

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
11 April 2002 (11.04.2002)

PCT

(10) International Publication Number
WO 02/28361 A2

(51) International Patent Classification⁷: **A61K 7/48, 7/50**

(21) International Application Number: PCT/US01/29391

(22) International Filing Date:
20 September 2001 (20.09.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/676,647 29 September 2000 (29.09.2000) US

(71) Applicant: **JOHNSON & JOHNSON CONSUMER COMPANIES, INC.** [US/US]; 199 Grandview Road, Skillman, NJ 08558 (US).

(72) Inventors: **ROBERTSON, Katherine, W.**; 9007 Tammaron Drive, Plainsboro, NJ 08889 (US). **DOLE, Victoria, F.**; 9 Minsi Road, Whitehouse Station, NJ 08889 (US).

(74) Agent: **JOHNSON, Philip, S.**; Johnson & Johnson, One Johnson and Johnson Plaza, New Brunswick, NJ 08933 (US).

(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— without international search report and to be republished upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: COMPOSITIONS FOR CLEANSING SKIN AND TREATING ACNE

(57) Abstract: A skin cleansing composition comprising: from about 0.1 to about 5 percent by weight of at least one anti-acne active ingredient; from about 1 to about 25 percent by weight of at least one alcohol; from about 0.1 to about 15 percent by weight of at least one solubilizer; and water is disclosed. The composition is stable and dries quickly, but does not make the skin feel dry after use.



WO 02/28361 A2

Compositions For Cleansing Skin And Treating Acne

Background of the Invention

1. Field of the Invention

The present invention relates to compositions that are useful for cleansing skin and for treating acne. The compositions contain salicylic acid, are low in alcohol, physically stable, and do not leave the skin feeling dry after use.

2. Description of the Prior Art

Acne is a common disorder characterized by blackheads, whiteheads, papules, pustules, cysts, and various nodules and scars. Acne is commonly seen on the face and back of the upper arm. It is theorized that acne is caused, at least in part, by bacteria such as *Propionibacterium acnes*. For this reason, anti-acne products frequently contain active ingredients that kill or inhibit the growth of bacteria. Benzoyl peroxide and salicylic acid are well known for their use as anti-acne active ingredients.

Acne can be quite unsightly and frequently causes embarrassment to the sufferer. For this reason, as well as for good hygiene, many people use skin cleansing products and anti-acne products on a daily basis. Skin cleansing products include astringents, toners, and the like. Anti-acne products include ointments, lotions, and the like. Astringent and toner formulations sometimes include anti-acne active ingredients.

Skin cleansing products and anti-acne products are known to contain water. Salicylic acid is poorly soluble in water. Therefore, when it is desirable to formulate salicylic acid in a cleansing product or an anti-acne product, keeping the salicylic acid in solution becomes a challenge. The formulations frequently are physically unstable, that is, the salicylic acid precipitates out of solution. Due to its poor water solubility, salicylic acid frequently is formulated with a relatively high amount of ethyl alcohol to aid in solubilizing the salicylic acid. As used herein, the term relatively high amount of ethyl alcohol means from 40 to 80 percent by weight ethyl alcohol, based on the total weight of the formulation.

The ethyl alcohol in the salicylic acid formulations is also utilized to aid in creating formulations that dry quickly on the skin. The formulations tend to dry quickly due to the evaporation of the ethyl alcohol. Unfortunately, evaporation of

ethyl alcohol from the skin tends to dry the skin. In general, people like their skin to feel moisturized after cleansing. Therefore, there is a need for a skin cleansing product that contains an anti-acne active ingredient, but does not make the skin feel dry after use.

Attempts have been made to develop alcohol-free skin cleansers that contain anti-acne active ingredients, however several problems are associated with the formulations. One problem is that it is difficult to make a stable formulation, as salicylic acid will tend to precipitate out of solution. Another problem is that the formulations do not dry as fast, due to the lack of ethyl alcohol. When alcohol-free formulations completely dry, there is frequently a sticky feeling left on the skin.

United States Patent No. 6,024,941 discloses an external skin treatment compositions comprising vitamin A and at least one stabilizer for the vitamin A. Suitable stabilizers include a salicylic acid compound and polyethylene glycol. The compositions are taught as being useful for the treatment of keratodermatitis and the prevention of or treatment of dermal aging. There is no teaching or suggestion of physically stable skin cleansing compositions containing an anti-acne ingredient and low levels of alcohol or the benefits thereof.

