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(54) Title: PRE-MOISTENED WIPES FOR USE IN TREATING ANAL-RECTAL IRRITATIONS AND DISORDERS

(57) Abstract: Many people who suffer from anal rectal discomfort and disorders need fibrous sheet materials which are pre-moistened with a solution for improved cleansing without excessive skin irritation. The invention particularly concerns wet wipes, such as anal-rectal wipes, which comprises a solution comprising hamamelis water or witch hazel, to effectively treat anal-rectal disorders.

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PRE-MOISTENED WIPES FOR USE IN TREATING ANAL-RECTAL  
IRRITATIONS AND DISORDERS

FIELD OF INVENTION

5           The present invention relates to fibrous sheet materials which are premoistened with a solution for improved cleansing without excessive skin irritation. The invention particularly concerns wet wipes, such as anal-rectal wipes, which include hamamelis water or witch hazel, which is suitable for a woman's anal-rectal and perineal area. The wet wipe should comprise an effective cleansing solution but also be non-irritating and  
10   convey a sense and smell of freshness.

BACKGROUND OF THE INVENTION

          Wet wipes are well known commercial consumer products which have been available in many forms. Perhaps the most common form of wet wipes has been a stack of moistened sheets which have been packaged in a plastic container. The wet wipes  
15   have been made from a variety of materials which have been moistened with a variety of suitable wiping solutions. Typically, the wet wipes have been available in either folded or unfolded configurations. For example, stacks of wet wipes have been available wherein each of the wet wipes in the stack has been arranged in a folded configuration such as a c-folded, z-folded or quarter-folded configuration as are well known to those  
20   skilled in the art. Each folded wet wipe has also been interfolded with the wet wipes immediately above and below in the stack of wet wipes. In an alternative configuration, the wet wipes have been in the form of continuous webs of material which include perforations to separate the individual wet wipes and which are wound into rolls and packaged in plastic containers. Such wet wipes have been used for baby wipes, hand  
25   wipes, household cleaning wipes, industrial wipes and the like.

          The solutions incorporated into conventional wet wipes have usually included a number of ingredients intended to enhance or impart particular properties to the wipe. These properties have related to, for example, cleaning efficacy, fragrance, medication, reduced irritation, skin health, aesthetics of the product and the like. For baby wipes, a  
30   solution providing a gentle soothing feeling without excessive irritation or foam while maintaining cleaning and antimicrobial efficacy is highly desirable for product performance. Suitable ingredients used to provide such properties have included water,

emollients, surfactants, preservatives, chelating agents, pH buffers or combinations thereof. The solutions have also contained lotions and/or medicaments.

However, the conventional solutions and, in particular, the surfactants in such solutions for wet wipes have not been completely satisfactory. For example, to reduce the level of skin irritation, conventional wet wipe solutions have included amphoteric surfactants which generally cause little or no skin irritation. Such amphoteric surfactants have included sodium cocoamphoacetate and disodium cocoamphodiacetate. However, such amphoteric surfactants have typically not exhibited the high levels of cleaning efficacy associated with other surfactants such as anionic surfactants. Such amphoteric surfactants typically have also not provided the optimum silky feeling to the skin which is desired by consumers, particularly female consumers.

On the other hand, anionic surfactants, while exhibiting such cleaning efficacy, have generally caused excessive skin irritation such as dryness and scaling and, as a result, have not been suitable for use in wet wipe applications. The high level of skin irritation caused by such surfactants is particularly undesirable in female anal-rectal and perineal area medicament applications due to the tenderness of the vaginal and anal skin. Moreover, most anionic surfactants are suitable for detergent compositions due to their high levels of foaming and deterative activity. However, such foaming is generally undesirable in wet wipe applications and, in particular, in anal-rectal medicament wipe applications. Consumers who use wet wipes prefer that the solution from the wet wipes not leave any soapy or bubbly residue on the surface of the skin since the solution is usually not wiped off the skin after the wet wipe is used.

For a woman's anal-rectal and perineal area medicament wipes, a solution providing a gentle soothing feeling without excessive irritation or foam while maintaining cleaning and antimicrobial efficacy is highly desirable for product performance. The solution must be effective but also non-irritating and convey a sense and smell of freshness. Baby wipes are more for mild and effective cleansing whereas the novel wipes disclosed in the present application are designed for mild and effective cleansing but also soothing relief.

Accordingly, it remains desirable to provide solutions for wet wipes which include surfactants which exhibit improved cleaning efficacy while not causing excessive skin irritation or foaming.

It is highly desirable to use a surfactant that is specifically designed for cleansing the delicate and sensitive skin of the female anal-rectal and perineal area. The betaine class of surfactants are desirable because they provide effective cleansing, generally do not foam and are known for their mildness characteristics.

#### SUMMARY OF THE INVENTION

In response to the difficulties and problems discussed above, new wet wipes which have improved solutions for application to a woman's anal-rectal and perineal area have been discovered.

In one aspect, the present invention relates to a wet wipe comprising a fibrous sheet material and a non-oily aqueous-based solution which comprises:

- a) from about 10 to about 50 percent witch hazel;
  - b) from about 0.01 to about 2 percent of at least one emulsifier; and
  - c) from about 0.01 to about 0.20 percent of at least one emollient;
- wherein the weight percent is based on a total weight of said solution.

In another aspect, the present invention relates to a wet wipe comprising a fibrous sheet material and a non-oily aqueous-based solution which comprises:

- a.) about 20 weight percent witch hazel;
  - b.) about 9 weight percent glycerin;
  - c.) about 5 weight percent propylene glycol;
  - d.) about 1.5 weight percent ethoxylated shea butter;
  - e.) about 0.2 weight percent cucumber extract;
  - f.) about 0.2 weight percent chamomile extract;
  - g.) about 0.2 weight percent diazolidinyl urea;
  - h.) about 0.2 weight percent fragrance;
  - i.) about 0.2 weight percent methylparaben;
  - j.) about 0.1 weight percent capryl/capramidopropyl betaine;
  - k.) about 0.1 weight percent aloe vera;
  - l.) about 0.1 weight percent vitamin E acetate;
  - m.) about 0.09 weight percent citric acid;
  - n.) about 0.09 weight percent sodium citrate;
  - o.) about 0.05 weight percent edetate disodium; and
  - p.) about 0.05 weight percent propylparaben;
  - q.) about 63 weight percent added purified water;
- wherein the weight percent is based on a total weight of said solution.

In yet another aspect, the present invention relates to a method of using a wet wipe made in accordance with the wet wipe described above comprising using the wet

wipe with the solution contained thereon to wipe a human's skin and leaving a solution deposited by using the wet wipe on the human's skin after wiping is completed.

The present invention, in its various aspects, advantageously relates to wet wipes for application to a woman's anal-rectal and perineal area, which, when compared to conventional wet wipes, have improved cleaning efficacy without excessive skin irritation or foaming and convey a sense and smell of freshness. Moreover, the present invention provides solutions for wet wipes which leave a lubricious, silky feeling to the skin during and after application.

### DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to fibrous materials and, in particular, wet wipes which have a multi-component preservation system that is appropriate for a multiple-use-packaged-product for the anal/peri-anal area. The wet wipes comprise a mild surfactant to promote cleaning and provide soothing relief to the irritated area and is appropriate for potentially irritated peri-anal tissues. The wet wipes of the present invention can be used for anal rectal disorders, such as hemorrhoids and the like. Such wet wipes are generally folded and arranged in a stacked configuration inside a suitable container for consumer sale.

Materials suitable for such wet wipes are well known to those skilled in the art. The wet wipes are typically made from fibrous sheet materials which may be woven or nonwoven. For example, the wet wipes of the present invention may include nonwoven fibrous sheet materials which include meltblown, coform, air-laid, bonded-carded web materials, hydro-entangled materials, combinations thereof and the like. Such materials can comprise synthetic or natural fibers or combinations thereof. Typically, the wet wipes define a basis weight of from about 25 to about 120 grams per square meter and desirably from about 40 to about 90 grams per square meter.

The wet wipes of the present invention may comprise a coform basesheet of polymeric microfibers and cellulosic fibers having a basis weight of from about 60 to about 80 grams per square meter and desirably about 75 grams per square meter. Such coform basesheets are manufactured generally as described in U.S. Pat. No. 4,100,324 to Anderson et al. which issued Jul. 11, 1978, and which is herein incorporated by reference. Typically, such coform basesheets comprise a gas-formed matrix of thermoplastic polymeric meltblown microfibers, such as, for example, polypropylene microfibers, and cellulosic fibers, such as, for example, wood pulp fibers.

Most preferably, the wet wipes of the present invention are commercially available Grade SX-810® nonwoven material sold by Ahlstrom Green Bay Inc. of Green Bay, Wisconsin.

