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(54) Title: SENSITIVE CARE AND CLEANSING COMPOSITIONS

(57) Abstract: Present invention relates to plant based compositions suitable for skin and hair care especially in newborns and children. The invention particularly relates to a shampoo composition that provides controlled and optimum pH and has cleansing and nurturing effects.

SENSITIVE CARE AND CLEANSING COMPOSITIONS

Field of the Invention

Present invention relates to a composition with cleansing and nurturing effects that contains plant-based ingredients. In particular, the present invention relates to providing the composition of interest for use in cosmetic products intended for newborns.

Background of the Invention

Newborns have thin skin and they are cleaned almost every day since they are sensitive. Currently, there is a need for products that will not harm the babies and especially newborns while providing effective cleansing and care, as this cleansing should be performed using significantly gentle and effective methods and products. Since these products will be used on sensitive skin, many important parameters are considered in product selection such as pH value, contained surfactant, and effectiveness in moisturizing and care.

Document no. US 2014/0349902 A1 describes compositions that contain water, biosurfactant and at least one fatty acid for use in shower gels, shampoos, care agents, body or skin cleansers. Compositions described in this document were characterized as “sensitive” and described compositions that contain chamomile extract have a pH value around 4,9 and they contain anionic surfactants.

US patent no. 5,124,078 describes extra sensitive shampoo and shower gel compositions that contain a small amount of surfactants. However, compositions described in this document contain some irritant anionic surfactants such as SLS (sodium lauryl sulfate) and their pH values range between 6,5-6,8.

In the light of this information, present invention provides a sensitive and non-irritant composition that has antimicrobial effects and that can provide intensive skin and hair care. Plant-based ingredients in this composition provide direct antimicrobial effect while the combination of lactic acid and urea prevents the presence of harmful organisms by regulating the pH value of the composition. In addition, present inventors have found that the combination of lactic acid and urea, which is used as buffer, also increases the nurturing effect. Surfactants in the composition are directly effective in cleansing, wherein they don't cause any irritating effects since they are nonionic and/or amphoteric. Care agents provided

by the composition of the invention including panthenol and hydrolyzed wheat proteins, collectively provide intensive moisturizing and care.

Brief Description of the Invention

Present invention essentially relates to a composition that contains at least one antimicrobial plant extract, panthenol, urea and lactic acid. The mentioned plant extract is preferably selected from the group that comprises *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract. This plant extract more preferably contains a combination of *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract.

In preferred embodiments of the present invention, a composition that contains the following components at the following amounts by weight based on the total weight of the composition is provided;

-	*Antimicrobial plant extract*	5 – 35%
-	Panthenol	0,1 – 5%
-	Urea	>0 – 1%
-	Lactic acid	>0 – 1%

The composition of the invention may also contain at least one additional agent selected from a care agent, preservative, emollient, chelating agent, surfactants, pH regulating agent, perfuming agent, rheology agents and solvents.

Compositions of the invention may contain an amphoteric and/or nonionic surfactant. Amphoteric surfactant can be selected from the group that contains cocamidopropyl betaine, cocodimethylsulfopropyl betaine and lauryl-betaine and nonionic surfactants can be selected from the group that contains sodium cocoamphoacetate, lauryl glycoside, octaethylene glycol, monododecyl ether, glyceryl laurate, cocamide DEA and coco-glycoside.

Compositions of the invention may contain an emollient and the emollient is preferably selected from the group that comprises glyceryl oleate and myristyl lactate. Composition of the invention may also contain additional care agent(s), wherein these agents are preferably selected from the group that contains hydrolyzed wheat protein, sodium PCA, glycine, glucose, sodium levulinate, sorbitol, glycerin, propylene glycol, hexylene glycol, butylene glycol, maltose and sodium glucuronate.

Preservative of the invention may be selected from the group that comprises potassium sorbate and/or sodium benzoate, and the composition of interest may contain tetrasodium glutamate diacetate as a chelating agent in order to boost the activity of the preservative.

Composition of the invention may be presented in shampoo, cream, gel or lotion form. The composition is more preferably presented as a shampoo and even more preferably as a newborn shampoo.

According to another aspect, the present invention relates to a production method of a composition that contains antimicrobial plant extract, panthenol, urea and lactic acid including the following steps:

- adding at least one antimicrobial plant extract as active ingredient into water and mixing while heating,
- adding panthenol, urea and lactic acid to the mixture, mixing until the mixture is homogenous and obtaining the final product.

