

[54] **CLEANSING COMPOSITIONS**  
 [75] Inventors: **Michael Royston Billany; Arthur Raymond Longworth; John Shatwell**, all of Macclesfield, England

[73] Assignee: **Imperial Chemical Industries Limited**, London, England

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[51] Int. Cl. .... **C11d 1/72, C11d 3/48**

[58] Field of Search ..... **252/106, 107, 547; 424/326**

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*Primary Examiner*—Mayer Weinblatt

*Assistant Examiner*—P. E. Willis

*Attorney, Agent, or Firm*—Cushman, Darby & Cushman

[57]

**ABSTRACT**

The disclosure relates to cleansing compositions containing a soluble salt of chlorhexidine, a polyoxyethylene-polyoxypropylene block co-polymer and an inert diluent or carrier.

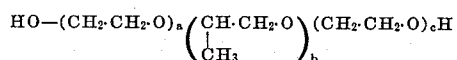
**6 Claims, No Drawings**

## CLEANSING COMPOSITIONS

This invention relates to cleansing compositions, and in particular it relates to cleansing compositions, containing the antibacterial compound chlorhexidine (1,1'-hexamethylenebis[5-(p-chloro-phenyl)biguanide]) or a salt thereof, which are suitable for skin cleansing. The compositions of the invention are therefore useful in surgical practice as a pre-operative scrub; they may be used routinely by hospital ward staff.

The essential constituents of such a composition are a suitable salt of chlorhexidine and a surfactant. Very many common surfactants are, however, incompatible with chlorhexidine. Thus, anionic surfactants are known to destroy the antibacterial activity of chlorhexidine solutions by complexing with the cationic chlorhexidine, and cationic surfactants are not preferred because of their irritancy, and because in combination with a soluble chlorhexidine salt double decomposition can occur, with the formation of insoluble chlorhexidine salts and consequent loss of antibacterial activity. Amphoteric surfactants, with contain either anionic or cationic centres depending upon pH, suffer from the above described disadvantages of anionic and cationic surfactants, and are therefore equally unsuitable for the present purpose. Thus, for example, of 13 amphoteric surfactants examined as aqueous solutions containing 20 percent w/v of surfactant and 2 percent v/v of chlorhexidine gluconate (provided as a 20 percent w/v solution in water) the best combination possessed only 14 percent of the antibacterial activity of a 2 percent solution of chlorhexidine gluconate alone.

Non-ionic surfactants were therefore examined in combination with chlorhexidine gluconate (20 percent w/v of surfactant and 2 percent v/v of chlorhexidine gluconate provided as a 20 percent w/v solution) in water. Of 17 non-ionic surfactants of various types which were investigated, only four possessed 70 percent or more of the antibacterial activity of a 2 percent solution of chlorhexidine gluconate alone. These four non-ionic surfactants were all members of a class of polyoxyethylene/polyoxypropylene block copolymers of the general formula:



wherein  $a$ ,  $b$  and  $c$  are integers, having molecular weights between 1,000 and 16,000, and in which the terminal polyoxyethylene chains represent 10-80 percent of the molecule, which copolymers are available commercially under the trade name "Pluronic." However, from the results of comparative tests, we have found that not all "Pluronic"s are equally suitable for the present purpose.

Thus, according to the invention there is provided a composition comprising from 0.5 to 10.0 percent w/v of a salt of chlorhexidine which is soluble to the extent of at least 0.5 percent w/v in water at ambient temperature, and a polyoxyethylene-polyoxypropylene block copolymer consisting of 20-80 percent of polyoxyethylene, and wherein the polyoxypropylene part of the polymer molecule has a molecular weight of between 1,000 and 2,750, together with an inert diluent or carrier.

Suitable salts of chlorhexidine which are soluble in water at ambient temperature to the extent of at least

0.5 percent w/v are, for example, the gluconate, isethionate (2-hydroxyethanesulphonate), formate, acetate, glutamate, succinamate, monodiglycollate, dimethanesulphonate, lactate, di-isobutyrate and glucoheptonate, and of these, the gluconate is particularly preferred.

Particular polyoxyethylene-polyoxypropylene block copolymers which are useful in the compositions of the invention are those known as "Pluronic"s, and having the following designations, (wherein the figures in parentheses following the designation indicate the typical molecular weight of the polyoxypropylene part of the molecule, and the percentage of polyoxyethylene in the molecule, respectively):-

L44 (12,00 40), L62 (1750, 20), **1200, 63** (1750, 30), L64 (1750, 40), P65 (1750, 50), F68 (1750, 80), P75 (2050, 50), F77 (2050, 70), P84 (2250, 40), P85 (2250, 50) and F87 (2250, 70).

Preferred "Pluronic"s are those comprising 40 to 70 percent of polyoxyethylene, and wherein the typical molecular weight of polyoxypropylene is between about 2,000 and about 2,500. Particularly preferred "Pluronic"s are those with a polyoxypropylene typical molecular weight of about 2,250, and containing 40 to 70 percent of polyoxyethylene, that is "Pluronic"s P84, P85 and F87, which possess the optimum combination of foaming ability, mild detergency, viscosity, water solubility and non-irritancy. The surfactant of choice is "Pluronic" F87.