Accordingly, there is a continuing need for a skin cleansing product that contains an anti-acne active ingredient, is physically stable, and does not make the skin feel dry or sticky after use.

Summary of the Invention

We have discovered that it is possible to provide a skin cleansing product, which contains an anti-acne active ingredient, is physically stable, and does not make the skin feel dry or sticky after use. The present invention provides a skin cleansing composition including: from about 0.1 to about 5 percent by weight of at least one anti-acne active ingredient; from about 1 to about 25 percent by weight of at least one alcohol; from about 0.1 to about 15 percent by weight of at least one solubilizer; and water.

Detailed Description of Preferred Embodiments

The invention relates to a physically stable skin cleansing composition including: from about 0.1 to about 5 percent by weight of at least one anti-acne active ingredient; from about 1 to about 25 percent by weight of at least one alcohol; from about 0.1 to about 15 percent by weight of at least one solubilizer; and water. In the context of this invention the term “physically stable” means compositions that are clear and do not phase separate or form a precipitate at room temperature.

The skin cleansing compositions of the present invention include at least one anti-acne active ingredient. Suitable anti-acne active ingredients include, but are not limited to, salicylic acid, sulfur, lactic acid, glycolic acid, pyruvic acid, urea, resorcinol, N-acetylcysteine, retinoic acid, benzoyl peroxide, octopirox, triclosan, azelaic acid, phenoxyethanol, phenoxypropanol, flavinoids, derivatives thereof, and combinations thereof. Salicylic acid and benzoyl peroxide are preferred. Salicylic acid is most preferred. The amount of anti-acne active ingredient in the composition of the invention may range from about 0.1 to about 5, preferably from about 0.5 to about 2 percent by weight, based on the total weight of the composition.

At least one alcohol is included in the compositions of this invention. The alcohol may be selected from ethanol, n-propanol, isopropanol, t-butyl alcohol, and combinations thereof. Ethanol is preferred. The amount of alcohol in the compositions of the invention is high enough that the compositions dry quickly and do not leave the skin feeling sticky, yet, not so high that the skin feels dry after cleansing with the compositions. The amount of alcohol in the compositions of the invention may range from about 1 to about 25, preferably from about 5 to about 20, more preferably from about 10 to about 20 percent by weight, based on the total weight of the composition.

At least one solubilizer is included in the compositions of the invention to stabilize the composition so that the anti-acne active ingredient does not precipitate out of solution under normal storage conditions. Suitable solubilizers include, but are not limited to, propylene glycol, butylene glycol, hexylene glycol, polyethylene glycol (“PEG”), polysorbate-20, polysorbate-40, isoceteth-15, isoceteth-20, isoceteth-30, sorbeth-20, sorbeth-40, PEG-40 castor oil, and combinations thereof.

The most preferred solubilizer is PEG. It has been discovered that the number of repeating units in the PEG effects the performance of PEG as a solubilizer for anti-acne active ingredients. If the number of repeating units is too high or too low, the formulation will turn cloudy, and will not be physically stable. Generally, suitable PEGs include PEG's having from about 20 to about 75 repeating ethylene glycol units, preferably 20, 32, 40, 55, 60, and 75, more preferably, 20, 32, and 40, most preferably 32 repeating ethylene glycol units. The amount of solubilizer in the compositions of the invention may range from about 0.1 to about 15, preferably from about 0.5 to about 10, more preferably from about 1 to about 5 percent by weight, based on the total weight of the composition.

Water is also included in the compositions of the invention. The amount of water utilized will depend on the amounts of the required components and any optional components in the formulation. Generally, the amount of water may range from about 60 to about 99, preferably from about 75 to about 85 percent by weight, based on the total weight of the composition.

The skin cleansing compositions of the invention optionally include humectants, UV absorbers, pH adjusting agents, skin soothers, emollients, preservatives, conditioning agents, and fragrances.