According to another aspect, present invention relates to the use of a composition that contains at least one antimicrobial plant extract, panthenol, urea and lactic acid in a shampoo composition.

Detailed Description of the Invention

Skin and scalp of newborns are quite thin and sensitive. The scalp of newborns is generally covered with a white, waxy, protective and greasy substance called vernix. There are many points to pay attention considering the cleansing of newborns: they can get sick even due to a very minor microbial contamination since their immune system is weak and epidermal barrier is thin, their sensitive and thin skin can easily get irritated and should always be moist. Therefore, content of a cleansing product that will be used in newborns is important.

Today, newborns are cleaned using some special shampoos. Generally, shampoos achieve cleansing with the surfactants they contain. In addition to these surfactants, the shampoo composition may also contain thickening agents, stabilizers, preservatives, various perfumes and aroma, care agents, thinners and opacifiers. For baby shampoos, it is generally desired to keep those ingredients at the optimum level and provide effective cleansing while preventing harmful effects.

Compositions described within the scope of the present invention essentially contain at least one antimicrobial plant extract, panthenol, urea and lactic acid. The mentioned antimicrobial

plant extract is preferably selected from the group that comprises *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract. In a preferred embodiment, antimicrobial plant extract contains the combination of Chamomilla recutita (Matricaria) flower juice and Malva sylvestris extract.

The composition may also contain hydrolyzed wheat protein as an additional hair and skin care agent. These compositions may additionally contain surfactants, emollients, care agents, preservatives, chelating agents and/or perfuming agents.

Chamomilla Recutita/Matricaria flower has been used from past to present in various cosmetic and pharmaceutical compositions due to its anti-inflammatory, antibacterial, antiviral and antifungal effects. The amount of *Chamomilla recutita (Matricaria)* flower juice, which also shows moisturizing and nurturing effects, is between 5 to 35%, preferably 10 to 25% by weight in the composition described within the scope of the present invention. Another ingredient *Malva sylvestris* extract is used in herbal treatments due to its sedative effects. In the present invention, when it is used in combination with *Chamomilla recutita (Matricaria)* flower juice, it boosts the antimicrobial and hair nourishing effect and it can be contained in the total composition in an amount between 0,1%-5%, preferably between 0,1%-1% by weight.

Hydrolyzed wheat proteins provide intensive scalp and hair care and show nourishing and moisturizing effects. The amount of hydrolyzed wheat protein in the composition of the present invention is higher than 0 and lower than or equal to 1%, preferably higher than 0 and lower than or equal to 0,1% by weight in the total composition. Wound healing and moisturizing effects of panthenol have been known for many years. The amount of panthenol in the present invention is between 0,1% and 5%, preferably between 0,1% and 1% by weight in the total composition. When panthenol and hydrolyzed wheat proteins are used in combination, they provide intensive moisturizing and care for the baby's scalp.

The mixture of lactic acid and urea act as an acidity regulator and in addition, increase the moisture in the upper layer of the skin. Acidity is of significant importance since the composition described here will be used in babies and especially newborns. Very high or low pH values may pose harmful effects for the baby's skin and health. For instance, the use of compositions with high pH value may lead to creating a suitable environment for some harmful microorganisms to live on the baby's skin, whereas compositions with low pH value may irritate the highly sensitive skin of the baby. Therefore, compositions according to the present invention may have a pH value between 5-6, and preferably a pH value of 5,5. This value prevents harmful organisms from living on the scalp as it provides a sensitive acidity.

Other agents in addition to the mixture of lactic acid and urea might be used in order to set the pH value at the desired level. For example, citric acid is suitable for use here. However, lactic acid and urea are added to the compositions of the present invention since they are less toxic in comparison to other buffer agents and they have advantages in terms of skin care. These components with buffer properties can be present in the total composition in an amount higher than 0 and equal to or lower than 1%, preferably higher than 0 and equal to or lower than 0,5% by weight.

