Title: USE OF HONEYBUSH OR HONEYBUSH EXTRACTS FOR SKIN AND HAIR

Abstract: The present invention relates to the use of honeybush or honeybush extract for improving skin or hair health by preventing, alleviating or treating skin or hair disorders or damages such as is effected by inflammatory reactions, environmental factors, ageing or cancer. In particular the present invention relates to the use of honeybush or honeybush extracts to improve UV protection or skin glow or reduce skin wrinkles or skin inflammation.
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Background of the Invention

The most prominent epithelial tissue in living beings is the skin, which represents the largest organ in the organism. The system of skin integument, which comprises the epidermis, dermis and the stratum corneum, correlates with those of internal organs and concurrently interacts with the surroundings. Being the interface between the environment and organism itself, the skin is heavily influenced by external factors and also variable parameters of the organism's inner system. The skin's regulative mechanisms need, therefore, always be active to induce systemic changes necessary to maintain normal pathological events concerning skin integument morphology and activities.

A great deal of processes assuring the adequate consumption of increased affluence of energetic and plastic substances according to the skin's needs become guarantors of morphological and functional stability of skin structures. So, the state of integuments determines the realization of metabolic processes necessary for skin cell viability and activity leading to the presence of healthy skin peculiarities such as barrier function, elasticity, turgor properties, humidity or pigmentation, for example.

During the lifetime of a living being different signs, characteristic of ageing, appear on the skin or hair, with the principal clinical signs being the appearance of fine lines and deep wrinkles which increase or are accentuated with age, loss of hair, reduced hair density, glossiness, color, oiliness, fiber diameter, for example. It can also promote hair growth.
These signs of ageing are even promoted by exposure of the skin and hair to exogenous influences, such as e.g. UV-radiation, pollutants, free radicals or chemical substances.

Moreover, the cutaneous barrier is exposed daily to chemicals, xenobiotic and particles composing urban pollution. Among these atmospheric pollutants likely to exert noxious effects on the skin and the hair, three main categories can be distinguished. They are essentially gas, heavy metals, and particles which are the residues of combustion on which are adsorbed many organic compounds. The gases contribute more particularly to the formation of an environment "pro-oxidant" to which the most external surface tissues are directly exposed.

The oxidation and the degradation of the lipids of the stratum corneum can deteriorate the function barrier of the stratum corneum. The disturbance of the external lipids and the architecture of proteins are factors starting in many dermatoses (psoriasis, atopic dermatitis, irritating dermatitis). In addition, a significant oxidative attack on the level of the surface layers of the stratum can initiate subjacent localised inflammatory processes. This deterioration of the cutaneous barrier can be in particular translated for a subject by feelings of cutaneous discomfort, phenomena sensory and/or the demonstration of undesirable cutaneous signs, even painful such as irritations. The above mentioned signs of discomfort can be moreover associated with undesirable cutaneous signs, such as rednesses, irritations, scabs, erythemas inflammatory, oedemas and/or buttons.

In the art several means have been proposed to prevent destructive effects of environment or ageing on skin epithelial cells. For example, means to prevent skin deterioration or ageing is to provide compounds scavenging free radicals. In this respect EP 0 761 214 discloses singlet oxygen quenchers comprising aniline derivatives and difurfuryl amine derivatives, which are reported to reduce the oxidative stress to the skin.

Although there is a great diversity of active compounds for ameliorating skin and hair or coat health, there still exists a need in the art to provide new active compounds,
naturally occurring. In particular, an object of the present invention is to provide compositions that may be used over a long period of time by humans or pets, and susceptible to be provided in the form of a nutritional supplement, a food or petfood composition or a beverage.

Summary of the invention

The present inventors were surprised to see that they could achieve this object by using Honeybush or Honeybush extract.

Honeybush is a wild South African plant that grows in a specific area of the south-western part of South Africa, and that is commonly used by local populations to prepare infusion in the same manner as tea. The scientific names of Honeybush species - thus called since its flowers have the smell of honey - that are most commonly consumed are \textit{Cyclopia intermedia}, \textit{C. Subternata}, \textit{C. Genistoides}, \textit{C. Maculata}.