Emollients which can be included in the compositions of the invention function by their ability to remain on the skin surface or in the stratum corneum to act as lubricants, to reduce flaking, and to improve the skin appearance. Typical emollients include fatty esters, fatty alcohols, mineral oil, polyether siloxane copolymers and the like. Examples of suitable emollients include, but are not limited to, polypropylene glycol ("PPG")-15 stearyl ether, PPG-10 cetyl ether, steareth-10, oleth-8, PPG-4 lauryl ether, vitamin E acetate, PEG-7 glyceryl cocoate, lanolin, and combinations thereof. Vitamin E acetate, PEG-7 glyceryl cocoate and combinations thereof are preferred. When utilized, the emollient can be present in an amount from about 0.01 to about 5, preferably from about 0.1 to about 2, more preferably from about 0.1 to about 1 percent by weight, based on the total weight of the composition.

Polyhydric alcohols can be utilized as humectants in the compositions of the invention. The humectants aid in increasing the effectiveness of the emollient,

reduce scaling, stimulate removal of built-up scale and improve skin feel. Suitable polyhydric alcohols include, but are not limited to, glycerol (also known as glycerin), polyalkylene glycols, alkylene polyols and their derivatives, including propylene glycol, dipropylene glycol, polypropylene glycol, polyethylene glycol and derivatives thereof, sorbitol, hydroxypropyl sorbitol, hexylene glycol, 1,3-dibutylene glycol, 1,2,6,-hexanetriol, ethoxylated glycerol, propoxylated glycerol and mixtures thereof. Glycerin is preferred. When utilized, the humectant is present in an amount from about 0.1 to about 5, preferably from about 0.1 to about 3 percent by weight, based on the total weight of the composition.

Skin soothers may be added to the compositions of the invention. Suitable skin soothers include, but are not limited to, panthenol, bisabolol, allantoin, and combinations thereof. When utilized, the skin soother is present in an amount from about 0.01 to about 0.75, preferably from about 0.01 to about 0.1 percent by weight, based on the total weight of the composition.

Conditioning agents may also be added to the compositions of the invention. Suitable conditioning agents include, but are not limited to, dimethicone propyl PG-betaine, dimethicone copolyols, polyquaternium-10, and combinations thereof. When utilized, the conditioning agent is present in an amount from about 0.01 to about 1, preferably from about 0.01 to about 0.5 percent by weight, based on the total weight of the composition.

It has also been discovered that the pH of the compositions according to the invention has an effect on the physical stability of the composition. Generally, the pH of the compositions of the invention ranges from about 3 to about 4, preferably from about 3.25 to about 3.75., most preferably about 3.6. The pH may be adjusted through the use of cosmetically acceptable pH adjusters, such as, but not limited to sodium citrate. The amount of pH adjuster utilized will depend on the initial pH of the composition and the volume of composition to be adjusted. Generally, the amount of pH adjuster utilized may range from about 0.1 to about 0.5, preferably from about 0.2 to about 0.4 percent by weight, based on the total weight of the composition.

UV absorbers may be added to the compositions of the invention. Suitable UV absorbers include, but are not limited to, benzophenone and its derivatives,

cinnamic acid and its derivatives, azoles, imidazoles and the like. When utilized, the amount of UV absorber ranges from about 0.001 to about 0.01 percent by weight, based on the total weight of the composition.

Botanicals, such as aloe barbadensis extract, chamomile extract, thyme extract, rosemary extract, and the like may also be useful in the compositions of the invention. When utilized, botanicals are present at from about 0.01 to about 1, preferably from about 0.01 to about 0.1 percent by weight, based on the total weight of the composition.

Sensates, such as menthyl lactate, menthol, camphor, peppermint, eucalyptus oil, menthoxypropanediol, and the like may also be useful in the compositions of the invention. When utilized, sensates are present at from about 0.01 to about 1, preferably from about 0.05 to about 0.5 percent by weight, based on the total weight of the composition.

Preservatives are typically added to compositions to inhibit the growth of microbial organisms. Suitable preservatives to be added to the compositions of the invention include benzoic acid, and Quaternium-15, available commercially as "Dowicil 200" from the Dow Chemical Corporation of Midland, Michigan. Benzoic acid is preferred. When utilized, the preservative is present in an amount from about 0.01 to about 1, preferably from about 0.05 to about 0.5 percent by weight, based on the total weight of the composition.

Any fragrance may be added to the compositions of the invention for aesthetic purposes. Suitable fragrances include, but are not limited to, eucalyptus oil, camphor synthetic, peppermint oil, clove oil, lavender, chamomile and the like. When utilized, fragrances are present in an amount from about 0.05 to about 0.5, preferably from about 0.1 to about 0.3 percent by weight, based on the total weight of the composition.