Surfactants basically lower the surface tension of the liquids they are added to and therefore provide cleansing by increasing their wetting capacity. In general, surfactants can be anionic, cationic, amphoteric and nonionic. Anionic surfactants used in cleansing compositions cause severe irritation in the skin and eyes although they lead to intense foam formation. Therefore, surfactants used within the scope of the present invention can be selected from amphoteric and/or nonionic surfactants. Amphoteric surfactants can be selected from the group that contains cocamidopropyl betaine, cocodimethylsulfopropyl betaine and lauryl-betaine. Present inventors have found that cocamidopropyl betaine within amphoteric surfactants group is very effective in the compositions' foam production and this surfactant can be used in combination with other amphoteric and/or nonionic surfactants in order to increase the volume of the generated foam. Preferred nonionic surfactants can be selected from the group that contains sodium cocoamphoacetate, lauryl glycoside, octaethylene glycol monododecyl ether, glyceryl laurate, cocamide DEA and coco-glycoside. Sodium cocoamphoacetate, lauryl glycoside and coco-glycoside are preferred from this group. Nonionic surfactants can be used alone or in combination with other nonionic surfactants, wherein when used in combination with other amphoteric surfactants, cleansing capacity of the formed foam is increased and the foam becomes more stable. The amount of amphoteric surfactant is between 5-30%, preferably between 10-25% and the amount of nonionic surfactant is between 1-10% and preferably 1-5% by weight in the total composition.

The invention, according to some embodiments, may contain emollients in order to prevent the possible hardness of the composition. Emollients are effective in enabling the composition that contains them to provide a softness sensation. Emollients that can be used in the compositions of the present invention can be selected from the group that comprises cetearyl isononanoate, cetearyl octanoate, decyl oleate, glyceryl oleate, glyceryl stearate, isooctyl stearate, isopropyl myristate, dicaprylyl ether, myristyl lactate and dimethicone copolyol. One emollient or a combination of emollients can be selected from this group. Preferred emollient for the composition is glyceryl oleate and myristyl lactate combination,

wherein this combination provides softness as well as having viscosity regulating and dispersing effects.

In some embodiments, the present invention can contain additional care agents in order to increase the scalp and skin care effect and provide moisture for a long time. *"Care agents"* increase the moisture value on the outer layer of the skin and enable keeping the skin moist for a long time, in addition to providing smooth softness of the skin with panthenol and hydrolyzed wheat proteins. These agents can be selected from the group that comprises sodium PCA, glycine, glucose, sodium levulinate, sorbitol, glycerin, propylene glycol, hexylene glycol, butylene glycol, maltose and sodium glucuronate. One or more agents can be selected from this group, wherein the amount can be between 0,1% and 10%, preferably 0,1% and 5% by weight in the total composition. In some embodiments, the present invention may contain additional hair care agents in order to preserve the softness in the baby's hair, which is generally soft and thin. This agent is preferably sodium glutamate, whose nurturing effect is more intensive when used in combination with *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract.

The invention may contain preservative(s) in addition to the above-mentioned components. Selection of these agents is of utmost importance as some harmful organisms may reproduce as a result of the microbial contamination that may occur during product storage. It is possible to observe this situation in the compositions of the invention especially since plant extracts are used. These agents can be selected from potassium sorbate and/or sodium benzoate. In some embodiments, chelating agents can be used to boost the activity of the preservative. Today, chelating agents are used in high amounts in various cleansing products, chemical agricultural products, textile products, drugs, dyes and coating products, and they can provide the desired effect when used in small amounts in cosmetic formulations. Chelating agents that can be used within the scope of the present invention can be magnesium aspartate and tetrasodium glutamate diacetate, and the preferred agent is tetrasodium glutamate diacetate since it is biocompatible, environment friendly and boosts the activity of the employed preservative. In addition, it was found that tetrasodium glutamate diacetate when added in combination with surfactants increased the solubility of especially amphoteric and nonionic surfactant combination in the composition and therefore provided a homogenous composition, and it can be present in an amount less than 0,5% by weight in the total composition.

In some embodiments, composition of the invention may contain perfuming agents and these agents can be essences, perfumes, plant extracts and/or vegetable oils. Synthetic or natural

perfuming components may be present in the composition of the present invention in an amount less than 1% by weight.

Table 1 shows the range of amounts by weight of the components within the composition of the present invention according to a preferred embodiment.

Table 1. Sensitive Care and Cleansing Compositions

Ingredients	**Amount (weight %)**
Water	50-75
Chamomilla recutita flower juice	10-25
Cocamidopropyl betaine	10-25
Lauryl Glycoside	1-5
Sodium Chloride	1-5
Myristyl Lactate	1-5
Sodium Cocoamphoacetate	0,1-1
Sodium Levulinate	0,1-1
Coco-Glycoside	0,1-1
Panthenol	0,1-1
Glycerin	0,1-1
Glyceryl Oleate	0,1-1
Perfume	0,1-1
Malva sylvestris extract	0,1-1
Potassium Sorbate	0,1-1
Citric Acid	0,1-1
Glucose	0-0,1
Sodium Glutamate	0-0,1
Sorbitol	0-0,1
Tetrasodium Glutamate Diacetate	0-0,1
Urea	>0-0,1
Sodium PCA	0-0,1
Lactic acid	>0-0,1
Hydrolised Wheat Proteins	0-0,1
Sodium Benzoate	0-0,1
Glycine	0-0,1

