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NEW ZEALAND

PATENTS ACT, 1953

PROVISIONAL SPECIFICATION

"A Herbal Composition and Uses Thereof"

We, Phytomed Medicinal Herbs Limited a company duly incorporated under the laws of New Zealand of 23 Covil Avenue, Te Atatu South, Auckland, New Zealand, do hereby declare this invention to be described in the following statement:

Field Of The Invention

The present invention relates to a herbal composition useful as a method of treatment and/or prophylaxis of oral pathogens.

Background To The Invention

People suffering from oral disease caused by oral pathogens, such as gum disease and/or halitosis, find such diseases a social inhibitor, such that it affects a person's social interaction and loss of dignity. In some cases affected people do not realise they suffer from gum disease and left untreated can lead to serious loss of gum and eventual loss of teeth.

Such pathogens are in hard to reach places inside the mouth, where conventional cleaning methods of brushing the teeth or flossing is not sufficient by themselves to remove the pathogens causing halitosis and/or gum disease. Indeed such pathogens can be harboured in pieces of food remaining in the mouth and if the pathogens are provided with an environment to their liking, such pathogens can get under the gum, thus brushing with a tooth brush will not remove such pathogens.

Conventional mouthwashes used for the treatment and/or prophylaxis of these conditions, such as those based upon chlorhexidine, have certain disadvantages. These can include their unpleasant taste, staining of the teeth with prolonged use, a burning sensation of the tongue on initial use, and altering taste sensation. These factors can make it very difficult to encourage young children (who have high caries risk) to use chlorhexidine.

In terms of herbal remedies, those containing tannins such as manuka (*Leptospermum scoparium*) and tanekaha (*Phyllocladus trichomanoides*) can be useful in attacking oral pathogens as some tannins have such activity.

Object of the Invention

It is an object of the present invention to provide an herbal composition which has advantages over what is currently known or which at least provides the public with a useful choice.

Summary Of The Invention

In a first aspect of the invention there is provided **a herbal composition useful in the treatment and/or prophylaxis of oral pathogens** comprising or including an effective amount of Manuka extract.

Preferably the manuka extract is a hydroethanolic extract.

Preferably the composition includes one or more of:

- one or more liquid carriers,
- one or more excipients,
- one or more compatible carriers,
- one or more orally acceptable carriers,
- one or more flavouring agents.

Preferably the excipients and/or flavouring agents and/or carriers (which many take the form of a hydroethanolic extract and/or essential oil) may include:

Liquorice liquid extract,

Aniseed liquid extract,

Peppermint essential Oil,

Mint,

Honey.

Preferably also benzoic acid (as a preservative) and/or glycerine may be added.

Preferably the composition is administered as a mouthwash. Alternatively the composition is administered as an oral spray.

Preferably the manuka extract is sourced from the East Cape of New Zealand.

Preferably the effective amount of manuka extract is between 0.3 to 1.0% v/v.

Preferably the liquid carrier is de-ionised water and/or ethanol.

In a second aspect of the invention there is provided **a herbal composition useful in the treatment and/or prophylaxis of oral pathogens** comprising or including an effective amount of Tanekaha extract.

Preferably the Tanekaha extract is a hydroethanolic extract.

Preferably the composition includes one or more of:

- one or more liquid carriers,
- one or more excipients,
- one or more compatible carriers,
- one or more orally acceptable carriers,
- one or more flavouring agents.

Preferably the excipients and/or flavouring agents and/or carriers (which many take the form of a hydroethanolic extract and/or essential oil) may include:

Liquorice liquid extract,

Aniseed liquid extract,

Peppermint essential Oil,

Mint,

Honey.

Preferably also benzoic acid (as a preservative) and/or glycerine may be added.

Preferably the composition is administered as a mouthwash. Alternatively the composition is administered as an oral spray.

Preferably the Tanekaha is sourced from the trees found in their natural habitat in the New Zealand bush.

Preferably the effective amount of Tanekaha extract is between 10 to 25% v/v.

Preferably the liquid carrier is de-ionised water and/or ethanol.

In another aspect of the present invention there is provided a herbal composition useful in the treatment and/or prophylaxis of oral diseases comprising or including:

- an effective amount of manuka extract, and
- an effective amount of tanekaha extract.

Preferably one or both of the manuka and tanekaha extracts are hydroxyethanolic extracts.

Preferably the composition is a synergistic composition.

Preferably there is further included an effective amount of manuka essential oil

Preferably the composition includes one or more of:

- one or more liquid carriers,
- one or more excipients,

- one or more compatible carriers,
- one or more orally acceptable carriers,
- one or more flavouring agents.

Preferably the excipients and/or flavouring agents and/or carriers (which many take the form of a hydroethanolic extract and/or essential oil) may include:

Liquorice liquid extract,

Aniseed liquid extract,

Peppermint essential Oil,

Mint,

Honey.

