



(43) International Publication Date
17 October 2013 (17.10.2013)

(51) International Patent Classification:
A45D 44/22 (2006.01)

(21) International Application Number:
PCT/US2013/035913

(22) International Filing Date:
10 April 2013 (10.04.2013)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/623,466 12 April 2012 (12.04.2012) US

(71) Applicant: THE PROCTER & GAMBLE COMPANY
[US/US]; One Procter & Gamble Plaza, Cincinnati, OH
45202 (US).

(72) Inventors: GUAY, Gordon, Gerald; 40 Wight Avenue,
Hunt Valley, MD 21030 (US). WILSON, David, Edward;
40 Wight avenue, Hunt Valley, Maryland 21030 (US).

(74) Agent: GUFFEY, Timothy, B.; c/o The Procter & Gamble
Company, Global Patent Services, 299 East 6th Street, Sy-
camore Building, 4th Floor, Cincinnati, OH 45202 (US).

(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,

AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY,
BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM,
DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,
HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KN, KP,
KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD,
ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI,
NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU,
RW, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ,
TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA,
ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ,
UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ,
TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK,
EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM,
TR), OAPI (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 (Rule 48.2(g))

(54) Title: SKIN EXFOLIATION DEVICES AND KITS

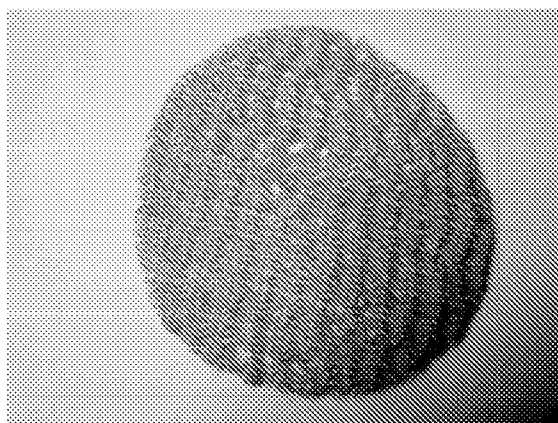


Fig. 1A

(57) Abstract: A hand held exfoliation device suitable for repeated use on a facial skin surface is provided. The exfoliation device includes a body and an exfoliating material attached thereto that is sized for application to a facial skin surface. The exfoliating material includes a substrate and an exfoliating surface. The exfoliating surface is formed from a plurality of particles, wherein the plurality of particles are attached to the substrate to form peaks and valleys thereon. The exfoliating material has a surface roughness S_a from about 2 μm to about 16 μm and the particles have an average Mohs hardness from about 4 to about 8.



SKIN EXFOLIATION DEVICES AND KITS

TECHNICAL FIELD

Skin exfoliation devices are provided along with methods and kits related thereto.

5

BACKGROUND

The process of removing dead skin cells, often referred to as exfoliation, has been practiced for a long time. Exfoliation can be accomplished by a variety of means. Mechanical exfoliation typically involves the physical removal of skin cells by an abrasive. In some instances, abrasive particles may be incorporated into a composition that is rubbed on the skin. In other instances, a mechanical device may be used to scrub the skin. Some examples of various types of exfoliation means are described, for example, in USPNs 7,255,704; 7,297,668; 6,563,012 and 6,391,863 and U.S. Publication Nos. 2007/0281033 and 2007/0264224.

Exfoliation is purported to provide a number of benefits including, removing dull, dry skin cells to reveal smoother and/or softer skin; simulating cell renewal and turnover rates; and facilitating hydration and absorption of materials. While one or more of these benefits may be realized by exfoliation, it is possible to over exfoliate resulting in skin irritation and/or a drying of the skin. In addition, facial skin surfaces may be more susceptible to over exfoliation, as facial skin may be particularly sensitive compared to some other skin surfaces. A particular challenge associated with exfoliation is providing a means for sufficiently exfoliating facial skin surfaces without inducing irritation whilst providing enough exfoliation to improve the penetration of cosmetic skin care agents, such as vitamins, peptides, retinoid compounds, botanicals, etc. in order to deliver an enhanced skin care benefit. Some examples of cosmetic skin care benefits include treating fine lines and wrinkles (particularly in the periorbital area (e.g., to treat crow's feet) and the forehead), treating age spots and hyper pigmentation, and improving the hydration status or barrier properties of facial skin.