Colorants may also be added to the compositions of the invention for aesthetic purposes. Suitable colorants and typical use levels are well known in the art.

The compositions of the invention are useful for cleansing the skin and treating acne. The compositions may be supplied as a liquid, which may be applied to the skin utilizing cotton swabs, cloths, and the like. Alternatively, the

composition may be absorbed onto wipes, which is known technology, and sold as cleansing wipes.

The advantages of the invention and specific embodiments of the compositions prepared in accordance with the present invention are illustrated by the following examples. It will be understood, however, that the invention is not confined to the specific limitations set forth in the individual examples, but rather to the scope of the appended claims.

Materials Utilized In The Examples

<u>Trade Name</u>	<u>Active</u>	<u>Supplier</u>
Glycerine 916	Glycerin	Henkel
Univul MS-40	Benzophenone-4	BASF
Ritapan DL	Panthenol	RITA
Actiphyte of Aloe Vera	Aloe barbadensis extract	Active Organics
Carbowax PEG	Polyethylene glycol	Union Carbide
Arlasolve 200	Isoceteth-20	Uniqema
Cetiol HE	PEG-7 glyceryl cocoate	Henkel
Frescolat MR	Menthyl lactate	Haarmann & Reimer
Dow Corning 345 Fluid	Cyclomethicone	Dow Corning
Abil B 9950	Dimethicone propyl PG-betaine	Goldschmidt
Abil AV 20HS	Phenyl trimethicone	Goldschmidt
Abil Wax 9801	Cetyl dimethicone	Goldschmidt
Abil B 8832	Dimethicone copolyol	Goldschmidt
Abil B 8843	Dimethicone copolyol	Goldschmidt
Arlamol E	PPG-15 stearyl ether	ICI Surfactants
Procetyl AWS	PPG-5-ceteth-20	Croda
Solubilisant LRI	PPG-26-buteth-26 and PEG -40 hydrogenated castor oil	Wackherr
Polymer JR 400	Polyquaternium-10	Amerchol
Tween 20	Polysorbate 20	Uniqema
Carbomer EX-518	Acrylates copolymer	BF Goodrich

Example1

In the example, the oil phase and water phase were prepared separately, then combined. The samples were mixed and stored at room temperature. Samples were

monitored visually. For a sample to be considered useful, the formulation should be clear and no precipitate should form at room temperature. The procedure for preparing the samples was as follows (all amounts are on a percent by weight basis):

The oil phase was prepared by combining Vitamin E acetate, Arlamol® E, and Dow Corning 345 fluid and mixing well. The water phase was prepared by melting PEG 1450 in a glass beaker, adding salicylic acid and mixing until dissolved, adding ethyl alcohol and mixing. In a separate container Carbomer EX-518 was added to water with mixing. The solution containing the alcohol was then added to the solution containing the water and mixed to form the water phase. The oil phase was then combined with the water phase and mixed. The following samples were prepared:

<u>Ingredient</u>	<u>Sample Number</u>						
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>
Vitamin E Acetate	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Dow Corning 345 Fluid	5	9	9	9.75	10	9.75	9.75
Arlamol E	5	1	0.5	0.25	0	0.1	0.1
Water	Qs	qs	qs	Qs	qs	qs	Qs
Ethanol	10	10	10	10	10	10	10
Salicylic Acid	0.5	0.5	0.5	0.5	0.5	0.5	0.5
PEG 1450* (flake)	1	0	1	1	1	1	1
Sodium Citrate	0	0	0	0	0.5	0.37	0.25
Carbomer EX-518	0	0	0	0	0	0	0.1

*PEG 1450 = polyethylene glycol containing 32 repeating ethylene glycol units and having a molecular weight of 1450.