Alternatively, the wet wipes of the present invention can comprise a composite which includes multiple layers of materials. For example, the wet wipes may include a three layer composite which includes an elastomeric film or meltblown layer between two coform layers as described above. In such a configuration, the coform layers may define a basis weight of from about 15 to about 30 grams per square meter and the elastomeric layer may include a film material such as a polyethylene metallocene film.

The individual wet wipes are generally arranged in a folded configuration. Such folded configurations are well known to those skilled in the art and include c-folded, z-folded, quarter-folded configurations and the like. Each wet wipe may also be interfolded with the wet wipes immediately above and below in the stack of wet wipes. The wet wipes generally define an unfolded width and an unfolded length. The wet wipes may have any suitable unfolded width and length. For example, the wet wipes may have an unfolded length of from about 2.0 to about 80.0 centimeters and an unfolded width of from about 2.0 to about 80.0 centimeters.

The wet wipes of the different aspects of the present invention also contain a solution which is absorbed into the wet wipes. The amount of solution contained within each wet wipe may vary depending upon the type of material being used to provide the wet wipe, the type of solution being used, the type of container being used to store the wet wipes, and the desired end use of the wet wipes. Generally, each wet wipe can contain from about 150 to about 600 weight percent and desirably from about 250 to about 450 weight percent solution based on the dry weight of the wipe for improved wiping.

In one aspect of the present invention, the wet wipes are packaged in a stack in a plastic container. In such an container, the preferred ratio of solution to dry weight of the wipe is from about 3.5:1 to about 4.5:1, more preferably from about 3.8:1 to about 4.3:1 and most preferably from about 4:1 solution to wipe based on dry weight of said wet wipe. If the amount of solution is less than the above-identified range, the wet wipe may be too dry and may not adequately perform. If the amount of solution is greater than the above-identified range, the wet wipe may be oversaturated and soggy and the solution may pool in the bottom of the container.

In a particular aspect, wherein the wet wipes are individually packaged in a foil pouch, the preferred ratio of solution to dry weight of the wipe is from about 3.5:1 to about 6:1, more preferably from about 3.5:1 to about 5.2:1 and most preferably from about 4.7:1 solution to wipe based on dry weight of said wet wipe.

5           The solution in the wet wipe of the present invention comprises witch hazel, which is an effective cleansing agent and contributes a soothing, cooling and distinctive fragrance to the solution of the present invention. The amount of witch hazel present in the solution varies in a range from about 10 to about 50 percent, more preferably in a range from about 10 to about 20 percent, and most preferably about 20 percent, based  
10       on a total weight of the solution. In a particular embodiment, the present invention comprises witch hazel or hamamelis water as a suitable cleaning agent, commercially available from American Distilling Inc. and having an alcohol content of 14%.

To provide improved tactile properties and cleaning efficacy without excessive foaming or skin irritation, the solution in the wet wipes of the present invention  
15       comprises an amphoteric or zwitterionic surfactant. The betaine family of zwitterions possesses the positive-negative head group structure of trimethyl glycine (betaine), an amino acid derived from sugar beets. The hydrophobic tail group can be a straight chain alkyl group (such as in coco betaine), or can contain an amido group, such as cocamidopropyl betaine. Other betaines include lauramidopropyl betaine,  
20       oleamidopropyl betaine, ricinoleamidopropyl betaine, cetyl betaine and dimer dilinoleamidopropyl betaine. Additional variants are sulfobetaines, hydroxysulfobetaines and sultaines. Betaines are more resistant to thickening via addition of salts than their anionic cousins. For this reason, in order to achieve a pleasingly thick product, addition of viscosity-boosting polymeric additives may be necessary, which can increase the cost  
25       and complexity of the formula (see <http://www.naturallycurly.com/curlreading/ingredients/zwitterionic-surfactants-a-milder-alternative>).

To provide the improved tactile and cleansing properties to the wet wipe of the present invention without excessive foaming or skin irritation, the solution of the present invention comprises at least one surfactant, preferably a betaine surfactant. The  
30       solution may include any amount of the betaine surfactant which provides the desired properties. The specific betaine selected can have a significant impact upon the viscosity, foaming behavior and detergency of the final product. In a particular embodiment, the solution includes from about 0.01 to about 10 weight percent and

desirably from about 0.01 to about 5 weight percent of the betaine surfactant based on a total weight of the solution. Most preferably, the present invention comprises a capryl/capramidopropyl betaine, sold under the tradename Tego Betaine 810®, commercially available from Evnolk Degussa, in a range of about 0.1 w/w% based on a total weight of the solution. Solutions having a less than the preferred surfactant weight percent ratios can be undesirable because of undesirable tactile properties such as tackiness and loss of silky after feel, reduced deterative activity and increased skin irritation.

The solution contained within the wet wipes of the present invention defines a pH from about 5 to about 7 and desirably from about 5 to about 6. A pH level below about 5 is generally undesirable because of potential skin irritation. Whereas, a pH level greater than about 7 is also undesirable due to possible compromising of preservative activity and can lead to skin irritation. Suitable buffers, such citric acid and sodium citrate, can be employed to relative amounts to achieve the desired pH. The solution of the present invention comprises a buffer system of about from 0.05 to about 0.25 weight percent of said solution.

The solution may also comprise a variety of other components which may assist in providing the desired wiping and cleaning properties. For example, the components may include water, emollients, at least one surfactant, at least one preservative, at least one chelating agent, at least one pH buffer, at least one fragrance or combinations thereof. The solution may also contain at least one lotion and/or medicament. To provide reduced skin irritation, the solution desirably includes at least from about 30 weight percent to about 80 weight percent of added purified water based on a total weight of the solution, more preferably about 63 weight percent of added purified water based on a total weight of the solution.

For example, the solution may include an effective amount of at least one preservative to inhibit the growth of microorganisms. Suitable preservatives are well known to those skilled in the art and may include, for example, parabens, sodiumhydroxymethylglycinate, organic acids such as benzoic and malic acid, DMDM hydantoin and the like and combinations thereof. In a particular embodiment, the antimicrobial preservative comprises methylparaben, propylparaben and diazolidinyl urea which is commercially available from ISP Technologies, Inc. under the trade designation GERMALL II. The solution may include any amount of the preservatives



which provides the desired antimicrobial effect. For example, the solution may include from about 0.1 to about 0.5 weight percent of the antimicrobial preservative based on a total weight of the solution, preferably 0.40 weight percent on a total weight of the solution.

5 Applicants have discovered that, when compared to conventional wet wipes which have included other types of surfactants, the wet wipes according to the different aspects of the present invention which comprise a betaine surfactant have improved tactile properties and cleaning efficacy without excessive levels of skin irritation. The solution may further include additional surfactants which can act as an emulsifier or  
10 provide additional cleansing properties. Suitable cosurfactants include, for example, anionic surfactants such as acyl glutamates and acyl isethionates, alkanolamids, amphoteric surfactants, nonionic surfactants and the like or combinations thereof. For example, a suitable acyl glutamate anionic surfactant is potassium cocyl glutamate, a suitable acyl isethionate anionic surfactant is ammonium cocyl isethionate, and suitable  
15 amphoteric surfactants include disodium capryloamphdipropionate and disodium cocoamphodiactetate. Suitable nonionic surfactants include diethanolamides having an average of from 12 to 16 carbon atoms, alkylphenol ethoxylates, alcohol ethoxylates, sorbitan esters, glycerol esters and the like. The solution may include any amount of the cosurfactant which provides the improved cleaning or tactile properties. For example,  
20 the solution may include from about 0.01 to about 5 weight percent of the cosurfactant based on a total weight of the solution. The present invention, in its most preferred embodiment, does not comprise the presence of co-surfactants in order to limit the irritation potential.

Moreover, the wet wipes of the present invention desirably exhibit low levels of  
25 foaming for improved performance. The wet wipes also exhibit a lubricious, silky feeling to the user for improved consumer acceptance.

The present invention comprises at least one suitable emollient or a combination of suitable emollients, such as botanical butters, vitamin E acetate, and aloe vera. The present invention comprises at least one emollient individually in a range of from about  
30 0.01 percent to about 2 percent, more preferably individually in a range from about 0.01 percent to about 1.8 percent, and most preferably individually about 1.5 percent emollient wherein the weight percent is based on a total weight of said solution of the

present invention. Preferably, the emollient is a vitamin derivative, most preferably vitamin E acetate.