Thus, the present invention relates to the use of an orally administrable composition comprising Honeybush or an extract thereof for the preparation of a product to improve skin or hair health, treat, alleviate and/or prevent skin or hair disorders.

The skin disorders or damages that can be treated, alleviated or prevented according to the present invention can for example be selected from the group consisting of skin inflammation, such as UV or chemical-induced skin inflammation, reactive or dry skin, psoriasis, vitiligo, acne, ageing, UV protection, photo ageing, wrinkles. It can also provide beneficial effects on skin hydration, skin moisture or skin glow.

The hair (or coat) disorders or damages that can be treated or prevented are hair and coat gloss, hair density, color, oiliness, ameliorating hair fiber diameter, sebum production, glossiness and preventing hair and coat loss.

Also, the composition according to the present invention is administered to a human or to an animal, for ameliorating antioxidant status or barrier function of the skin.

Detailed Description of the Invention
In a particular preferred embodiment of the present invention, suitable extracts of Honeybush may be prepared by any means that are known in the art, e.g., by steam extraction, solvent extraction, distillation, pressing or grinding.

It is however preferred if the extract is obtainable, in particular obtained, by extraction with a solvent from *Cyclopia ssp.* plant material, in particular by a water extraction or an alcohol/water extraction, for example by a ethanol/water extraction.

The use of water as extraction medium has the advantage that the obtained product can be directly incorporated into final products without having to eliminate the extraction medium first.

The traditional process to prepare infusible leaves out of Honeybush plants was as follows: plants are harvested by cutting their stems and leaves which are then put in a heap. The temperature inside the heap rapidly raises up to 40°C, which causes fermentation of the leaves. After about one day, the leaf and stem pieces are dried in the sun and sieved, ready for infusion. This process is progressively replaced by batch rotary fermentation of moistened leaves and stems, after which a sun-drying step is still preferred. The infusion is then prepared in large quantities which are filtered and concentrated. Preferably after further purification, the ingredient is then ready to be added to any food preparation.

The *Cyclopia* extracts may also be obtainable, and are in particularly obtained by a method comprising the steps of: i) mixing and milling *Cyclopia* material in milk or a milk protein-containing liquid medium, ii) optionally separating insoluble material to obtain an aqueous suspension iii) optionally pasteurising the resulting suspension iv) optionally add synthetic or natural bioactive components during the processing v) and further optionally drying the suspension to obtain a powder.

This process has the advantage of being natural and cost effective enabling improved delivery of multi-nutrients in the form of a combination of stabilized water-
and fat-soluble compounds in their natural compositions, free of organic solvent residues.

If an extract of *Cyclopia spp* is used in the present invention it is preferred if at least 50wt.-%, preferably at least 70 wt.-% more preferably at least 95 wt.-% of the extract are water soluble. This has the advantage that the extract can easily be admixed with other water based foodstuffs before consumption.

One typical example of an extract of *Cyclopia spp* that can be used in the framework of the present invention is honeybush tea and also extracts that are commercially available, such as for example Honeybush from Afplex or Honeybush from Rooibos Ltd.

The product comprising a composition comprising honeybush or an extract thereof according to the present invention may be for example a food product, a drink, a food supplement, a nutraceutical, a pet food product or a medicament.

The product may also further comprise a protein source, a carbohydrate source, a lipid source, a mineral source and/or a vitamin source. The presence of proteins, carbohydrates, lipids, minerals and/or vitamins may have several advantages. These compounds generally contribute to the taste and mouthfeel of the final product. They also provide the body with nutrients that it may need urgently when it is affected by skin/hair disorders. They also allow formulating the product of the present invention as a complete nutritional formula, so that no additional nutrition is needed. This might be in particular helpful for consumers that do not ingest sufficient amounts of food or that have trouble swallowing and that hence wish to ingest only small amounts of food.