The samples were checked for physical stability. The results were as follows:

Sample 1 – formed a cloudy emulsion, took over 3 hours to phase separate

Sample 2 – salicylic acid precipitated out when the oil phase and the water phase were combined

Sample 3 - formed a cloudy emulsion, took less than 3 hours to phase separate

Sample 4 - formed a cloudy emulsion, took less than 3 hours to phase separate

Sample 5 - formed a cloudy emulsion, phase separated rapidly upon pH adjustment

Sample 6 - formed a cloudy emulsion, phase separated within 5 minutes

Sample 7 - formed a cloudy emulsion, phase separated

Example 2

The following formulations were prepared by the following process:

A beacker was charged with water and glycerin and mixed. An alcohol phase was prepared by melting PEG 1450, adding salicylic acid and mixing until dissolved. Alcohol was added to this solution with mixing. An oil phase was prepared by combining vitamin E acetate, vitamin A palmitate, fragrance, and Procetyl® AWS or Arlasolve® and mixing. The alcohol phase was then added to the water and glycerin and mixed. The oil phase was then added to the water/alcohol phase mixture and mixed.

<u>Ingredient</u>	<u>Sample Number</u>			
	<u>8</u>	<u>9</u>	<u>10</u>	<u>11*</u>
Vitamin E Acetate	0.1	0.1	0.1	0.1
Procetyl® AWS	1	1.5	0	0
Vitamin A palmitate	0.1	0.1	0.1	0.1
Fragrance ()	0.2	0.2	0.2	0.2
Arlasolve® 200	0	0	1.5	1.5
Water	86.6	80	80	80
Ethanol	10	10	10	10
Salicylic Acid	0.5	0.5	0.5	0.5
PEG 1450	1	1	1	1
Glycerin	0.5	0.5	0.5	0.5

*For sample #11, a portion of the alcohol phase was added to the oil phase, and then the phases were combined.

The samples were checked for physical stability. The results were as follows:

Sample 8 – opaque emulsion

Sample 9 – opaque emulsion

Sample 10 – clear solution

Sample 11 – cloudy, yellow oil phase, phase separated.

Sample 10 was physically stable at room temperature, and was clear.

Example 3 Accelerated Aging Studies

Storage conditions vary due to season and geographic location. It is therefore useful to test lead candidate formulations at both elevated temperatures (summer storage conditions) and reduced temperatures (winter storage conditions).

The following formulations were tested for accelerated aging. For these studies, samples were stored at 4°C, room temperature (~25°C), 40°C, and 50°C. In addition, samples were stored at -4°C for a minimum of 24 hours, then stored at room temperature for 24 hours, and evaluated. This freeze/thaw testing was repeated for a total of three cycles. Samples were inspected visually. Samples failed if they phase separated, became cloudy, formed a precipitate, or changed color.

<u>Ingredient</u>	<u>Sample Number</u>	
	<u>12</u>	<u>13</u>
Vitamin E Acetate	0.1	0.1
Vitamin A palmitate	0.1	0.1
Fragrance ()	0.2	0.2
Arlasolve® 200	1.5	1.5
Ethanol	10	10
Salicylic Acid	0.5	0.5
PEG 1450	1	1
Water	85.27	85.30
Glycerin	0.5	0.5
Sodium Citrate	0.25	0.25
0.1% FD&C orange #4	0.58	0
0.1% FD&C blue #1	0	0.55

The results are as follows:

After 5 days storage, Sample 12 was clear at both 4°C and room temperature, but turned cloudy at 40°C and very cloudy both at 50°C and after one freeze/thaw cycle. Sample 13 was clear at both 4°C and room temperature, but turned cloudy at 40°C and very cloudy both at 50°C and after one freeze/thaw cycle. All samples

were also sniffed to determine if accelerated aging storage had any adverse effect on the fragrance. No difference in fragrance scent was noticed in any sample.

Example 4

A base formulation was as follows: a beaker was charged with water and glycerine and mixed, benzophenone was added and mixed. A pre-mix of melted PEG-1450, salicylic acid, alcohol, and benzoic acid was made. To the water mixture the premixed was added and mixed; the pH was adjusted to 3.5 with sodium citrate; then dyes were added. The base formulation contained the following ingredients (all in weight percent): 10% ethanol, 1% glycerine, 0.005 % benzophenone-4, 0.5 % salicylic acid, 1% PEG-1450, 80% water, 0.1% benzoic acid, 0.035% FD&C blue #1 (0.1% solution), 0.015% FD&C yellow #10 (0.1% solution), and 0.35% sodium citrate.