Applicants have discovered that the use of an ethoxylated shea butter emollient, preferably the PEG-75 ethoxylated shea butter glyceride, serves multiple functions of providing emolliency, emulsification, and of co-solubilizing at least one additional emollient, preferably vitamin E acetate, which is well known in the art to be water-insoluble. Preferably, the emulsifier of the present invention is a botanical butter, more preferably an ethoxylated botanical butter, and most preferably an ethoxylated shea butter. In a preferred embodiment of the present invention, the solution comprises PEG-75 ethoxylated shea butter, commercially available from Aarhuskarlshamn under the trade name of Lipex 102 E-75®, as a most preferred emulsifier. The present invention comprises at least one emulsifier individually in a range of from about 0.01 percent to about 2 percent, more preferably individually in a range from about 0.01 percent to about 1.8 percent, and most preferably individually about 1.5 percent emulsifier wherein the weight percent is based on a total weight of said solution of the present invention.

During manufacture of the solution of the present invention, the ethoxylated shea butter glyceride is melted at 50 degrees C in a separate side-phase mixing vessel. The vitamin E acetate is added to this side-phase vessel and dissolved in the ethoxylated shea butter glycerides with mixing. This side phase is then added to the main batch which is at ambient room temperature (about 25 degrees C) with vigorous mixing of the main batch. The ethoxylated shea butter glycerides/vitamin E acetate phase is added as the second to last ingredient addition. If the ethoxylated shea butter glyceride and vitamin E acetate were to be added to the main batch as separate, independent additions (instead of manufacturing the side phase), the Vitamin E Acetate would not be solubilized in the main batch; when mixing is terminated, the vitamin E acetate will rise to the top of the solution as an oil. Once the ethoxylated shea butter /vitamin E acetate phase is added, then the propylene glycol preservative phase (containing the propylene glycol, parabens and the fragrance) is added and mixed at ambient temperature for approximately 15 minutes.

Additional emulsifiers, preferably mild emulsifiers, such as polysorbate 20 and other ethoxylated botanical butters may be employed in the solution of the present invention, in the range of from about 0.1 to about 2 weight percent, wherein the weight percent is based on a total weight of said solution.

The present invention comprises glycerin to improve the smoothness, to provide lubrication and as a humectant. Essential oils and botanical extracts can be added for fragrance. The present invention comprises the use of at least one fragrance to help convey a sense of freshness and scent pleasurable to one's olfactory senses.

5     Fragrances derived from botanical extracts such as cucumber and chamomile, along with various fragrances, such as Bell Fragrances®, commercially available from the Bell Fragrances Corporation, may be employed in the present invention. The amount of at least one fragrances may range from about 0.05 weight percent to about 0.3 weight percent each wherein the weight percent is based on a total weight of said solution.

10     The present invention further comprises at least one chelating agent designed to protect the structural integrity and fragrance of the botanical extracts from unnecessary and unwanted iron which the solution may be exposed to during manufacturing. The presence of chelating agents may range from about 0.01 to about 0.1 weight percent, wherein the weight percent is based on a total weight of said solution. Preferred  
15     chelating agents of the present invention are edetate disodium, commercially available from Dow Chemical Company.

   The wet wipes of the different aspects of the present invention may be manufactured using several different processes well known to those skilled in the art. The particular method and sequence of steps described herein is not a limitation to the  
20     present invention, but is disclosed only as one method of producing a wet wipe and stack of wet wipes. Initially, a supply roll of the material being converted into the wet wipes is unwound to provide a continuously moving web of material. The web of material is saturated or otherwise impregnated with the solution of the present invention by any suitable means such as spraying, dipping, or the like as are well known to those  
25     skilled in the art.

   The web of material is slit in the machine direction into multiple ribbons, each of which may be folded into the type of fold desired for the individual wet wipe. The web of material is slit using a cutter as are well known to those skilled in the art. For example, the web of material can be slit into a pre-determined number of individual ribbons. The  
30     ribbons of material are then be folded into a folded configuration such as a z-folded configuration. For example, each ribbon of material may define a top flap portion, a central portion and a bottom flap portion. The top and bottom flap portions are

connected to and folded over and under the central portion, respectively to provide the z-folded configuration.

Each folded ribbon may then be combined, one ribbon on top of the other, with the other pre-determined number of folded ribbons from the same web of material to form a continuous towel. The towel is then cut into "clips" of wet wipes and the clips of wet wipes are arranged in a stacked configuration. The number of clips in a stack depends on the desired number of stacks and the number of wet wipes, such as 48 or 60 individual wet wipes, in the final package. The wet stacks are periodically weight checked, to assure the solution add-on is correct. If not, the solution add-on is adjusted. After the stack of wet wipes is properly configured, it may be overwrapped, preferably with a plastic wrap, and then placed in the interior of a container, such as a plastic tub, to provide a package of wet wipes. The container provides a substantially hermetically sealed environment for the wet wipes to minimize the escape of any solution therefrom.

With respect to the manufacturing process for the individual wipe wrapped in a foil pouch, the pre-cut (preferably 5 inches by 6 inches), dry wipe is placed in the pouch and then the solution of the present invention is added to the pouch. The ratio of solution to dry wipe is greater in the pouch because there is some solution pooling in the pouch.

Accordingly, the different aspects of the present invention can advantageously provide wet wipes which, when compared to conventional wet wipes, have improved tactile properties and cleaning while maintaining low levels of skin irritation and foaming. Such wet wipes can advantageously be used for application to a woman's anal-rectal and perineal area, which, when compared to conventional wet wipes, have improved cleaning efficacy without excessive skin irritation or foaming and convey a sense and smell of freshness. Additional uses may comprise baby wipes, hand wipes, face wipes, cosmetic wipes, household wipes, industrial wipes and the like.

## EXAMPLES

The following examples are presented to provide a more detailed understanding of the invention. The particular materials and parameters are exemplary and are not intended to limit the scope of the invention.

Example 1

A particularly suitable solution for the wet wipes of the present invention was prepared according to the following formulation:

This formula is described as a clear solution, which contains 20 %w/w Witch Hazel as the active ingredient. The final product is a white, moist wipe saturated with this solution.

<b>Active Ingredients</b>		
<b>Component Name/Commercially available from Vendor</b>	<b>%w/w</b>	<b>Label Designations (LD)</b>
Witch Hazel USP (14% Alcohol)/American Distilling Inc. <i>Alcohol, 14.0-15.0%</i>	20.0	<i>Witch Hazel<sup>1</sup></i>
<b>Inactive Ingredients</b>		
<b>Component Name / Vendor</b>	<b>%w/w</b>	<b>Label Designations (LD)</b>
Water Purified USP / Manufacturing Site	63 <sup>2</sup>	Purified Water
Glycerin USP, 96%/ The Procter & Gamble Company, Cincinnati, OH	9.0	Glycerin
Propylene Glycol USP / The Dow Chemical Company, Midland, MI	5.0	Propylene Glycol
PEG 75 Shea Butter, Ethoxylated, Lipex 102 E-75/ Aarhuskarlshamn	1.5	PEG 75 Shea Butter Glycerides (emollient and co-solubilizer)
Cucumber Extract, / Medallion International Inc. <i>Cucumber Extract, 44.4%</i> <i>Propylene Glycol, 50.0%</i> <i>Water, 5.0%</i> <i>Neolone PE (preservative), 0.6%</i>	0.2	N/A <i>Cucumis Sativus (Cucumber) Fruit Extract</i> <i>Propylene Glycol</i> <i>Purified Water</i>
Chamomile Extract/ Medallion International Inc. <i>Chamomile Extract, 39.0%</i>  <i>Propylene Glycol, 50.0%</i> <i>Water, 10.0%</i> <i>DMDM Hydantoin (preservative), 1.0%</i>	0.2	N/A <i>Chamomilla Recutita (Matricaria) Flower Extract</i> <i>Propylene Glycol</i> <i>Purified Water</i> <i>DMDM Hydantoin</i>
Germall II (Diazolidinyl Urea)/ ISP Technologies, Inc.	0.2	Diazolidinyl Urea
Methylparaben NF/ Ueno Fine Chemicals Industry, Ltd	0.2	Methylparaben
Tego Betaine 810 / Evnolk Degussa	0.1	Capryl/Capramidopropyl Betaine
Aloe Vera Gel / Concentrated Aloe Inc.	0.1	N/A

<i>Aloe Barbadensis Leaf Juice</i> <i>Potassium Sorbate</i> <i>Sodium Benzoate</i>		<i>Aloe Barbadensis Leaf Juice</i> <i>N/A</i> <i>N/A</i>
Vitamin E Acetate USP-FCC; / DSM Nutritional Products Ltd	0.1	Vitamin E Acetate
Citric Acid USP Anhydrous Granular/ Archer Daniels Midland Company	0.09	Anhydrous Citric Acid
Sodium Citrate USP Hydrous/Archer Daniels Midland Company	0.09	Sodium Citrate
Edetate Disodium USP (Versene NA); VERSENE NA CHELATING AGENT / The Dow Chemical Company	0.05	Edetate Disodium
Fragrance/ Bell Flavors and Fragrances/Bell Fragrances Corporation <i>Polysorbate 20, &gt;50%</i> <i>Dipropylene Glycol, 10-20%</i> <i>Synthetic Aromatics, 25-50%</i>	0.05	N/A <i>Polysorbate 20</i> <i>Dipropylene Glycol</i> <i>Fragrance</i>
Propylparaben NF/ Ueno Fine Chemicals Industry, Ltd	0.05	Propylparaben

**Endnotes**

- 1 Witch Hazel USP contains 14.5 %v/v alcohol. The alcohol content of the formulation is from about 2.8 to about 3.0 %w/w, which is contributed entirely by the witch hazel component.
- 5 2 Purified water is employed as rinse water and as a direct addition. In all cases, the rinse water is subsequently added to the main mixing vessel.