Preferred compositions contain from 10 to 30 percent of "Pluronic" F87, ideally about 25 percent, and from 0.5 to 5.0 percent of chlorhexidine gluconate.

For user acceptability, the compositions should preferably possess moderate foaming properties, and to achieve this it is necessary to include a foaming agent. Most foaming agents deactivate chlorhexidine to a large extent, but with amine oxide foaming agents the deactivation is kept to a minimum. Nevertheless, some deactivation is unavoidable, so it is preferable to use a surfactant having maximum foaming properties, so that the quantity of deactivating foaming agent is kept to a minimum. "Pluronic"s P84, P85 and F87 have the greatest foaming ability and with these, the addition of 3.75 percent of an amine oxide foaming agent gives a composition having acceptable foaming properties, but with other "Pluronic"s it is necessary, in order to obtain a sufficiently foaming composition, to increase the quantity of foaming agent incorporated, and to increase also the quantity of chlorhexidine in order to overcome the deactivating effect of the additional foaming agent.

Suitable amine oxide foaming agents are, for example, cetyldimethylamine oxide, lauryldimethylamine oxide, cetylmethylmyristylamine oxide and dimethylmyristylamine oxide, and of these, cetyldimethylamine oxide is preferred as being the most stable and the least deactivating as a constituent of the composition of this invention.

An especially preferred group of compositions of the invention comprises those compositions containing 0.5 to 5.0 percent of chlorhexidine gluconate, about 25 percent of a copolymer as described above containing 40 to 70 percent of polyoxyethylene, and with a polyoxypropylene typical molecular weight of about 2,250, and about 3.75 percent of an amine oxide foaming agent, selected from those named above, together with an inert diluent or carrier.

The compositions may also optionally contain perfumes, colouring agents and preservatives, for example isopropyl alcohol, ethyl alcohol, methyl p-hydroxybenzoate or propyl p-hydroxybenzoate. It is also advantageous to adjust the pH of the composition to between 5 and 7, preferably to about 5.5, to minimise the precipitation of insoluble chlorhexidine salts on storage. A suitable agent for adjusting the pH of the compositions is, for example, gluconolactone, or the acid from which the anion of the chlorhexidine salt in use is derived.

The invention is illustrated but not limited by the following Examples in which the parts are by weight:

#### EXAMPLE 1

Chlorhexidine gluconate (20 parts of a 20 percent w/w solution), lauryldimethylamine oxide (3.75 parts) and water (47.145 parts) are heated to 60°C. with stirring, then "Pluronic" F87 (25 parts) is added slowly, with continuous stirring until all is dissolved. The solution is cooled, and isopropyl alcohol (4 parts), Edicol Supra Carmoisine W.S. (0.005 part) and Herbacol 15.393/T (0.1 part) are added, in any order. The pH of the preparation is then adjusted to 5.5 by the addition of 6 parts of a 10 percent w/v solution of d-gluconolactone.

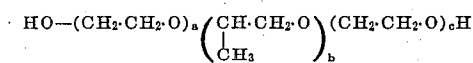
#### EXAMPLE 2

The process described in Example 1 is repeated, using 0.05 percent w/v of Edicol Supra Ponceau 4RS in place of Edicol Supra Carmoisine W.S., and adjusting the water content in proportion.

What we claim is:

1. A skin-cleansing composition which consists essentially of from 0.5 to 10.0 percent w/v of a salt of chlorhexidine which is soluble to the extent of at least 0.5 percent w/v in water at ambient temperature, se-

lected from the group consisting of the gluconate, isethionate, formate, acetate, glutamate, succinamate, mono-diglycollate, di-methanesulphonate, lactate, diisobutyrate and glucoheptonate salt, a polyoxyethylene-polyoxypropylene block copolymer of the formula



wherein  $a$ ,  $b$  and  $c$  are integers, such that said copolymer consists of 70 percent of polyoxyethylene and wherein the molecular weight of the polyoxypropylene content is about 2250, and water.

2. The composition of claim 1 which contains between 10 and 30 percent of copolymer.

3. The composition of claim 1 which contains from 0.5 to 5.0 percent of chlorhexidine gluconate.

4. The composition of claim 1 which additionally contains an amine oxide foaming agent selected from the group consisting of cetyldimethylamine oxide, lauryldimethylamine oxide, cetylmethylmyristylamine oxide and dimethylmyristylamine oxide.

5. A composition according to claim 1 wherein gluconolactone is included to provide a pH between 5 and 7.

6. The composition of claim 1 which consists essentially of from 0.5 to 5.0 percent of chlorhexidine gluconate, 25 percent of the copolymer containing 70 percent of polyoxyethylene and with a polyoxypropylene molecular weight of about 2250, and about 3.75 percent of an amine oxide foaming agent selected from the group consisting of cetyldimethylamine oxide, lauryldimethylamine oxide, cetylmethylmyristylamine oxide and dimethylmyristylamine oxide, together with said water.

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