Samples were then made by combining menthyl lactate and fragrance and heating until the menthyl lactate melted; adding solubilizer and mixing; and adding the mixture to the base formulation and mixing. The following samples were made from sub-samples of the base formulation:

<u>Ingredient</u>	<u>Sample Number</u>					
	<u>14</u>	<u>15</u>	<u>16</u>	<u>17</u>	<u>18</u>	<u>19</u>
Base Formulation	98.8	99.1	98.8	93	93	93
Menthyl Lactate	0.1	0.1	0.1	0.1	0.1	0.1
Fragrance ()	0.2	0.2	0.2	0.2	0.2	0.2
Solubilisant LRI	0.9	0	0	0	0	0
Arlasolve 200	0	0.6	0.9	0	0	0
Procetyl AWS	0	0	0	0.61	0.90	1.21

Samples 17 and 18 wer cloudy. Samples 14, 15, 16, and 19 were clear and stored for accelerated aging studies. The results were as follows: After 1 day of storage, all of samples 14, 15, 16 and 19 were clear at 50°C and at room temperature. Samples 14 and 16 were clear after one freeze/thaw cycle, and samples 15 and 19 were cloudy after one freeze/thaw cycle.

Example 5

A large beaker was charged with water, glycerin was added and mixed, benzophenone was added and mixed, sodium citrate was added and mixed. A salicylic acid pre-mix was prepared by melting PEG-1450, adding Solubilisant and heating to approximately 40°C, salicylic acid was added and mixed until the salicylic acid dissolved. The mixture was cooled to 40°C, then menthyl lactate was added and mixed until dissolved, vitamin E acetate was added and mixed, benzoic acid was added and mixed; alcohol was added and mixed, and fragrance was added and mixed. The salicylic acid pre-mix was then added to the water solution and mixed, then dyes were added and mixed.

The sample contained 85.6% water, 1% glycerine, 0.005% benzophenone-4, 1% PEG-1450, 0.5% salicylic acid, 10% ethanol, 0.1% benzoic acid, 0.35% sodium citrate, 0.044% FD&C blue #1 (0.1% solution), 0.112% FD&C yellow #10 (0.1% solution), 0.1% menthyl lactate, 0.2% fragrance, 0.1% vitamin E acetate, and 0.9% Solubilisant LRI. The formulation was one phase and was clear. After 5 weeks storage, the samples at 4°C, 25°C, 40°C, and 50°C remained clear.

Example 6 – Comparison of Solubilizers

The following samples were made following the procedure of Example 4:

<u>Ingredient</u>	<u>Sample Number</u>		
	<u>20</u>	<u>21</u>	<u>22</u>
Water	85.7	85.6	80.6
Glycerine	1	1	1
Benzophenone-4	0.005	0.005	0.005
PEG 1450	1	1	1
Salicylic Acid	0.5	0.5	0.5
Ethanol	10	10	15
Benzoic Acid	0.1	0.1	0.1
Sodium Citrate	0.35	0.35	0.35
FD&C blue #1 (0.1% solution)	0.023	0.023	0.023
FD&C yellow #10 (0.1% solution)	0.058	0.058	0.058
Menthyl Lactate	0.1	0.1	0.1
Fragrance	0.2	0.2	0.2
Arlasolve 200	0.9	0.9	0.9

Vitamin E Acetate	0.1	0.1	0.1
Panthenol (70% active)	0	0.071	0.05*

* = used Panthenol powder instead of 70% active liquid

Samples 20, 21, and 22 were clear, and samples 20 and 21 were stored for accelerated aging studies. The results were as follows: After 4 and ½ weeks of storage, samples 20 and 21 were clear at room temperature, 4°C, 40°C, and 50°C. Samples 20 and 21 were both clear after three freeze/thaw cycles.

<u>Ingredient</u>	<u>Sample Number</u>	
	<u>23</u>	<u>24</u>
Water	81	81
Glycerine	0.5	0.5
Benzophenone-4	0.005	0.005
PEG 1450	1	1
Salicylic Acid	0.5	0.5
Ethanol	15	15
Benzoic Acid	0.1	0.1
Sodium Citrate	0.35	0.35
FD&C blue #1 (0.1% solution)	0.014	0.023
FD&C yellow #10 (0.1% solution)	0.035	0.058
Menthyl Lactate	0.1	0.1
Fragrance	0.2	0.2
Arlasolve 200	0.9	0
Vitamin E Acetate	0.1	0.1
Panthenol (powder)	0.05	0.05
Tween 20	0	0.9
Actiphyte Of Aloe	0.05	0.05
Cetiol HE	0.1	0

Sample 23 was clear, therefore accelerated aging studies were run on it. The results were as follows: After 8 weeks of storage, sample 23 was clear at room temperature, 4°C, 40°C, and 50°C, and after 3 freeze/thaw cycles.