**Example 2**

10 A suitable solution for the wet wipes of the present invention was prepared according to the following formulation:

The amount of witch hazel was increased to 50 w/w% and the amount of water was reduced to about 33 w/w%.

15 While the invention has been described in detail with respect to the specific aspects thereof, it will be appreciated that those skilled in the art, upon attaining an understanding of the foregoing, may readily conceive of alterations to, variations of, and equivalents to these aspects. Accordingly, the scope of the present invention should be assessed as that of the appended claims and any equivalents thereto.

Claims

What is claimed is:

1. A wet wipe comprising a fibrous sheet material and a non-oily aqueous-based solution which comprises:
  - a.) from about 10 to about 50 percent witch hazel;
  - b.) from about 0.01 to about 2 percent of at least one emulsifier; and
  - c.) from about 0.01 to about 0.20 percent of at least one emollient;wherein the weight percent is based on a total weight of said solution.
2. The wet wipe according to claim 1 wherein the at least one emollient in the solution is vitamin E acetate.
3. The wet wipe according to claim 1 wherein the at least one emulsifier in the solution is an ethoxylated shea butter.
4. The wet wipe according to claim 1 wherein said fibrous sheet material comprises a nonwoven material.
5. The wet wipe according to claim 1 wherein said wet wipe comprises from about 10 to about 90 weight percent of said solution based on a dry weight of said wet wipe.
6. The wet wipe according to claim 1 wherein said wet wipe comprises from about 4:1 solution to wipe based on dry weight of said wet wipe.
7. The wet wipe according to claim 1 wherein the solution comprises a ratio of at least one emulsifier to at least one emollient of about 10:1.
8. The wet wipe according to claim 3 wherein the solution comprises about 1.5% ethoxylated shea butter, wherein the weight percent is based on a total weight of said solution.

9. The wet wipe according to claim 1 wherein the solution comprises at least one surfactant.

10. The wet wipe according to claim 9 wherein the at least one surfactant is capryl/capramidopropyl betaine.

11. The wet wipe according to claim 1 wherein the solution further includes from about 0.1 to about 0.5 weight percent based on a total weight of said solution of at least one antimicrobial preservative.

12. The wet wipe according to claim 11 wherein the antimicrobial preservative comprises diazolidinyl urea, propylparaben, and methylparaben.

13. The wet wipe according to claim 1 wherein the solution has a pH of from about 5 to about 7.

14. The wet wipe according to claim 1 wherein said solution further comprises from about 0.01 to about 10 weight percent glycerin based on a total weight of said solution.

15. The wet wipe according to claim 1 said solution further comprises from about 0.01 to about 0.5 weight percent botanical extracts based on a total weight of said solution.

16. The wet wipe according to claim 1 wherein the solution comprises about 20 weight percent witch hazel based on a total weight of said solution.

17. A method of using a wet wipe made in accordance with claim 1 comprising using the wet wipe with the solution contained thereon to wipe a human's skin and leaving a solution deposited by using the wet wipe on the human's skin after wiping is completed.

18. A wet wipe comprising a fibrous sheet material and a non-oily aqueous-based solution which comprises:

- a.) about 50 weight percent witch hazel;
- b.) about 9 weight percent glycerin;
- c.) about 5 weight percent propylene glycol;



d.) about 1.5 weight percent ethoxylated shea butter;  
e.) about 0.2 weight percent cucumber extract;  
f.) about 0.2 weight percent chamomile extract;  
g.) about 0.2 weight percent diazolidinyl urea;  
5 h.) about 0.2 weight percent fragrance;  
i.) about 0.2 weight percent methylparaben;  
j.) about 0.1 weight percent capramidopropyl betaine;  
k.) about 0.1 weight percent aloe vera;  
l.) about 0.1 weight percent vitamin E acetate;  
10 m.) about 0.09 weight percent citric acid;  
n.) about 0.09 weight percent sodium citrate;  
o.) about 0.05 weight percent edetate disodium; and  
p.) about 0.05 weight percent propylparaben;  
q.) about 33 weight percent added purified water;  
15 based on a total weight of said solution.

19. A method of using a wet wipe made in accordance with claim 18 comprising using the wet wipe with the solution contained thereon to wipe a human's skin and leaving a solution deposited by using the wet wipe on the human's skin after wiping is completed.

20. A wet wipe comprising a fibrous sheet material and a non-oily aqueous-based solution which comprises:

a.) about 20 weight percent witch hazel;  
b.) about 9 weight percent glycerin;  
25 c.) about 5 weight percent propylene glycol;  
d.) about 1.5 weight percent ethoxylated shea butter;  
e.) about 0.2 weight percent cucumber extract;  
f.) about 0.2 weight percent chamomile extract;  
g.) about 0.2 weight percent diazolidinyl urea;  
30 h.) about 0.2 weight percent fragrance;  
i.) about 0.2 weight percent methylparaben;  
j.) about 0.1 weight percent capramidopropyl betaine;  
k.) about 0.1 weight percent aloe vera;  
l.) about 0.1 weight percent vitamin E acetate;  
35 m.) about 0.09 weight percent citric acid;  
n.) about 0.09 weight percent sodium citrate;  
o.) about 0.05 weight percent edetate disodium; and  
p.) about 0.05 weight percent propylparaben;  
q.) about 63 weight percent added purified water;  
40 based on a total weight of said solution.

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/IB2014/066698

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61K8/34 A61K8/44 A61K8/67 A61K8/86 A61Q19/10  
A61K8/97 A61K8/02  
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
A61K A61Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EP0-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	<p>"Witch Hazel with 14% alcohol", INTERNET CITATION, 3 March 2015 (2015-03-03), page 2pp, XP007923030, Retrieved from the Internet: URL:http://www.whazel.com/sites/default/files/American_Distilling_SELLSHEET_W-H_14_6-10.pdf [retrieved on 2015-03-03] the whole document</p> <p>----- -/--</p>	



Further documents are listed in the continuation of Box C.



See patent family annex.

## \* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

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Skulj, Primoz

## INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2014/066698

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
T	KHATIASHVILI N S ET AL: "Lipids from Sterculia platanifolia and Hamamelis virginiana seeds", MEDICINAL & AROMATIC PLANTS ABSTRACTS, SCIENTIFIC PUBLISHERS, SCIENTIFIC PUBLISHERS, NEW DELHI - INDIA, vol. 30, no. 1, 1 February 2008 (2008-02-01), XP018023723, ISSN: 0250-4367 -----	
T	Anonymous: "Witch Hazel, Hamamelis virginiana, witch hazel photos and article by Steven Foster",  16 December 2013 (2013-12-16), XP055173542, Retrieved from the Internet: URL:https://web.archive.org/web/20131216095902/http://www.stevenfoster.com/education/monograph/witchhazel.html [retrieved on 2015-03-04] -----	
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## INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2014/066698

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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X	DATABASE GNPDP [Online] MINTEL; 1 April 2011 (2011-04-01), "Soft Nose Wipes", XP002736734, Database accession no. 1520918 the whole document -----	1,2,4-7, 9,11-17
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Y		18-20
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## INTERNATIONAL SEARCH REPORT

