

(12) **UK Patent Application** (19) **GB** (11) **2 302 808** (13) **A**

(43) Date of A Publication 05.02.1997

(21) Application No **9513553.9**

(22) Date of Filing **04.07.1995**

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(51) INT CL⁶
A61K 31/57 // (A61K 31/57 31:045)

(52) UK CL (Edition O)
**A5B BJA B170 B24Y B244 B246 B40Y B402 B822 B823
B826
U1S S2416**

(56) Documents Cited
**GB 1543907 A WO 96/20712 A1 WO 94/06434 A1
WO 87/04617 A1 US 4853379 A US 4797402 A
US 4305936 A US 4289764 A US 4246261 A
US 4213979 A
CAS ONLINE Abstract Accession No. 109:134984 & JP
620292716 A2**

(58) Field of Search
**INT CL⁶ A61K 31/57
ONLINE: CAS ONLINE, WPI**

(54) **Propylene glycol with low potency corticosteroids for topical treatment of the scalp**

(57) Propylene glycol in synergistic combination with a low potency corticosteroid, i.e. hydrocortisone is topically applied to treat scaling conditions of the scalp, i.e. dandruff, seborrhoeic dermatitis and psoriasis. The compositions may be in the form of solutions, lotions, creams, ointments or gels and may also contain water, isopropyl alcohol and citric acid.

GB 2 302 808 A

**METHOD AND COMPOSITION FOR PREVENTION AND/OR TREATMENT OF
DANDRUFF AND SEBORRHOEIC DERMATITIS**

This invention relates to a method and composition for the prevention and/or treatment of scaling conditions of the scalp, such as dandruff, seborrhoeic dermatitis and psoriasis.

Previously known methods for preventing and treating dandruff generally involve applying to the scalp various anti-dandruff agents contained in lotions, gels and shampoos. Examples of such anti-dandruff agents include sulphur and selenium compounds, zinc pyrithione and bacteriostatic and bactericidal agents such as, for example, hexachlorophene. In many individuals, the use of such anti-dandruff agents can give rise to adverse reactions, for example allergic reactions and erythematous lesions. Consequently, known anti-dandruff agents cannot be used in the long term and it is frequently found that dandruff symptoms recur. Known anti-dandruff agents are often difficult to formulate into cosmetically acceptable compositions.

Known treatments for seborrhoeic dermatitis and psoriasis generally involve the use of corticosteroids or other pharmacologically active agents which have a profound metabolic effect. However in order to be effective, known corticosteroids formulation either need to contain a corticosteroid which has an inherently high level of corticosteroid activity, for example Betnovate, Dermovate, Diprosalic or Locoid, or the corticosteroid needs to be present in a high concentration. There is an awareness that these potent products, in the form of alcoholic based scalp lotions, need to be used with caution and sparingly.

Thus the risk of side effects run parallel with the strength of the steroid, the duration of therapy and the site treated. For example, the face, genital area and intertriginous areas will absorb more steroids than other areas. In the UK topical corticosteroids are listed in terms of potency; mild, moderate, potent and very potent. The potent and very potent steroids should be carefully monitored and

limited to a few weeks use when a milder steroid should be substituted if possible. Cutaneous side effects may be apparent after two weeks.

Only mild steroids should be used in children to avoid the potential of growth retardation and possible long lasting cosmetic disfiguration.

UK Patent No. GB 2,205,743 described the finding that propylene glycol is effective as an anti-dandruff agent and that a significant anti-dandruff effect may be observed following application of propylene glycol to the scalp, e.g. in the form of a lotion, gel or shampoo. Propylene glycol, when used in accordance with the teachings of GB 2,205,743, avoided undesirable side effects which occur following use of known anti-dandruff agents.

Propylene glycol has hitherto also been described for use as a diluent, thinning agent or vehicle for various pharmaceutical products including such products intended for topical use. Thus US-A-3,984,866 describes the use of certain alpha-substituted carboxylic acid derivatives as active ingredients for treating keratinization defects.

It has now been found that by combining propylene glycol with a relatively low concentration of a weak corticosteroid (neither of which would in itself possess a substantial effect against scaling conditions of the scalp), a synergistically effective combination results. The preferred weak corticosteroid is hydrocortisone or a hydrocortisone salt.

Such combinations have been found to be especially effective against not only dandruff, but also more serious scaling conditions of the scalp, such as seborrhoeic dermatitis and psoriasis.

A possible reason for the actions of the combination therapy of the invention is that combinations of propylene glycol and the weak corticosteroid have enhanced activity against *Pityrosporum ovale*, an organism that is now thought to

be implicated as an aetiological agent responsible for both psoriasis and seborrhoeic dermatitis and possibly also dandruff.