Sample 24 was opaque, therefore no accelerated aging studies were run on it.

Example 7 – Addition Of Dimethicone Containing Compounds

Sub-samples from sample 22 were taken and tested for compatibility with dimethicone containing compounds. The samples were prepared to see if the cleansing properties of the formulation would improve upon the addition of dimethicone containing compounds. The samples were prepared by adding the silicone containing compound to the sub-sample and mixing. The following samples were prepared:

<u>Ingredient</u>	<u>Sample Number</u>					
	<u>25</u>	<u>26</u>	<u>27</u>	<u>28</u>	<u>29</u>	<u>30</u>
Sample 22 (sub-sample)	99.9	99.9	99.5	99.995	99.9	98.75
Abil B 8832	0.1	0	0	0	0	0
Abil B 8843	0	0.1	0.5	0	0	0
Polymer JR 400	0	0	0	0.005	0	0
Abil B 9950	0	0	0	0	0.1	0
Glycolic Acid	0	0	0	0	0	1
Sodium Citrate	0	0	0	0	0	0.25

Sample 25 was cloudy. Sample 27 was slightly hazy. Samples 26, 28 and 29 were clear. Some of the samples were applied to the arm of a person. The skin did not feel noticeably different after cleansing with these samples than when cleansed with sample 22. Accelerated aging studies were not performed on these samples. It was later determined experimentally that the dimethicone containing compound goes into solution best when added to the salicylic acid pre-mix, just after the addition of ethanol.

Example 8 – Adjusting Menthyl Lactate and Fragrance Levels

A set of samples was prepared to optimize the levels of menthyl lactate and fragrance in the formulation. The samples were prepared by making a pre-mix of Carbowax PEG-1450, Arlasolve 200, salicylic acid, vitamin E acetate, Cetiol HE, benzoic acid, Frescolat MR, ethanol, and fragrance; and a main batch of water, glycerine, Univul MS-40, sodium citrate, FD&C blue #1 (0.1% solution), FD&C yellow #10 (0.1% solution), Ritapan DL, and Actiphyte of Aloe Vera; then combining the main batch and the pre-mix. The following samples were prepared:

<u>Ingredient</u>	<u>Sample Number</u>			
	<u>31</u>	<u>32</u>	<u>33</u>	<u>34</u>
Water	80.96	80.96	80.96	80.96
Glycerine	0.5	0.5	0.5	0.5
Univul MS-40	0.005	0.005	0.005	0.005
Sodium citrate	0.35	0.35	0.35	0.35
FD&C blue #1 (0.1% solution)	0.023	0.023	0.023	0.023
FD&C yellow #10 (0.1% solution)	0.059	0.059	0.059	0.059
Ritapan DL	0.05	0.05	0.05	0.05
Actiphyte of Aloe Vera	0.05	0.05	0.05	0.05
Carbowax PEG-1450	1	1	1	1
Arlasolve 200	0.9	0.9	0.9	0.9
Salicylic acid	0.5	0.5	0.5	0.5
Vitamin E acetate	0.1	0.1	0.1	0.1
Cetiol HE	0.1	0.1	0.1	0.1
Benzoic acid	0.1	0.1	0.1	0.1
Frescolat MR	0.1	0.1	0.075	0.075
Ethanol	15	15	15	15
Fragrance	0.2	0.15	0.15	0.1

Samples were stored at room temperature, 4°C, 40°C, and 50°C and checked for smell. Over time, no change in smell was detected for any sample, except at 50°C, where all 4 samples had a slight alcohol odor. After three freeze/thaw cycles, no change in smell was detected for any sample, except for sample 33, where a slight alcohol odor was noticed after two and three cycles.

Example 9 – The Effect Of Varying PEG and pH

The following samples were prepared to compare the effect of different molecular weight PEGs. Sub-samples were pH adjusted to determine the effect of pH on the stability of the samples.