International application No

PCT/IB2014/066698

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/260806 A1 (MILLER RISA [US]) 23 October 2008 (2008-10-23)	1
Y	paragraphs [0020], [0036], [0023], [0027]; claims 1,8,,9-19 -----	1,3,8, 18-20
X	US 2006/089277 A1 (HARDING CLIVE R [US] ET AL HARDING CLIVE RODERICK [US] ET AL) 27 April 2006 (2006-04-27) example 7 -----	1
Y	"Lipex(R)102 E75 Lipex(R)203 E70", INTERNET CITATION, August 2008 (2008-08), page 1, XP007923034, Retrieved from the Internet: URL:http://www.aak.se/Global/Products/Beau ty%20and%20personal%20care/Surfactants/aak -lfc_lipex_102-203_E75-E70_0808.pdf [retrieved on 2015-03-03] the whole document -----	1,3,8, 18-20
T	Anonymous: "Ingredient Showdown: Cocamidopropyl Betaine and Betaine",  ' 12 May 2014 (2014-05-12), XP055173609, Retrieved from the Internet: URL:http://www.naturallycurly.com/curlread ing/ingredients/ingredient-showdown-cocami dopropyl-betaine-and-betaine/ [retrieved on 2015-03-04] the whole document -----	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IB2014/066698

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		WO 2006045471 A1	04-05-2006
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A61K 8/86(2006.01)

A61Q 19/10(2006.01)

A61K 8/97(2006.01)

A61K 8/02(2006.01)

权利要求书2页 说明书9页

### (54)发明名称

用于治疗肛门直肠刺激和障碍的预先润湿的擦拭物

### (57)摘要

许多患有肛门直肠不适与障碍的人需要用于改善清洁,但不会过度刺激皮肤的预先以溶液湿润的纤维状薄片材料。尤其是,本发明涉及包含含有金缕梅属水或金缕梅的溶液以有效地治疗肛门直肠障碍的湿擦拭物(比如肛门直肠擦拭物)。

1. 一种湿擦拭物,其包含纤维状薄片材料和非油性的基于水性的溶液,该非油性的基于水性的溶液包含:

- a)约10至约50%的金缕梅;
  - b)约0.01至约2%的至少一种乳化剂;及
  - c)约0.01至约0.20%的至少一种软化剂;
- 其中该重量百分比基于该溶液的总重量。

2. 根据权利要求1的湿擦拭物,其中在该溶液中的至少一种软化剂为维生素E乙酸酯。

3. 根据权利要求1的湿擦拭物,其中在该溶液中的至少一种乳化剂为乙氧基化的牛油树脂。

4. 根据权利要求1的湿擦拭物,其中该纤维状薄片材料包含非织造材料。

5. 根据权利要求1的湿擦拭物,其中基于该湿擦拭物的干燥重量,该湿擦拭物包含约10至约90重量%的该溶液擦拭物。

6. 根据权利要求1的湿擦拭物,其中基于该湿擦拭物的干燥重量,该湿擦拭物包含约4:1的溶液对擦拭物。

7. 根据权利要求1的湿擦拭物,其中该溶液包含比例为约10:1的至少一种乳化剂对至少一种软化剂。

8. 根据权利要求3的湿擦拭物,其中该溶液包含约1.5%的乙氧基化的牛油树脂,其中该重量百分比基于该溶液的总重量。

9. 根据权利要求1的湿擦拭物,其中该溶液包含至少一种表面活性剂。

10. 根据权利要求9的湿擦拭物,其中至少一种表面活性剂为辛酸/癸酰氨基丙基甜菜碱。

11. 根据权利要求1的湿擦拭物,其中该溶液进一步包含基于该溶液的总重量约0.1至约0.5重量%的至少一种抗微生物防腐剂。

12. 根据权利要求11的湿擦拭物,其中该抗微生物防腐剂包含二偶氮烷基脒、对羟基苯甲酸丙酯和对羟基苯甲酸甲酯。

13. 根据权利要求1的湿擦拭物,其中该溶液的pH值为约5至约7。

14. 根据权利要求1的湿擦拭物,其中该溶液进一步包含基于该溶液的总重量约0.01至约10重量%的甘油。

15. 根据权利要求1的湿擦拭物,其中该溶液进一步包含基于该溶液的总重量约0.01至约0.5重量%的植物提取物。

16. 根据权利要求1的湿擦拭物,其中该溶液包含基于该溶液的总重量约20重量%的金缕梅。

17. 一种使用根据权利要求1制造的湿擦拭物的方法,其包括使用该具有包含在其上的溶液的湿擦拭物来擦拭人的皮肤并通过使用该湿擦拭物使溶液在擦拭完成后留存在人的皮肤上。

18. 一种湿擦拭物,其包含纤维状薄片材料和非油性的基于水性的溶液,该基于水性的溶液包含:

- a.)约50重量%的金缕梅;
- b.)约9重量%的甘油;



- c.)约5重量%的丙二醇;
  - d.)约1.5重量%的乙氧基化的牛油树脂;
  - e.)约0.2重量%的黄瓜提取物;
  - f.)约0.2重量%的春黄菊提取物;
  - g.)约0.2重量%的二偶氮烷基脲;
  - h.)约0.2重量%的香料;
  - i.)约0.2重量%的对羟基苯甲酸甲酯;
  - j.)约0.1重量%的癸酰氨基丙基甜菜碱;
  - k.)约0.1重量%的芦荟;
  - l.)约0.1重量%的维生素E乙酸酯;
  - m.)约0.09重量%的柠檬酸;
  - n.)约0.09重量%的柠檬酸钠;
  - o.)约0.05重量%的乙二胺四乙酸二钠;和
  - p.)约0.05重量%的对羟基苯甲酸丙酯;
  - q.)约33重量%的添加的纯水;
- 基于该溶液的总重量。

19.一种使用根据权利要求18制造的湿擦拭物的方法,其包括使用该具有包含在其上的溶液的湿擦拭物来擦拭人的皮肤并通过使用该湿擦拭物使溶液在擦拭完成后留存在人的皮肤上。

20.一种湿擦拭物,其包含纤维状薄片材料和非油性的基于水性的溶液,该基于水性的溶液包含:

- a.)约20重量%的金缕梅;
  - b.)约9重量%的甘油;
  - c.)约5重量%的丙二醇;
  - d.)约1.5重量%的乙氧基化牛油树脂;
  - e.)约0.2重量%的黄瓜提取物;
  - f.)约0.2重量%的春黄菊提取物;
  - g.)约0.2重量%的二偶氮烷基脲;
  - h.)约0.2重量%的香料;
  - i.)约0.2重量%的对羟基苯甲酸甲酯;
  - j.)约0.1重量%的癸酰氨基丙基甜菜碱;
  - k.)约0.1重量%的芦荟;
  - l.)约0.1重量%的维生素E乙酸酯;
  - m.)约0.09重量%的柠檬酸;
  - n.)约0.09重量%的柠檬酸钠;
  - o.)约0.05重量%的乙二胺四乙酸二钠;和
  - p.)约0.05重量%的对羟基苯甲酸丙酯;
  - q.)约63重量%的添加的纯水;
- 基于该溶液的总重量。

## 用于治疗肛门直肠刺激和障碍的预先润湿的擦拭物

### 技术领域

[0001] 本发明涉及预先以用于改善清洁,但不会过度刺激皮肤的溶液润湿的纤维状薄片材料(fibrous sheet material)。尤其是,本发明涉及包含金缕梅属(hamamelis)水或金缕梅(witch hazel)的湿擦拭物(wet wipe),比如肛门直肠擦拭物,其适合用于女性肛门直肠和会阴区。此湿擦拭物应包含有效的清洁液,但也为非刺激性且传递清新的感觉和气味。

### 背景技术

[0002] 湿擦拭物是众所周知的消费性商品,其可以多种形式获得。或许最常见的湿擦拭物形式是已经包装在塑料容器中的一叠润湿的薄片。湿擦拭物是由各种已经以各种合适的擦拭溶液润湿的材料制造的。典型地,湿擦拭物可以折叠或未折叠构形获得。例如,已可获得其中在擦拭物堆叠中的各湿擦拭物是以折叠构形安排(比如本领域技术人员所熟知的c型折叠构形、z型折叠构形或四分之一型折叠构形)的湿擦拭物叠。各折叠的湿擦拭物也与该叠湿擦拭物中紧接在其上和其下的湿擦拭物交错折叠。在替代的构形中,湿擦拭物为连续材料卷(web of material)的形式,该材料卷包括穿孔以分开单个湿擦拭物且该单个湿擦拭物卷绕成卷,并包装在塑料容器中。这类湿擦拭物已经用于婴儿擦拭物、手部擦拭物、家庭清洁擦拭物、工业擦拭物。

[0003] 被纳入传统湿擦拭物中的溶液通常包括一些意在增强或赋予该擦拭物特殊性质的成分。这些性质与,例如清洁效力、香料、药物、降低刺激性、皮肤健康、产品的美观性等有关。在婴儿擦拭物方面,提供轻柔舒缓感觉而无过度刺激性或泡沫,同时保持清洁及抗微生物效力的溶液对产品性能是高度希望的。用于提供这样的性质的合适成分已经包括水、软化剂、表面活性剂、防腐剂、螯合剂、pH缓冲剂或其组合。该溶液也含有洗剂和/或药物。

