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ANTISEPTIC SOAP BAR

5 This invention relates to soap bars having good antiseptic activity and in particular to soap bars containing reduced concentrations of chelating agents.

10 Many so-called medicated soap products are available through the world, the majority still being sold in the form of bar soaps. Such products are
15 generally referred to as antiseptic if they contain one or more antimicrobial agents, although their actual efficacy in use is rarely substantiated.

20 Thus many products contain higher than necessary levels of antimicrobial agents (resulting in increased costs and wastage) or levels that are not actually effective in use.

25 It is well known that the activity of many antimicrobial agents may be improved by the use of chelating agents and such agents are often used
30 indiscriminately in such products as antiseptic soaps.

35 In fact chelating agents are often used as stabilising agents in the soap base but are then added again during manufacture of the finished soap, in the belief that they will increase antimicrobial
40 activity.

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However, there are a number of drawbacks associated with the use of chelating agents, notably their cost, their potential as irritants and their environmental impact (eg their effect on river life etc).

Thus there is a continuing need for soap bar products having good, measurable, antiseptic activity but using the lowest possible concentrations of antimicrobial agents and chelating agents.

We have now found that a particular combination of active agents will produce satisfactory antiseptic activity in a bar soap (including a substantive effect on the skin) without the use of high levels of EDTA chelating agent.

There is therefore provided an antiseptic bar soap comprising:

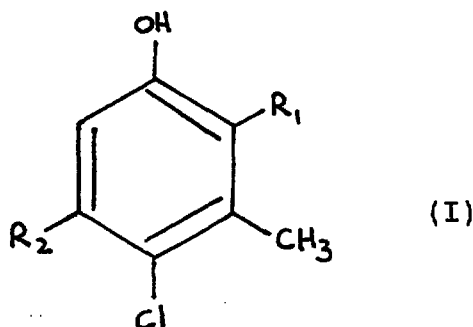
- a) 0.35 to 0.75% w/w of an antimicrobially active chlorinated methyl substituted phenol;
- b) 0.15 to 0.25% w/w triclosan (or a salt thereof); and
- c) less than 0.075% w/w (preferably less than 0.05% w/w) EDTA chelating agent.

Preferably the antiseptic bar soaps of the present invention contain no chelating agents other than those included in the soap base as stabilising agents.

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Chelating agents that may be included as stabilising agents in the soap base of the antiseptic bar soaps of the invention include EDTA (ethylene diamine tetraacetic acid and its soluble salts). Preferably the antiseptic bar soaps of the invention comprise less than 0.05% w/w EDTA and most preferably about 0.025% w/w EDTA.

The antimicrobially active chlorinated methyl substituted phenol used in the antiseptic bar soaps of the invention are preferably compounds of formula I



wherein R_1 is chlorine or hydrogen, and R_2 is methyl or hydrogen

Preferred compounds of formula I include PCMC (4-chloro-3-methylphenol), PCMX (4-chloro-3,5-di-

methylphenol), DCMX (2,4-dichloro-3,5-dimethylphenol) or mixtures thereof.

Preferably the antiseptic bar soaps of the invention comprise from 0.4 to 0.6% w/w of a compound of formula I, more preferably about 0.5% w/w.

Preferably the antiseptic bar soaps of the invention comprise about 0.2% w/w triclosan

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(2-hydroxy-4,2', 4'-trichloro-diphenyl ether) or a salt thereof.

5 The antiseptic bar soaps of the invention also
comprise a conventional soap base, which will
generally comprise saponified fatty acids derived
from natural sources. Examples of suitable soap bases
10 include an 80:20 mixture of tallow and coconut oil
fatty acids and an 80:20 mixture of distilled palm
oil fatty acids and distilled palm kernel fatty
15 acids. As stated previously the soap base may further
comprise chelating agents as stabilisers therefore
but it will preferably comprise no more than 0.05%
w/w total chelating agents and most preferably no
20 more than 0.025% w/w EDTA.

 The antiseptic bar soaps of the invention may
contain further conventional additives eg. colours,
25 fragrances (eg pine oil), etc.

 The antiseptic bar soaps of the invention may
be produced by any conventional method, such as
30 mixing of the components together in a hopper, roll
milling, extruding and then cutting and stamping into
the final shape.

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The invention will be illustrated by the following Examples.

5 Example 1

An antiseptic soap bar is produced to the following formula:

10		% w/w
	PCMX	0.5
	Triclosan	0.2
15	Pine Oil	1.5
	(fragrance)	
	Colours *	0.12
20	Water *	0.13
	DFA Soap	to 100%
	Chips	

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DFA Soap Chips:

Distilled fatty acids of Palm Oil 80 +/-3%

Distilled fatty acids of palm kernel oil 20 +/- 3%

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Additions: EDTA tetra sodium 0.025%.

