid paraffins or other commonly used cosmetic fats and oils. The fats and/or oil form an oil in water emulsion.

The emulsifying agent is preferably polyethoxylated. Preferred examples include tween 80 polysorbate 20, 21, 40, 60, 61, 65, 81, 85, 120 and other polyoxyethylene adducts of sorbitan esters; fatty acids; fatty alcohols; lanolin; lanolin alcohols; castor oil (natural or hydrogenated) or alkylbenzenes. The emulsifying agent has a high HLB and emulsifies the fat and/or oils into the oil in water emulsion. The composition preferably comprises from 0.3 to 10% wt and still more preferably from 0.5 to 2% wt of emulsifying agent.



The water soluble viscosity improver increases the viscosity of the aqueous phase for stabilisation. One preferred material is xanthan gum. The composition preferably comprises from 0.05% to 4.0% of viscosity improver and more preferably from 0.05 to 1.2%.

In a preferred embodiment of the invention the compositions preferably comprise the following ingredients either alone or in combination: at least one low HLB emulsifying agent to emulsify the fats/and or oils and glycerol which acts as a humectant in order to improve the water retention of the composition and to provide emollient properties to the skin.

In order that the present invention may be more readily understood a specific embodiment thereof will now be described with reference to the following example:-

EXAMPLE 1

A topical composition in accordance with the present invention was made according to the following formula:

	<u>% w/w</u>
Purified Water Ph Eur	49.9
Glycerol Ph Eur	30.0
Zinc Oxide Ph Eur	15.0
Fractionated Coconut Oil (Miglyol 812)	2.0
Aluminium Magnesium Silicate BP (Veegum F)	1.0
Xanthan Gum USNF (Keltrol F)	0.8
Polysorbate 80 Ph Eur (Tween 80)	0.5
Synthetic Spermocetti USNF (Crodamol SS)	0.5
Sorbitan Mono-oleate BP (Span 80)	0.3



The said formula of Example 1 was made in the following manner:

<u>Part A</u>	<u>Per 100 Kg of Batch</u>
Purified Water Ph Eur	49.9 Kg
5 Veegum F	1.0 Kg
Tween 80	500 g
Glycerol Ph Eur	30 Kg
Zinc Oxide	15 Kg
Keltrol F	800 Kg
10 <u>Part B</u>	
Miglyol 812	2.0 Kg
Crodamol SS	500 g
Span 80	300 g

The Veegum F was added to the water of the Part A Mixture and mixed with high shear agitation, whilst heating to 60°C. The other ingredients of Part A were then added and mixed with high shear agitation at 60°C. The Part B mixture was mixed in a separate small vessel and heated to 60°C. A 10 litre portion of Part A was slowly added to the Part B mixture with brisk stirring. The Part A/B mixture was then added to the remainder of the Part A mixture and mixed with agitation. The vessel used for the A/B mixture was rinsed out with portions of the batch. The batch was periodically mixed with agitation whilst cooling, until the viscosity increased and the batch was then cooled to room temperature with periodic stirring, prior to assembly.

The composition of Example 1 was stable when subjected to 120°C for 15 minutes. The composition was also stable when



subjected to gamma irradiation.

The formulation of Example 1 therefore provides a stable zinc oxide containing emulsion which may be subjected to conventional sterilisation techniques.

5 It is to be understood that the example described above is by way of illustration only. Many modifications and variations are possible.



The claims defining the invention are as follows:-

5 1. A topical paste for impregnating a bandage comprising zinc oxide in a stable emulsion comprising from 0.2 to 16% wt of at least one fat and/or oil, at least one emulsifying agent, at least one inorganic suspending agent, at least one water soluble viscosity improver and water, in the absence of a preservative.

10 2. A paste as claimed in claim 1, wherein the composition comprises from 0.5% to 40.0% wt of zinc oxide.