[0004] 然而,用于湿擦拭物的传统溶液和,尤其是,在这样的溶液中的表面活性剂尚未完全令人满意。例如,为了降低皮肤刺激的程度,传统的湿擦拭物溶液已经包括两性表面活性剂,其通常导致很少或不会引起皮肤刺激。这样的两性表面活性剂已经包括椰油酰两性乙酸钠和椰油酰两性二乙酸二钠。然而,这样的两性表面活性剂典型地不会表现出与其他表面活性剂(比如阴离子表面活性剂)相关的高水平的清洁效力。这样的两性表面活性剂一典型地也不提供消费者,尤其是女性消费者的皮肤所需要的最理想的柔滑感。

[0005] 另一方面,阴离子表面活性剂虽然表现出这样的清洁效力,其典型地会造成过度的皮肤刺激,比如干燥和脱皮,因此不适合用于湿擦拭物应用中。在女性肛门直肠及会阴区的用药中,由于阴道和肛门皮肤柔软,由这样的表面活性剂所引起的高度皮肤刺激特别不希望的。此外,由于阴离子表面活性剂高度起泡和去污活性,大多数阴离子表面活性剂适合用于洗涤剂组成物。然而,这类起泡在湿擦拭物中的应用通常是不希望的,尤其是在肛门直肠药物擦拭应用中。使用湿擦拭物的消费者更喜欢来自湿擦拭物的溶液不在皮肤表面上遗留任何皂类或多泡的残留,因为使用湿擦拭物后通常不会擦掉留在皮肤上的溶液。

[0006] 在女性肛门直肠和会阴区药物擦拭物方面,提供轻柔舒缓感觉而无过度刺激性或泡沫,同时保持清洁及抗微生物效力的溶液对产品性能是非常希望的。婴儿擦拭物更需要

温和而有效的清洁,而本发明中公开的新颖擦拭物是设计成不仅温和且有效清洁,而且还舒缓。

[0007] 因此,提供用于湿擦拭物的包括显示出改善的清洁效力,同时不会引起过度的皮肤刺激或起泡的表面活性剂的溶液仍是希望的。

[0008] 使用专门设计用来清洁女性肛门直肠和会阴区的脆弱而敏感的皮肤表面活性剂是高度希望的。甜菜碱类的表面活性剂是希望的,因为它们提供有效的清洁,通常不会起泡且以其温和的特性闻名。

## 发明内容

[0009] 响应上文所讨论的困难和问题,现已发现具有用于应用于女性肛门直肠和会阴区的改善的溶液的新的湿擦拭物。

[0010] 一方面,本发明涉及包含纤维状薄片材料和非油性的基于水性的(aqueous-based)溶液的湿擦拭物,该非油性的基于水性的溶液包含:

[0011] a)约10至约50%的金缕梅;

[0012] b)约0.01至约2%的至少一种乳化剂;及

[0013] c)约0.01至约0.20%的至少一种软化剂;

[0014] 其中该重量百分比基于所述溶液的总重量。

[0015] 另一方面,本发明涉及包含纤维状薄片材料和非油性的基于水性的溶液的湿擦拭物,该非油性的基于水性的溶液包含:

[0016] a.)约20重量%的金缕梅;

[0017] b.)约9重量%的甘油;

[0018] c.)约5重量%的内二醇;

[0019] d.)约1.5重量%的乙氧基化的牛油树脂;

[0020] e.)约0.2重量%的黄瓜提取物;

[0021] f.)约0.2重量%的春黄菊提取物;

[0022] g.)约0.2重量%的二偶氮烷基脲;

[0023] h.)约0.2重量%的香料;

[0024] i.)约0.2重量%的对羟基苯甲酸甲酯;

[0025] j.)约0.1重量%的辛酰/癸酰氮丙基甜菜碱(capryl/capramidopropyl betaine);

[0026] k.)约0.1重量%的芦荟;

[0027] l.)约0.1重量%的维生素E乙酸酯;

[0028] m.)约0.09重量%的柠檬酸;

[0029] n.)约0.09重量%的柠檬酸钠;

[0030] o.)约0.05重量%的乙二胺四乙酸二钠;及

[0031] p.)约0.05重量%的对羟基苯甲酸丙酯;

[0032] q.)约63重量%的添加的纯水;

[0033] 其中重量百分比基于所述溶液的总重量。

[0034] 再另一方面,本发明涉及使用根据上述湿擦拭物来制造湿擦拭物的方法,其包括

使用具有包含在其上的溶液的湿擦拭物来擦拭人的皮肤并通过使用该湿擦拭物使溶液在擦拭完成后留存在人的皮肤上。

[0035] 在本发明的各种方面中,有利的是,本发明涉及用于应用于女性肛门直肠和会阴区的湿擦拭物,当与传统的湿擦拭物相比较时,其具有改善的清洁效力,而无过度的皮肤刺激或起泡,且传递清新感和气味。另外,本发明提供用于湿擦拭物的溶液,其在应用期间和应用后留给皮肤光滑、柔滑的感觉。

[0036] 发明详述

[0037] 本发明涉及具有多组分保存系统的纤维材料,尤其是湿擦拭物,其适合用于肛门/肛周区域的多次使用包装的产品。该湿擦拭物包含温和的表面活性剂,以促进清洁并舒缓受刺激的区域,且适合用于可能受刺激的肛周组织。本发明的湿擦拭物可用于肛门直肠障碍,比如痔疮等。这样的湿擦拭物通常被折叠并以堆叠构形在供售于消费者的合适的容器内。

[0038] 适合用于这样的湿擦拭物的材料是本领域技术人员所熟知。该湿擦拭物典型地是由织造或非织造的纤维状薄片材料制造。例如,本发明的湿擦拭物可包括非织造纤维状薄片材料,此非织造纤维状薄片材料包括熔喷(melt blown)、共成形(coform)、气流铺置(air-laid)、黏合梳理纤网(bonded-carded web)材料、水刺(hydro-entangled)材料、其组合等。这样的材料可包含合成或天然纤维、或其组合。典型地,该湿擦拭物限定每平方米约25至约120克的基础重量,且希望地为每平方米约40至约90克。

[0039] 本发明的湿擦拭物可包含聚合性微纤维和纤维素纤维的共成形基片(base sheet),其具有每平方米约60至约80克的基础重量,其希望地为每平方米约75克。这样的共成形基片通常是如1978年7月11日出版的授让予Anderson等人的美国专利第4,100,324号(其以引用方式被并入本文)中的描述制造。经典地,这类共成形基片包含热塑性聚合性熔喷微纤维(比如,例如聚丙烯微纤维)和纤维素纤维(比如,例如木浆纤维)的气体成形基质。

[0040] 最优选地,本发明的湿擦拭物是市售Green Bay, Wisconsin的Ahlstrom Green Bay Inc.的Grade **SX-810®** 非织造材料。

[0041] 可选地,本发明的湿擦拭物可包含包括多层材料的复合材料(composite)。例如,该湿擦拭物可包括3层复合材料,此3层复合材料包括介于如上述两共成形层之间的弹性体膜或熔喷层。在这样的构形中,该共成形层可限定每平方米约15至约30克的基础重量,且该弹性体层可包括膜材料,比如聚乙烯茂金属(metallocene)膜。

[0042] 单个湿擦拭物通常是以折叠构形排列。这样的折叠构形为本领域技术人员所熟知,且包括c形折叠、z形折叠及四分之一折叠构形等。各湿擦拭物也可与该叠湿擦拭物中紧接在其上和其下的湿擦拭物交错折叠。该湿擦拭物通常限定展开的宽度和展开的长度。该湿擦拭物可具有任何合适的展开的宽度和长度。例如,该湿擦拭物可具有约2.0至约80.0厘米的展开的长度,和约2.0至约80.0厘米的展开的宽度。

[0043] 本发明的不同方面的湿擦拭物也含有被吸收入该湿擦拭物中的溶液。包含在各湿擦拭物内的溶液的量可根据所使用的提供该湿擦拭物的材料类型、所使用的溶液类型、用于储存该湿擦拭物的容器类型和希望地该湿擦拭物的最终用途而变化。一般而言,各湿擦拭物可基于该擦拭物的干燥重量含有约150至约600重量%的溶液,希望约250至约450重量%的溶液,以用于改善擦拭。

[0044] 在本发明的一个方面中,该湿擦拭物是在塑料容器中包装成叠。在这样的容器中,优选的溶液对擦拭物的干燥重量比为约3.5:1至约4.5:1,更优选为约3.8:1至约4.3:1且最优选为约4:1的溶液对擦拭物(基于所述湿擦拭物的干燥重量)。若该溶液的量少于上述限定范围,该湿擦拭物可能太干且可能无法充分地进行。若该溶液的量大于上述限定范围,该湿擦拭物可能会过饱和且湿透,而该溶液可能汇集在容器的底部。