Preferably also benzoic acid (as a preservative) and/or glycerine may be added.

Preferably the composition is administered as a mouthwash. Alternatively the composition is administered as an oral spray.

Preferably the manuka extract is sourced or derived from the East Cape of New Zealand.

Preferably the Tanekaha is sourced from the trees found in their natural habitat in the New Zealand bush.

Preferably the effective amount of manuka extract is between 0.3 to 1.0% v/v.

Preferably the effective amount of tanekaha extract is between 10 to 25% v/v.

Preferably the liquid carrier is de-ionised water and/or ethanol.

Preferably the Manuka extract and oil can be sourced or derived from Tairawhiti Pharmaceuticals who produce this from Manuka harvested from the East Cape of New Zealand.

Preferably the Tanekaha and Manuka liquid extracts are extracted from the raw material using a cold percolation extract or a maceration process.

In a further aspect of the invention there is provided a method of extracting manuka and/or tanekaha to form one or more hydroethanolic extracts for use in a herbal composition useful in the treatment and/or prophylaxis of oral pathogens comprising or including the steps of:

1 Powdering dried manuka and/or tanekaha (hereafter "plant"),

2 Wetting the dried plant from above with a mixture of ethanol and water,

3 Packing the wetted plant material into a percolator vessel,

4 Addition of a mixture of more ethanol and water to the plant material in the percolator vessel,

5 Allowing the ethanol/water mixture to slowly permeate down the length of the percolator vessel, extracting active constituents from the plant in the process,

6 Collecting the plant extract thus produced at the outlet tap of the percolator.

Preferably the method further includes the step:

7 Once percolation is complete, pressing the remaining plant material to extract remaining hydroethanolic extract.

Preferably the combination of the liquid extracts obtained from 6) and 7) produce the finished plant extract.

Alternatively and/or additionally, extracts may be obtained by simply blending/homogenising fresh herb with a mixture of ethanol and water.

Preferably the extracts of manuka and/or tanekaha are combined with one or more of:

- one or more liquid carriers,
- one or more excipients,
- one or more compatible carriers,
- one or more orally acceptable carriers,
- one or more flavouring agents.

Preferably the excipients and/or flavouring agents and/or carriers (which many take the form of a hydroethanolic extract and/or essential oil) may include:

Liquorice liquid extract,

Aniseed liquid extract,

Peppermint essential Oil,

Mint,

Honey.

Preferably also benzoic acid (as a preservative) and/or glycerine may be added.

In a further aspect of the invention there is provided one or both of manuka and/or tanekaha extracts as hydroethanolic extracts for use in a herbal composition useful in the treatment and/or prophylaxis of oral pathogens and/or oral diseases prepared or extracted substantially according to the above method.

In a further aspect the present invention consists in the use of such a herbal composition for the treatment and/or prophylaxis of oral diseases.

Preferably the oral diseases include halitosis and/or gum disease. The elimination from the mouth of food material which can be difficult to remove through methods of brushing or flossing alone, is an additional application of the present invention.

Detailed Description of the Invention

The present invention has surprisingly shown that the use of the traditional New Zealand herbs Manuka (*Leptospermum scoparium*) and Tanekaha (*Phyllocladus trichomanoides*) administered either together or separately as a mouthwash provides an effective treatment against such oral diseases, especially the oral diseases of halitosis and gum disease.

The Manuka and Tanekaha have been sourced from New Zealand Native trees using an extraction process to obtain the herbs as hydroethanolic extracts. These extracts have been found to exhibit special characteristics including *in vitro* bactericidal activity against 3 known oral pathogens, Streptococcus mitis, Streptococcus mutans, and Actinomyces naeslundii.

The hydroethanolic extraction processes used (in the manufacture of these extracts), have been found to extract not only tannins, but also a range of other phytochemicals including terpenes and volatile oils, which contribute to this activity against oral pathogens.

The activity of a herbal composition of the present invention has been found to prevent and or treat halitosis and/or other infections causing mouth diseases.

This has shown by experiment where the bacterial pathogens studied were *Streptococcus mutan; Streptococcus mitis*; and *Actinomyces naeslundii.* Such plaque-forming gram positive bacteria are found in the mouth and are known to cause the oral diseases of halitosis and/or gum disease.

Administration:

The composition of the invention can be used in any number of ways as would be known in the art. However, specifically the invention is intended to be shaken before use, then 2-4ml diluted with 20-40ml of water, and used to rinse the mouth for a period of 20-30 seconds, twice daily. The liquid should then be expelled from the mouth.

DATED THIS 26th DAY OF March 2002
AJ PARK
PER
AGENTS FOR THE APPLICANT

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