<u>Ingredient</u>	<u>Sample Number</u>	
	<u>35</u>	<u>36</u>
Water	74.2	80.49
Versene NA	0.1	0.1
Glycerine	0.5	0.5
Univul MS-40	0.005	0.005

Ritapan DL	0.05	0.05
Actiphyte of Aloe Vera	0.05	0.05
Carbowax PEG-1450	0	1
Carbowax PEG-3350	1	0
Arlasolve 200	0.9	0.9
Salicylic acid	0.5	0.5
Vitamin E acetate	0.1	0.1
Cetiol HE	0.1	0.1
Frescolat MR	0.1	0.1
Ethanol	15	15
Abil B 9950	0.05	0.05
Fragrance	0.15	0.15
Sodium citrate (25% solution)	0.20	0.34

Samples 35 and 36 were tested for accelerated aging. Sub-samples of samples 35 and 36 were pH adjusted using sodium citrate. Three samples were prepared for sample 35: one at pH 3.23, one at pH 3.62, and one at pH 3.91. Two samples were prepared for sample 36: one at pH 3.63 and one at pH 3.89. The pH adjusted samples were also tested for accelerated aging.

After 5 weeks storage, sample 35 at pH 3.23 was slightly hazy at room temperature, but clear at 4°C, 40°C, and 50°C. Sample 35 at pH 3.62 was clear at room temperature, 4°C, 40°C, and 50°C. Sample 35 at pH 3.91 was clear at room temperature and at 50°C, but cloudy/opaque at 4°C and 40°C. The results of the freeze thaw studies were: at pH 3.23, crystals precipitated out after the 2nd cycle, at pH 3.63 the sample was clear after 3 cycles, and at pH 3.91, the sample was cloudy/opaque after each cycle.

After 5 weeks storage, sample 36 at pH 3.63 was clear at room temperature, 4°C, 40°C, and 50°C. Sample 36 at pH 3.89 was cloudy/opaque at room temperature, hazy at 40°C, and clear at 50°C. The freeze/thaw results were as follows: for pH 3.63, the sample was clear after 3 cycles, for pH 3.89, the sample was hazy after cycles 1 and 2, and cloudy/opaque after cycle 3.

Both the molecular weight of the PEG and the pH of the sample had an effect on the physical stability of the formulation.

We Claim:

1. A skin cleansing composition comprising:
from about 0.1 to about 5 percent by weight of at least one anti-acne active ingredient;
from about 1 to about 25 percent by weight of at least one alcohol;
from about 0.1 to about 15 percent by weight of at least one solubilizer; and
water.
2. The skin cleansing composition according to claim 1, wherein the anti-acne agent is selected from the group consisting of salicylic acid, sulfur, lactic acid, glycolic acid, pyruvic acid, urea, resorcinol, N-acetylcysteine, retinoic acid, benzoyl peroxide, octopirox, triclosan, azelaic acid, phenoxyethanol, phenoxypropanol, flavinoids, derivatives thereof, and combinations thereof.
3. The skin cleansing composition according to claim 2, wherein the anti-acne agent is selected from the group consisting of salicylic acid, benzoyl peroxide, derivatives thereof, and combinations thereof.
4. The skin cleansing composition according to claim 1, wherein the solubilizer is selected from the group consisting of propylene glycol, butylene glycol, hexylene glycol, polyethylene glycol, polysorbate-20, polysorbate-40, isoceteth-15, isoceteth-20, isoceteth-30, sorbeth-20, sorbeth-40, PEG-40 castor oil, polypropylene glycol-5 ceteth 20, and combinations thereof.
5. The skin cleansing composition according to claim 4, wherein the solubilizer is selected from the group consisting of polyethylene glycol, PEG-40 castor oil, polypropylene glycol-5 ceteth 20, and combinations thereof.

6. The skin cleansing composition according to claim 5, wherein the solubilizer is a polyethylene glycol containing from about 20 to about 40 repeating ethylene glycol units.
7. The skin cleansing composition according to claim 6, wherein the polyethylene glycol contains 32 repeating units.
8. The skin cleansing composition according to claim 7, wherein the alcohol is ethanol.
9. The skin cleansing composition according to claim 8, wherein the anti-acne agent is salicylic acid.
10. The skin cleansing composition according to claim 8, wherein the amount of anti-acne agent is from about 0.5 to about 2 percent by weight.
11. The skin cleansing composition according to claim 9, wherein the amount of ethanol is from about 10 to about 20 percent by weight.
12. The skin cleansing composition according to claim 10, wherein the composition further comprises at least one emollient.