15 3. A paste as claimed in claim 1 or claim 2, wherein the composition comprises one or more further additional active ingredients including at least one of the following: calamine, ichthammol, clioquinol or coal tar.

20 4. A paste as claimed in claim 3, wherein the composition comprises up to 40% wt of said at least one additional active ingredient.

25 5. A paste as claimed in any preceding claim, wherein the fat and/or oil comprises any of the following: fractionated coconut oil and/or synthetic spermacetti, combinations of cetyl alcohol; stearyl alcohol; other alcohols (C_8 to C_{24}); triglyceride oils or fats; esters such as cetyl palmitate, myristyl myristate; liquid and solid paraffins.

6. A paste as claimed in any preceding claim, wherein the



emulsifying agent comprises a polyethoxylated emulsifying agent.

5 7. A paste as claimed in any preceding claim, wherein the emulsifying agent includes any of the following: tween 80 polysorbate 20, 21, 40, 60, 61, 65, 81, 85, 120 or other polyoxyethylene adducts of sorbitan esters; fatty acids; fatty alcohols; lanolin; lanolin alkylbenzenes.

10 8. A paste as claimed in any preceding claim, wherein the composition comprises from 0.3 to 10% wt of emulsifying agent.

15 9. A paste as claimed in any preceding claim, wherein the composition comprises from 0.5% to 2% wt of emulsifying agent.

20 10. A paste as claimed in any preceding claim, wherein the water soluble viscosity improver comprises a water soluble gum.

25 11. A paste as claimed in claim 10, wherein the water soluble gum comprises xanthan gum.

12. A paste as claimed in any preceding claim, wherein the composition comprises from 0.05% to 4.0% wt of water soluble viscosity improver.

13. A paste as claimed in any preceding claim, wherein the composition comprises from 0.05% to 1.2% wt of water soluble



viscosity improver.

14. A paste as claimed in any preceding claim, wherein the composition comprises at least one emulsifying agent for emulsifying the fats and/or oils.

15. A paste as claimed in any preceding claim, wherein the composition further comprises glycerol.

16. A paste substantially as described with reference to Example 1.

17. A bandage impregnated by the paste of any of claims 1 to 16.

Dated this 9th day of August 1995

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ABSTRACT

TOPICAL COMPOSITION

A topical composition for impregnating a bandage comprises zinc oxide in a stable oil in water emulsion. The emulsion comprises one or more fats or oils, one or more emulsifying agents, at least one water soluble gum and water. No preservative is required.

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INTERNATIONAL SEARCH REPORT

Int'l. Application No
PCT/GB 93/01662

A. CLASSIFICATION OF SUBJECT MATTER IPC 5 A61K33/30 A61L15/44 A61K9/06		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC 5 A61K A61L		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practical, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	FR,A,2 083 366 (V.P. VARIOPHARM GMBH) 17 December 1971	1,2, 5-12, 14-16, 18,19
Y	see page 4; example 1	3,4,13, 17,20
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Y	DE,C,384 135 (SIEBERT) 4 November 1920 see page 1; example 1	3,4
Y	DATABASE WPI Derwent Publications Ltd., London, GB; AN 82-03408J & JP,A,57 171 907 (KANEBO) 22 October 1982 see abstract	13
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<input checked="" type="checkbox"/> Further documents are listed in the continuation of box C.		
<input checked="" type="checkbox"/> Patent family members are listed in annex.		
* Special categories of cited documents :		
A document defining the general state of the art which is not considered to be of particular relevance	*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	
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O document referring to an oral disclosure, use, exhibition or other means	*A* document member of the same patent family	
P document published prior to the international filing date but later than the priority date claimed		
Date of the actual completion of the international search <div style="text-align: center; font-weight: bold;">17 November 1993</div>	Date of mailing of the international search report <div style="text-align: center; font-weight: bold;">30. 11. 93</div>	
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Authorized officer <div style="text-align: center; font-weight: bold;">BENZ, K</div>	

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
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Information on patent family members

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