[0045] 在一个特殊的方面中,其中该湿擦拭物被单个包装在铝箔袋中,该溶液对擦拭物的干燥重量的优选比例为约3.5:1至约6:1,更优选为约3.5:1至约5.2:1且最优选为约4.7:1的溶液对擦拭物(基于所述湿擦拭物的干燥重量)。

[0046] 在本发明的湿擦拭物中的溶液包含金缕梅,此为有效的清洁剂且为本发明的溶液提供舒缓、凉感和独特的香味。存在于该溶液中的金缕梅的量在约10至约50%的范围内变化,更优选为在约10至约20%的范围内变化,最优选为约20%(基于溶液的总重量)。在一特殊的实施方式中,本发明包含购自American Distilling Inc.且具有14%的酒精含量的金缕梅(witch hazel)或金缕梅属(hamamelis)水作为合适的清洁剂。

[0047] 为了提供改善的触觉性质和清洁效力,但无过多起泡或皮肤刺激,本发明的湿擦拭物中的溶液包含两性或兼性离子(zwitterionic)表面活性剂。兼性离子的甜菜碱家族具有三甲基甘氨酸(甜菜碱)(源自甜菜根的氨基酸)的阳性-阴性头基结构。该疏水性尾基可为直链烷基(比如在椰油基甜菜碱(coco betaine)中)或可含有酰胺基,比如椰油酰氨丙基甜菜碱。其他甜菜碱包括月桂酰氨丙基甜菜碱、油酰氨丙基甜菜碱、蓖麻油酰氨丙基甜菜碱、十六烷基甜菜碱和二聚亚油酰氨丙基甜菜碱。另外的变体为磺基甜菜碱、羟磺基甜菜碱和磺基甜菜碱(sultaine)。经由加入盐类,甜菜碱比其阴离子同类(cousin)更能抵抗增稠。为此,为了取得令人合意的浓稠产品,添加黏度加强聚合性添加剂可能是必要的,这可能增加成本及配方的复杂性(见<http://www.naturallycurly.com/curlreading/ingredients/zwitterionic-surfactants-a-milder-alternative>)。

[0048] 为了提供本发明的湿擦拭物中改善的触感和清洁性质但无过量起泡或皮肤刺激,本发明的溶液包含至少一种表面活性剂,优选为甜菜碱表面活性剂。该溶液可包括任何量的能提供希望性质的甜菜碱表面活性剂。所选择的特定甜菜碱可对最终产品的黏性、起泡行为和去污性具有显著影响。在一个特殊的实施方式中,该溶液包括约0.01至约10重量%,希望地为约0.01至约5重量%的甜菜碱表面活性剂(基于该溶液的总重量)。最优选地,本发明包含范围为约0.1w/w%的商购自Evnoik Degussa,商品名为Tego Betaine 810®的辛酰/癸酰氨丙基甜菜碱(基于该溶液的总重量)。具有低于优选的表面活性剂重量百分比的比率的溶液可能因为不希望的触觉性质(比如黏性和触摸后失去柔滑)、去污活性降低和皮肤刺激增加而是不希望的。

[0049] 包含在本发明的湿擦拭物内的溶液的pH值限定为约5至约7,希望地为约5至约6。低于约5的pH值水平通常是不希望的,因为可能刺激皮肤。然而,高于约7的pH水平也是不希望的,因为可能危及防腐活性并可能导致皮肤刺激。可使用相对量的合适的缓冲剂(比如柠檬酸及柠檬酸钠),以取得希望的pH值。本发明的溶液包含约为所述溶液的约0.05至约0.25重量%的缓冲系统。

[0050] 该溶液也可包含各种可协助提供希望的擦拭和清洁性质的其他组分。例如,该组分可包括水、软化剂、至少一种表面活性剂、至少一种防腐剂,至少一种螯合剂、至少一种pH

缓冲剂、至少一种香料或其组合。该溶液也可含有至少一种洗剂和/或药物。为了降低皮肤刺激,希望地该溶液包含至少约30重量%至约80重量%的添加的纯水(基于该溶液的总重量),更优选为约63重量%的添加的纯水(基于该溶液的总重量)。

[0051] 例如,该溶液可包括有效量的至少一种防腐剂,以抑制微生物生长。合适的防腐剂为本领域技术人员所熟知,且包括,例如对羟基苯甲酸酯、羟甲基甘氨酸钠、有机酸(比如苯甲酸和苹果酸)、DMDM乙内酰脲(DMDM hydantoin)等及其组合。在一个特殊的实施方式中,该抗微生物防腐剂包含对羟基苯甲酸甲酯、对羟基苯甲酸丙酯和购自ISP Technologies, Inc,商品名为GERMALL II的二偶氮烷基脲(diazolidinyl urea)。该溶液可包括任何量的能提供希望抗微生物效果的防腐剂。例如,该溶液可包括约0.1至约0.5重量%的抗微生物防腐剂(基于该溶液的总重量),优选为0.40重量%(基于该溶液的总重量)。

[0052] 申请人已经发现,当与包括其他类型的表面活性剂的传统湿擦拭物比较时,根据本发明不同方面的包含甜菜碱表面活性剂的湿擦拭物具有改善的触觉性质和清洁效力,而无过度的皮肤刺激。该溶液可进一步包括可作为乳化剂或提供额外的清洁性质的另外的表面活性剂。合适的辅助表面活性剂包括,例如阴离子表面活性剂,比如酰基谷氨酸盐和酰基羟乙基磺酸盐、烷醇酰胺(alkaolamids)、兼性表面活性剂、非离子性表面活性剂等或其组合。例如,合适的酰基谷氨酸盐阴离子表面活性剂为椰油酰谷氨酸钾(cocyl glytamate),合适的酰基羟乙基磺酸盐阴离子表面活性剂为椰油酰羟乙基磺酸铵,而合适的兼性表面活性剂包括辛酰两性基二丙酸二钠(capryloamphdipropionate)和椰油酰两性基二乙酸二钠(disodium cocoamphodiactetae)。合适的非离子性表面活性剂包括具有平均12至16个碳原子的二乙醇酰胺、烷基酚乙氧基化物、醇乙氧基化物、山梨坦酯、甘油酯等。该溶液可包括任何量的能提供改善的清洁或触觉特性的辅助表面活性剂。例如,该溶液可包括约0.01至约5重量%的辅助表面活性剂(基于该溶液的总重量)。在本发明的最优选实施方式中,本发明不包含辅助表面活性剂以限制可能的刺激。

[0053] 此外,希望地本发明的湿擦拭物显现出低程度的起泡,以改善性能。该湿擦拭物也对使用者显现出光滑、柔滑的感觉,以改善消费者的接受度。

[0054] 本发明包含至少一种合适的软化剂或合适的软化剂的组合,比如植物油脂(botanical butter)、维生素E乙酸酯及芦荟。本发明包含至少一种软化剂,其单个含量在约0.01%至约2%的范围内,更优选地,单个含量在约0.01%至约1.8%的范围内,最优选地,软化剂的单个含量为约1.5%,其中该重量百分比基于本发明的溶液的总重量。优选地,该软化剂为维生素衍生物,最优选地,该软化剂为维生素E乙酸酯。

[0055] 申请人已发现,使用乙氧基化牛油树脂软化剂(优选为PEG-75乙氧基化牛油树脂甘油酯),可提供润肤性、乳化及共增溶至少一种另外的软化剂(优选为维生素E乙酸酯,其在本领域中众所周知不溶于水)的多种功能。优选地,本发明的乳化剂是植物油脂,更优选为乙氧基化的植物油脂,且最优选为乙氧基化的牛油树脂。在本发明优选实施方式中,该溶液包含购自Aarhuskarlshamn,商品名为Lipex102**E-75®**的最优选乳化剂,PEG-75乙氧基化牛油树脂。本发明包含至少一种乳化剂,其单个含量在约0.01%至约2%的范围内,更优选为单个含量在约0.01%至约1.8%的范围内,最优选为软化剂的单个含量为约1.5%,其中该重量百分比基于该本发明的溶液的总重量。