Compositions of the present invention may also contain vitamins, some structural agents and additional antimicrobial agents. Compositions described within the scope of the invention may be in any form that can be applied to the skin such as shampoo, cream, serum, gel and lotion. Compositions especially in shampoo form and more preferably in baby shampoo form are preferred. This form can have a viscosity value of 4000-8000 mPas at 20°C. Compositions described here are suitable for use in care products such as cleansing formulations, shampoos, hair conditioners, hair care sprays, shower gels and moisturizing products,

preferably in shampoo, more preferably in baby and children's shampoo, most preferably in newborn shampoo formulations.

According to another aspect, the present invention relates to a production method of a composition that contains antimicrobial plant extract, panthenol, urea and lactic acid including the following steps:

- adding at least one antimicrobial plant extract as active ingredient into water and mixing while heating,
- adding panthenol, urea and lactic acid to the mixture, mixing until the mixture is homogenous and obtaining the final product.

The mentioned antimicrobial plant extract is preferably selected from *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract and more preferably contains a combination thereof.

The expression *"until the mixture is homogenous"* means that the solid particles and liquid within the composition are homogenously distributed. The heating process can be continued until 45 °C, preferably until 40 °C, and more preferably until 35 °C. The mixing process is preferably performed in a turbo-emulsifier.

EXAMPLES

Example 1

Chamomilla recutita flower juice, *Malva sylvestris* extract, lauryl glycoside, tetrasodium glutamate diacetate, glycerin, sodium chloride, glucose, sorbitol, moisturizing mixture (sodium glutamate, urea, sodium PCA, glycine, lactic acid, hydrolyzed wheat protein, panthenol), sodium levulinate, potassium sorbate, coco-glycoside, glyceryl oleate, sodium cocoamphoacetate, scent essence, myristyl lactate, cocamidopropyl betaine, sodium benzoate and citric acid were respectively added into the water inside a turbo emulsifier, heated until 35 °C and mixed for 30 minutes.

Example 2

The composition of the invention contains the components, whose w/w percentages are provided in Table 2 below.

Table 2. Ingredients of the composition

Ingredients	Amount (weight %)
Water	61,6180
Chamomilla recutita flower juice	17,2000
Cocamidopropyl betaine	10,9500
Lauryl Glycoside	2,1200
Sodium Chloride	1,8250
Myristyl Lactate	1,8000
Sodium Cocoamphoacetate	0,8000
Sodium Levulinate	0,5400
Coco-Glycoside	0,5250
Panthenol	0,5050
Glycerin	0,4975
Glyceryl Oleate	0,4800
Perfume	0,3000
Malva sylvestris leaf/flower extract	0,2500
Potassium Sorbate	0,1625
Citric Acid	0,1350
Glucose	0,0750
Sodium Glutamate	0,0500
Sorbitol	0,0500
Tetrasodium Glutamate Diacetate	0,0470
Sodium PCA	0,0250
Urea	0,0250
Glycine	0,0050
Hydrolised Wheat Protein	0,0050
Lactic acid	0,0050
Sodium Benzoate	0,0050

Example 3

Physicochemical Data

Physicochemical data of the obtained formulation are provided in Table 3 below.

Table 3. Physicochemical analysis

Appearance (physical form at T: 20° C)	Transparent viscose tensiolyte
Color	Colorless, light yellow
Smell	Typical
pH	5-6
Viscosity (T=20°C; RV- @ rpm))	4000-8000 mPas, RV03, 5rpm

Example 4

Patch test

Possible irritation effect of the composition was evaluated according to Draize classification.

Method: a composition that was prepared according to Table 2 was applied to 25 male-female patients between the ages 18-70 that were selected according to the inclusion criteria, i.e. a) well general state of health b) absence of dermatopathy c) absence of ongoing pharmacological treatment d) acceptance of not changing the ordinary daily routine and e) absence of atopy in anamnesis, in order to provide outpatient treatment.

Application of the Examples

According to the ordinary use of the composition, it was applied as a leave on or 10% standard concentration rinse-off composition. Liquid composition was applied to the skin at 20 µl dose. Solid and semi-solid compositions were applied at a dose of 20 µg. Finn chamber (plastic that contains 7 mm aluminum disc and absorbent paper discs) is a patch test device that provides good occlusion. For liquid compositions, Finn chamber contains blotting papers that were immersed in a certain amount (20 µl) of the sample that will be tested. For solid compositions, the compositions (20 µg) that will be tested are directly applied to the skin.