Also 0.2% EHDP which is [phosphoric acid

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(1-hydroxy-ethylidene) bis] is added as a stabiliser.

* The colours and water are premixed and closed as a colour solution.

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The components are mixed together in a hopper and these then go through a roll mill, at ambient temperature and pressure. From there the mixture is passed into a plodder (extruder) also at ambient

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temperature and then from the extruder it is chopped and stamped into the requisite shape.

5 The soap bar has good antiseptic activity and is substantive on the skin.

10 Example 2

The substantive activity of soap bars of the invention was demonstrated in the following test.

15 Standard soap solutions were made by dissolving a tallow soap base in standard hard water to give a concentration of 8% (approximately the same
20 concentration as in lather during hand washing). Three solutions were prepared each containing 0.04% w/w PCMX (equivalent to 0.5% w/w in a soap bar) and either 0.008, 0.016, or 0.024% w/w triclosan
25 (equivalent to 0.1, 0.2 and 0.3% w/w in a soap bar).

Volunteers dabbed a finger onto the centre of a
30 Tryptone Soya Agar plate for 30 seconds, washed their hands for 1 minute in 5ml of one of the above solutions, rinsed them, and again dabbed their finger onto an agar plate.

35 The agar plates were then swabbed with a suspension of either *Staphylococcus aureus* or *Escherichia coli* and incubated overnight at 30°C.
40 They were inspected next day for the presence of a zone of inhibition.

45 In all cases the unwashed hands, and those washed in solutions equivalent to 0.1% w/w triclosan

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containing soaps, produced no zones of inhibition;
indicating no substantive effect on the skin.

5 In all cases the hands washed in solutions
equivalent to 0.2% or 0.3% w/w triclosan containing
soaps produced distinct zones of inhibition;
10 indicating a substantive antimicrobial effect on the
skin.

 This indicates that more than 0.1% w/w
15 triclosan is necessary to produce a soap bar with
substantive antiseptic activity, but that more than
0.2% w/w triclosan is not necessary (even in the
absence of added EDTA).

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Claims

1. An antiseptic bar soap, the bar soap comprising:

a) 0.35 to 0.75% w/w of an antimicrobially active chlorinated methyl substituted phenol;

b) 0.15 to 0.25% w/w triclosan (or a salt thereof); and

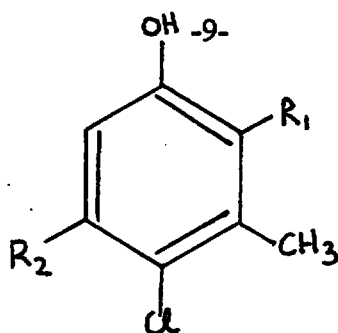
c) less than 0.075% w/w EDTA chelating agent.

2. An antiseptic bar soap according to Claim 1 in which any chelating agents present are in the soap base of the bar soap as stabilising agents.

3. An antiseptic bar soap according to Claim 1 or Claim 2 in which the chelating agents included as stabilising agents in the soap base are selected from ethylene diamine tetraacetic acid (EDTA) and its soluble salts and [phosphoric acid (1-hydroxy ethylidene) bis].

4. An antiseptic bar soap according to any one of the preceding claims comprising less than 0.05% w/w EDTA, preferably about 0.025% w/w EDTA.

5. An antiseptic bar soap according to any one of the preceding claims in which the antimicrobially active chlorinated methyl substituted phenol used in the antiseptic bar soaps of the invention are preferably compounds of Formula I



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wherein R_1 is chlorine or hydrogen, and
 R_2 is methyl or hydrogen

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6. An antiseptic bar soap according to Claim 5 in which the compounds of formula I are selected from
 15 4-chloro-3-methylphenol, 4-chloro-3,5-dimethylphenol, 2,4-dichloro-3,5-dimethylphenol and mixtures thereof.

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7. An antiseptic bar soap according to any one of the Claim 5 or Claim 6 comprise from 0.4 to 0.6% w/w of a compound of formula I, defined in Claim 5.

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8. An antiseptic bar soap according to any one of the Claim 5 or Claim 6 comprise about 0.05% w/w of a compound of formula I, defined in Claim 5.

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9. An antiseptic bar soap according to any one of the preceding claims which comprise about 0.2% w/w triclosan (2-hydroxy-4,2', 4'-trichloro-diphenyl ether) or a salt thereof.

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10. An antiseptic bar soap as claimed in any one of the preceding claims in which the soap base comprises
 40 saponified fatty acids derived from natural sources, preferably an 80:20 mixture of tallow and coconut oil fatty acids and an 80:20 mixture of distilled palm oil fatty acids and distilled palm kernel fatty acids

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