[0056] 在制造本发明的溶液的过程中,将该乙氧基化牛油树脂甘油酯在50℃下,在分开

的侧相(side-phase)混合容器中熔化。将维生素E乙酸酯加入此侧相容器中,并通过混合来将其溶解在乙氧基化牛油树脂甘油酯中。然后,在周围环境的室温下(约25℃)通过剧烈混合主要批次来将该侧相加入主要批次中。将乙氧基化牛油树脂甘油酯/维生素E乙酸酯相作为倒数第二种成分添加物加入其中。若该乙氧基化牛油树脂甘油酯和维生素E乙酸酯是以分开、独立的添加物形式(而非制造该侧相)添加在主要批次中,该维生素E乙酸酯将不会溶解在主要批次中;当混合终止时,该维生素E乙酸酯将以油的形式上升到该溶液的顶部。一旦加入乙氧基化牛油树脂甘油酯/维生素E乙酸酯后,然后加入丙二醇防腐剂相(含有丙二醇、对羟基苯甲酸酯和香料)并在周围温度下混合约15分钟。

[0057] 本发明的溶液中可使用于约0.1至约2重量%范围内的另外的乳化剂,优选为温和的乳化剂,比如聚山梨醇酯20和其他乙氧基化的植物油脂,其中该重量百分比基于所述溶液的总重量。

[0058] 本发明包含甘油以改善平滑度、提供润滑及作为保湿剂。可添加精油和植物提取物来作为香料。本发明包含使用至少一种香料以协助传达令个人的嗅觉愉悦的清新感和气味。本发明中可以采用源自植物提取物(比如黄瓜和春黄菊)的香料及各种香料,比如购自Bell Fragrances Corporation的Bell **Fragrances®**。该至少一种香料的量可为各自在约0.05重量%至约0.3重量%的范围内,其中该重量百分比基于所述溶液的总重量。

[0059] 本发明进一步包含至少一种螯合剂,该螯合剂是经过设计以保护该植物提取物的结构完整性和香味,防止在溶液制造过程中可能会接触到不必要和不想要的铁。螯合剂的存在量可在约0.01至约0.1重量%的范围内,其中该重量百分比基于该溶液的总重量。本发明的优选螯合剂为商购自Dow Chemical Company的乙二胺四乙酸二钠。

[0060] 本发明的不同方面的湿擦拭物可使用数种本领域技术人员所熟知的不同方法制造。本文所描述的特殊方法和步骤顺序并非用来限制本发明,而是仅公开来作为一种制作湿擦拭物和湿擦拭物叠的方法。首先,将被转换成湿擦拭物的材料供应卷展开,以提供连续移动的材料卷。通过本领域技术人员所熟知的任何合适的方式(比如喷洒、浸渍等)使材料卷饱和或以其它方式浸满本发明的溶液。

[0061] 将材料卷在机器中切成多个条带,各条带可被折叠成对单个湿擦拭物而言所希望的折叠类型。如本领域技术人员所周知使用切刀将材料卷切开。例如,可将材料卷切成预定数量的单个条带。然后,将该材料条带折叠成折叠构形,比如z形折叠构形。例如,各材料条带可限定顶部折边部分(flap portion)、中间部分及底部折边部分。该顶部和底部折边部分连接中央部分并分别折叠在其上方和下方,以提供z形折叠构形。

[0062] 然后,可组合各折叠条带,一个条带在另一个条带的上方,与其他预定数量的来自同一材料卷的折叠条带一起形成连续的巾(towel)。然后,将巾切成湿擦拭物的夹并将湿擦拭物的夹布置成堆叠构形。一叠中的夹的数量取决于在最后的包装中希望的叠数及湿擦拭物的数量,比如48或60张单个的湿擦拭物。定期检查湿擦拭物叠的重量,以确保该添加溶液是正确的。若不是,则调整该添加溶液。将湿擦拭物叠正确构形之后,可将其外加包装,优选使用塑料包装纸,再放置于容器(比如塑料桶)内部,以提供湿擦拭物包装。该容器提供用于湿擦拭物的基本上密封的环境,以尽量减少任何溶液从其中逸出。

[0063] 关于用于制造包装在铝箔袋中的单个擦拭物的过程,将预先切开(优选为5英寸×6英寸),干燥的擦拭物放置在小袋中,然后将本发明的溶液加入小袋中。该小袋中的溶液对

干燥擦拭物的比例较高,因为该小袋中会有一些溶液汇集。

[0064] 因此,本发明的不同方面可有利地提供当与传统的湿擦拭物相比较时,具有改善的触觉性质及清洁力,但同时保持低皮肤刺激性和起泡的湿擦拭物。这样的湿擦拭物可有利地用于应用于妇女的肛门直肠和会阴区,当与传统的湿擦拭物相比较时,其具有改善的清洁效力,但不会过度刺激皮肤或起泡,且传达清新感和气味。另外的用途可包含婴儿擦拭物、手部擦拭物、脸部擦拭物、美容擦拭物、家用擦拭物、工业擦拭物等。

#### 实施例

[0065] 下列实施例是用于提供对本发明的更详细的理解。该特定材料和参数为示例性,并不意在限制本发明的范围。

[0066] 实施例1

[0067] 根据下列配方制备用于本发明的湿擦拭物的特别合适的溶液:

[0068] 所描述的配方为澄清溶液,其含有20%w/w金缕梅作为活性成分。最终产品为以本溶液饱和的白色,湿润擦拭物。



[0069]

活性成分		
组分名称 / 销售商	%w/w	标签名称 (LD)
金缕梅 USP (14% Alcohol) / American Distilling Inc. 酒精, 14.0 - 15.0%	20.0	金缕梅 <sup>†</sup>
非活性成分		
组分名称 / 销售商	%w/w	标签名称 (LD)
纯水 USP / 制造处	63 <sup>†</sup>	纯水
甘油 USP, 96% / The Procter & Gamble Company, Cincinnati, OH	9.0	甘油
丙二醇 USP / The Dow Chemical Company, Midland, MI	5.0	丙二醇
PEG 75 牛油树脂, 乙氧基化, Lipex 102 E - 75 / Aarhuskarlshamn	1.5	PEG 75 牛油树脂 甘油酯 (软化剂及 辅助加溶剂)
黄瓜提取物, / Medallion International Inc. 黄瓜提取物, 44.4% 丙二醇, 50.0% 水, 5.0% Neolone PE (防腐剂), 0.6%	0.2	N/A 黄瓜属 (黄瓜) 果实 提取物 丙二醇 纯水
春黄菊提取物 / Medallion International Inc. 春黄菊提取物, 39.0%  丙二醇, 50.0% 水, 10.0% DMDM 乙内酰脲 (防腐剂), 1.0%	0.2	N/A 母菊属 (Chamomilla Recutita) (母菊 (Matricaria)) 花 提取物 丙二醇 纯水 乙内酰脲
Germall II (二偶氮烷基脲) / ISP Technologies, Inc.	0.2	二偶氮烷基脲
对羟基苯甲酸甲酯 NF / Ueno Fine Chemicals Industry, Ltd	0.2	对羟基苯甲酸甲酯
Tego Betaine 810 / Evnolk Degussa	0.1	辛酰 / 癸酰氨基丙基甜菜碱
芦荟胶 / Concentrated Aloe Inc. 库拉索芦荟叶汁 山梨酸钾 苯甲酸钠	0.1	N/A 库拉索芦荟叶汁 N/A N/A
维生素 E 乙酸酯; / DSM Nutritional Products Ltd	0.1	维生素 E 乙酸酯
柠檬酸 USP 无水颗粒 / Archer Daniels Midland Company	0.09	无水柠檬酸
柠檬酸钠 USP 含水 / Archer Daniels Midland Company	0.09	柠檬酸钠
乙二胺四乙酸二钠 USP (Versene NA); VERSENE NA CHELATING AGENT / The Dow Chemical Company	0.05	乙二胺四乙酸二钠
香料 / Bell Flavors and Fragrances / Bell Fragrances Corporation 聚山梨酸酯 20, >50%	0.05	N/A 聚山梨酸酯 20 双丙甘醇

[0070]

双丙甘醇, 10 - 20% 合成香料, 25 - 50%		香料
对羟基苯甲酸丙酯 NF / Ueno Fine Chemicals Industry, Ltd.	0.05	对羟基苯甲酸丙酯

[0071] 尾注

[0072] 1. 金缕梅 USP 含有 14.5% v/v 酒精。该配方的酒精含量为约 2.8 至约 3.0% w/w, 其完全由金缕梅组分提供。

[0073] 2. 采用纯水作为漂洗水且直接加入。在所有情况中, 该漂洗水随后被加入主要混合容器中。

[0074] 实施例 2

[0075] 根据下列配方制备用于本发明的湿擦拭物的合适溶液:

[0076] 将金缕梅的量增加至 50w/w% 并将水量减少至约 33w/w%。

[0077] 虽然有关于本发明的特定方面已进行详细描述, 可知本领域技术人员在理解前述内容后将可轻易地构想这些方面的替换、变化及等同方面。因此, 本发明的范围应依所附的权利要求及其任何等价物评估。