Consequently, the products used in the present invention are preferably intended for enteral application. Also a parenteral administration is possible. While the products are primarily intended to be used by humans, they may also be applied to animals, in particular companion animals, pets or livestock.
Particularly preferred products are products selected from the group consisting of teas, iced teas, a foamed beverage, a confectionery product, a culinary product, a nutritional complete formula, a dairy product, a chilled or shelf stable beverage, a product for lactating mothers, a liquid drink, a soup, a dietary supplement, a meal replacement, a nutritional bar, a milk or a fermented milk product, a yoghurt, a milk based powder, an enteral nutrition product, an infant formula, an infant nutritional product, a puree, a cereal product or a fermented cereal based product, an ice-cream, candy, sweets, biscuits, cakes, a chocolate, a cappuccino, a coffee, a culinary product such as mayonnaise, tomato puree or salad dressings, a pet food, a pet beverage, a tablet, a capsule, a pill, a solution, a suspension, a syrup, a powder, a gel, a dried oral supplement or a wet oral supplement.

The amounts of Cyclopia spp or an extract thereof in the product will depend on several factors, such as the nature of the extract, the condition of the plant, the age, condition and size of the person or animal to be treated, the frequency, the product will be applied and/or the specific kind of skin/hair disorder or damage to be treated or prevented.

The present inventors have found that the effectiveness of Cyclopia spp or an extract thereof according to the present invention is generally dose dependant and follows a dose response curve. If generally mild skin/hair disorders or damages are to be prevented and the product will be used frequently, very small amounts of Cyclopia spp or an extract thereof will be sufficient to achieve the desired effect. If a severe skin disorder is to be treated, larger amounts of Cyclopia spp or an extract thereof will be more appropriate, although also small amounts will produce an effect.

Generally, it is preferred if the product contains Cyclopia spp or an extract thereof in an amount in the range of about 0,1 g/l to 10 g/l, preferably in the range of 0,5 g/l to 3 g/l product. If the total amount of product cannot be measured in litres it is preferred if the product contains Cyclopia spp or an extract thereof in an amount in the range of about 0,1 g/kg to 10 g/kg, preferably in the range of 0,5 g/kg to 3 g/kg product.

Preferably the product contains Cyclopia spp or an extract thereof in a daily dose of 0,01 g-1 00g, preferably 0,25 g-1 0g.
The product may also comprise at least one kind of food grade micro-organism, in particular probiotics.

"Food grade" are all substances that are approved for human or animal consumption.

"Probiotic" means microbial cell preparations or components of microbial cells with a beneficial effect on the health or well-being of the host.

For the purpose of the present invention, the probiotics may be selected from the group consisting of Bifidobacterium, Lactobacillus, Streptococcus and Saccharomyces or mixtures thereof, in particular selected from the group consisting of Bifidobacterium longum, Bifidobacterium lactis, Lactobacillus acidophilus, Lactobacillus rhamnosus, Lactobacillus johnsonii, Lactobacillus plantarum, Lactobacillus salivahus, Streptococcus faecium, Saccharomyces boulardii and Lactobacillus reuteri or mixtures thereof, preferably selected from the group consisting of Lactobacillus johnsonii NCC 533 (CNCM 1-1225), Bifidobacterium longum NCC 490 (CNCM 1-2170), Bifidobacterium longum NCC 2705 (CNCM 1-2618), Bifidobacterium lactis Bb12, Bifidobacterium lactis NCC2818 (CNCM I-3446), Lactobacillus paracasei NCC 2461 (CNCM 1-2116), Lactobacillus rhamnosus GG, Lactobacillus rhamnosus NCC4007 (CGMCC 1.3724) Enterococcus faecium SF 68 (NCIMB 10415), and mixtures thereof.

The presence of probiotics in a composition comprising Honeybush or an extract thereof may have several important effects. Consequently, the combination of probiotics with honeybush or an extract thereof can be expected to have a further positive effect on the treatment and prevention of skin/hair disorders or damages.

Finally, the product prepared for the use of the present invention may also contain at least one phytonutrient.

The term "phytonutrient" describes those plant compounds which have health-protecting qualities. For example antioxidant, immune boosting or other health promoting properties of active compounds in plants are typical effects of
phytonutrients. Phytonutrients include but are not limited to terpenes, carotenoids, limonoids, polyphenols, and phytosterols.

The carotenoids may be selected from the group consisting of carotenes and xanthophylls such as lycopene, carotene, phytofluene, phytoene, canthaxanthin, beta-cryptoxanthin, capsanthin, lutein, zeaxanthin, or those in the form of fatty acid esters, or mixtures thereof.