Application of the Test

The relevant area on the skin (surface of the back) was cleaned using 70% alcoholic solution.

The composition was applied in an amount of 0,02 g or ml/cm^2 skin.

The relevant area of the skin was covered by the Finn chamber.

Composition was maintained in contact with the skin for 24 hours.

Finn chamber was removed.

Skin reactions were analyzed at minute 15, hour 1 and 24 after removing the Finn chamber.

Results*:* It was found that a composition according to Table 2 did not show any irritating effects on the subjects.

CLAIMS

1. A cosmetic composition that contains at least one antimicrobial plant extract, panthenol, urea and lactic acid.

2. The composition according to Claim 1, wherein the composition contains the following components in the following amounts by weight of the total composition;

-	*Antimicrobial plant extract*	5 – 35%
-	Panthenol	0,1 – 5%
-	Urea	>0 – 1%
-	Lactic acid	>0 – 1%

3. The composition according to Claim 1, wherein the antimicrobial plant extract is selected from the group that comprises *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract.

4. The composition according to Claim 3, wherein the antimicrobial plant extract contains a combination of *Chamomilla recutita (Matricaria)* flower juice and *Malva sylvestris* extract.

5. The composition according to Claim 1, wherein the composition also contains hydrolyzed wheat proteins.

6. The composition according to Claim 1, wherein the composition also contains at least one additional agent selected from a care agent, preservative, emollient, chelating agent, additional surfactants, pH regulating agent, perfuming agent, rheology agents and solvents.

7. The composition according to Claim 6, wherein the surfactant is amphoteric and/or nonionic.

8. The composition according to Claim 7, wherein the amphoteric surfactant is selected from the group that comprises cocamidopropyl betaine, cocodimethylsulfopropyl betaine and lauryl-betaine.

9. The composition according to Claim 7, wherein the nonionic surfactant is selected from the group that comprises sodium cocoamphoacetate, lauryl glycoside, octaethylene glycol, monododecyl ether, glyceryl laurate, cocamide DEA and coco-glycoside.

10. The composition according to Claim 6, wherein the emollient is selected from the group that comprises glyceryl oleate and myristyl lactate.

11. The composition according to Claim 6, wherein the care agents are selected from the group that comprises sodium PCA, glycine, glucose, sodium levulinate, sorbitol, glycerin, propylene glycol, hexylene glycol, butylene glycol, maltose and sodium glucuronate.

12. The composition according to Claim 6, wherein the preservative is selected from the group that comprises potassium sorbate and sodium benzoate.

13. The composition according to Claim 6, wherein the chelating agent is tetrasodium glutamate diacetate.

14. The composition according to Claim 1, wherein the composition is in shampoo, cream, gel or lotion form.

15. The composition according to Claim 14, wherein the composition is in shampoo form.

16. The composition according to Claim 15, wherein the composition is a baby shampoo.

17. The composition according to any one of the preceding claims, wherein the composition contains the following components:

Ingredients	**Amount (weight %)**
Water	50-75
Chamomilla recutita flower juice	10-25
Cocamidopropyl betaine	10-25
Lauryl Glycoside	1-5
Sodium Chloride	1-5
Myristyl Lactate	1-5
Sodium Cocoamphoacetate	0,1-1
Sodium Levulinate	0,1-1
Coco-Glycoside	0,1-1
Panthenol	0,1-1
Glycerin	0,1-1
Glyceryl Oleate	0,1-1
Perfume	0,1-1
Malva sylvestris extract	0,1-1
Potassium Sorbate	0,1-1
Citric Acid	0,1-1
Glucose	0-0,1
Sodium Glutamate	0-0,1
Sorbitol	0-0,1
Tetrasodium Glutamate Diacetate	0-0,1
Urea	>0-0,1
Sodium PCA	0-0,1
Lactic acid	>0-0,1
Hydrolised Wheat Proteins	0-0,1

Sodium Benzoate	0-0,1
Glycine	0-0,1

18. A method that contains the following steps for preparing the composition provided according to Claim 1:

- adding at least one antimicrobial plant extract as active ingredient into water and mixing while heating,
- adding panthenol, urea and lactic acid to the mixture, mixing until the mixture is homogenous and obtaining the final product.

19. The method according to Claim 18, wherein the heating process is continued until reaching 45°C.

20. Use of the composition according to Claim 1 in a shampoo composition.