According to one aspect of the invention there is provided a composition for use in the treatment of scaling conditions of the scalp, including dandruff, seborrhoeic dermatitis and psoriasis which comprises as active ingredients, propylene glycol and a low potency corticosteroid, together with a topically acceptable excipient.

Preferably the concentration of propylene glycol is from 5 to 50 wt %, most preferably from 5 to 20 wt %, especially 8 to 12 wt %.

The low potency corticosteroid is preferably present in a concentration of from 0.2 to 3 wt %, most preferably from 0.5 to 1 wt %.

The compositions according to the invention may be formulated in the form of solutions, lotions, creams, ointments or gels suitable for topical application. Compositions according to the invention may contain any conventional incidental adjuvants, for example, emollients, thickening agents, perfumes, colouring agents, stabilising agents, pH-adjusting agents and preservatives as well as water and/or a C₁₋₄ alkanol.

According to a further aspect of the invention there is provided a method of treating dandruff and/or seborrhoeic dermatitis and/or psoriasis which comprises applying a composition according to the invention to the affected region.

In carrying out the method of the invention, the compositions may be applied to the affected region at regular intervals of, for example, 1-4 times daily.

The following examples illustrate compositions according to the invention

HYDROCORTISONE SCALP LOTION

Ingredient	% Composition
Purified Water	28.50
Klucel HF	0.50
Propylene Glycol	10.00
Isopropyl Alcohol (99%)	60.00
Hydrocortisone	1.00
Citric Acid	qs

CLAIMS

1. A composition for use in the treatment of scaling conditions of the scalp, including dandruff, seborrhoeic dermatitis and psoriasis which comprises as active ingredients, propylene glycol and a low potency corticosteroid, together with a topically acceptable excipient.
2. A composition according to Claim 1 wherein the propylene glycol is present in a concentration of from 5 to 50 wt %.
3. A composition according to Claim 2 wherein the propylene glycol is present in a concentration of from 5 to 20 wt %.
4. A composition according to any preceding claim wherein the propylene glycol is present in a concentration of from 8 to 12 wt %.
5. A composition according to Claim 4 wherein the low potency corticosteroid is present in a concentration of from 0.2 to 3 wt %.
6. A composition according to any preceding claim wherein the topically acceptable excipients comprise water and/or a C₁₋₄ alkanol.
7. A composition according to any preceding claim in the form of a solution, lotion, cream, ointment or gel.
8. A composition according to any of Claims 1 to 7 in the form of a shampoo.

9. A composition according to any preceding claim wherein the low potency corticosteroid comprises hydrocortisone or a hydrocortisone salt.

10. A method for the prevention and/or treatment of scaling conditions of the scalp, including dandruff, seborrhoeic dermatitis and psoriasis which comprises applying to the scalp a composition as claimed in any preceding claim.



Application No: GB 9513553.9
Claims searched: 1 to 10

Examiner: Mr S.J.Pilling
Date of search: 25 September 1996

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.O): -

Int CI (Ed.6): A61K 31/57

Other: ONLINE: CAS ONLINE, WPI

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	GB 1543907 (DERMAL LABORATORIES) see page 1 lines 43 to 59 and the example.	1-3,6,7,9
E,X	WO 96/20712 A1 (AMERICAN HOME PRODUCTS) see the examples.	1,2,6,7,9
X	WO 94/06434 A1 (BROWN) see Example 2	1,7,9
X	WO 87/04617 A1 (MOBERG) see page 12 lines 20 to 21, page 16 line 6 to page 17 line 7, page 18 line 4 to page 19 line 14 and Claim 1.	1,2,6,7,9,10
X	US 4853379 (SHROOT <i>ET AL</i>) see column 2 lines 40 to 44, column 2 lines 58 to 63 and the examples.	1-3,6-10
X	US 4797402 (DORSEY) see column 1 lines 42 to 47 and Example 1.	1-5,7,9,10
X	US 4305936 (KLEIN) see Examples I and II.	1-3,6,7,9,10
X	US 4289764 (YARROW & WHITEFIELD) see column 1 lines 5 to 6 and the example.	1-3,6,7,9

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.



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Application No: GB 9513553.9
Claims searched: 1 to 10

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Date of search: 25 September 1996

Category	Identity of document and relevant passage	Relevant to claims
X	US 4246261 (VAN SCOTT & YU) see column 4 lines 11 to 16 and Example 22.	1-3,7,9,10
X	US 4213979 (LEVINE) see column 1 lines 6 to 9 and the examples	1-7,9,10
X	CAS ONLINE ABSTRACT ACCESSION NO. 109:134984 & JP 620292716 A2 (KAO CORP) 19.12.87 (see abstract)	1-3,6,7,9

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.