The polyphenols are preferably selected from the group consisting of flavones such as apigenin, luteolin or diosmetin, flavonols such as quercetin, myricetin, kaempferol, flavanones, anthocyanidins or isoflavones such as genistein, daidzein, or phenolic acids such as caffeic, ferulic acid or mixtures thereof.

Preferred phytonutrients for the present invention are beta-carotene, lutein, and/or catechin. The phytonutrients may be also provided in the form of a plant or plant extract.

It is clear to those of skill in the art that they can freely combine all features described herein without departing from the scope of the present invention as disclosed. In particular, features described for the use of the present invention may be applied to the composition comprising honeybush or an extract thereof or the product comprising the composition comprising honeybush or an extract thereof and vice versa.

Further advantages and features of the present invention are apparent from the following examples.

For example 1 below, Honeybush is added to the other ingredients as Honeybush extract powder. In all example compositions, "Honeybush" refers to Honeybush extract. This Honeybush sweetening powder is obtained by the following preparation process, comprising the steps of, in order:

(i) mixing 100g Honeybush dried leaves and stems with 1 litre boiling water,

(ii) infusing the mix for about 5 minutes, and then
(iii) discarding solids from the infusion so as to obtain a liquid beverage containing about 10 g/l of Honeybush dry matter,
(iv) removing water so as to obtain a dry extract powder.

Example 1:
Powdered beverage composition comprising cereals, fruit powder and/or bits, and/or chocolate ingredients are prepared that incorporate an extract of Honeybush plant. They are formulated as follows (quantities are given in % of total weight of the composition):

- Honeybush dry matter between 0 and 80 %
- Cocoa between 5 and 40 %
- Maltodextrine between 0 and 80 %
- Flavours, vitamins and Lecithin 1-5 %
- Sugar between 0 and 80%
Claims

1. Use of a composition comprising honeybush or an extract thereof for the preparation of an orally administrable product for improving skin or hair health by preventing, alleviating or treating skin or hair disorders or damages such as is effected by inflammatory reactions, environmental factors, ageing or cancer.

2. Use in accordance with claim 1, wherein the skin disorder or damage is selected from the group consisting of skin inflammation, reactive or dry skin, psoriasis, vitiligo, acne, ageing, UV protection, photo ageing, wrinkles

3. Use in accordance with claim 1; which improves skin glow, skin hydration or moisture of the skin

4. Use in accordance with claim 1, wherein the hair or coat disorder or damage is selected from the group consisting of hair and coat gloss, hair density, color, oilness, ameliorating hair fiber diameter, sebum production, glossiness and preventing hair and coat loss.

5. Use in accordance with claim 1, for promoting hair growth.

6. Use in accordance with one of the preceding claims, wherein the extract is obtainable by extraction with a solvent from *Cyclopia* spp. plant material, in particular by a water extraction or an alcohol/water extraction, for example by a ethanol/water extraction.

7. Use in accordance with one of the preceding claims, wherein at least 50 wt.-%, preferably at least 70 wt.-% more preferably at least 95 wt.-% of the extract are water soluble.

8. Use in accordance with one of the preceding claims, wherein the product is a food product, a drink, a food supplement, a nutraceutical, a pet food product or a medicament.
9. Use in accordance with one of the preceding claims, wherein the product contains *Cyclopia spp.* or an extract thereof in an amount in the range of about 0,1 g/l to 10 g/l, preferably in the range of 0,5 g/l to 3 g/l.

10. Use in accordance with one of the preceding claims, wherein the product contains *Cyclopia spp.* or an extract thereof in a daily dose of 0,01 g-1 00g, preferably 0,25 g-1 0g.

11. Use in accordance with one of the preceding claims, wherein the product further comprises a protein source, a carbohydrate source, a lipid source, a mineral source and/or a vitamin source and is for oral, enteral and/or parenteral application.

12. Use in accordance with one of the preceding claims, wherein the product comprises at least one kind of food grade micro-organisms, in particular probiotics.

13. Use in accordance with claim 12, characterized in that the probiotics are selected from the group consisting of group consisting of *Bifidobacterium, Lactobacillus, Streptococcus* and *Saccharomyces* or mixtures thereof.

14. Use in accordance with one of the preceding claims, wherein the product further contains at least one phytonutrient, preferably selected from the group consisting of lutein and catechin.