While various skin exfoliation means and benefits are known, there is a continuing desire to provide improved exfoliation devices, methods and kits relating thereto that are suitable for use on facial skin surfaces. There is also a continuing desire to provide improved exfoliation devices and methods relating thereto which are relatively simple to manufacture and can provide effective exfoliation without inducing substantial redness or irritation, particularly on sensitive facial skin. Further, there is a continuing desire to provide improved exfoliation devices, methods and kits relating thereto that, additionally, enhance the penetration of cosmetic skin care

agents into skin surfaces. Still further, there is a continuing desire to provide improved exfoliation devices, methods and kits relating thereto that are effective and may be used across a range of consumer habits and practices (e.g., applied pressure and/or number of strokes).

5

SUMMARY

In order to provide a solution to the problems above, a hand-held exfoliation device is provided. The exfoliation device comprises a body and an exfoliating material attached thereto that is sized for application to a facial skin surface. The exfoliating material comprises a substrate and an exfoliating surface. The exfoliating surface is formed from a plurality of particles, wherein the plurality of particles are attached to the substrate to form peaks and valleys thereon. The exfoliating material has a surface roughness S_a from about 2 μm to about 16 μm and the particles have an average Mohs hardness from about 4 to about 8.

BRIEF DESCRIPTION OF THE DRAWINGS

15

While the specification concludes with claims, it is believed that the same will be better understood from the following description taken in conjunction with the accompanying drawings in which:

FIG. 1A is a photograph of an abrasive material;

FIG. 1B is an Optical Coherence Tomography image of the abrasive material of FIG. 1A;

20

FIG. 1C is an Scanning Electron Microscopy (SEM) image of the abrasive material of FIG. 1A at 130X magnification;

FIG. 2A is a photograph of an abrasive material;

FIG. 2B is an SEM image of the abrasive material of FIG. 2A at 130X magnification;

FIG. 2C is an OCT image of the abrasive material of FIG. 2A;

25

FIG. 3A is a photograph of an abrasive material;

FIG. 3B is an SEM image of the abrasive material of FIG. 3A at 100X magnification;

FIG. 3C is an OCT image of the abrasive material of FIG. 3A;

FIG. 4A is a photograph of an abrasive material;

FIG. 4B is a OCT image of the abrasive material of FIG. 4A;

30

FIG. 5 is a SEM image of a portion of the surface of the abrasive material of FIG. 4A at 50X magnification;

FIG. 6 is an SEM image of a formation of particles of the material shown in FIG. 5 at a 500X magnification;

FIG. 7 is a SEM image of the formation of particles shown in FIG. 6 at 800X magnification;

FIG. 8 is a SEM image of a random distribution of particles shown in FIG. 4A at 10,000X magnification;

FIG. 9 is perspective view of an exfoliation device;

5 FIG. 10 is a cross-sectional side view of the exfoliation device of FIG. 9, taken along line A-A thereof;

FIG. 11 is a perspective view of an embodiment of an exfoliation device comprising a rounded exfoliating surface;

10 FIG. 12 is a perspective view of an embodiment of an exfoliation device comprising a strap for attaching the exfoliation device to a finger; and

FIG. 13 is a perspective view of an embodiment of an exfoliation device comprising a hollow cylinder into which one or more fingers may be inserted.

DETAILED DESCRIPTION

15 “Cosmetic skin care composition” means a composition suitable for topical application to mammalian skin, which is intended to improve the condition and/or appearance of the skin or otherwise provide a skin care benefit. Some non-limiting examples of skin care benefits include improving skin appearance and/or feel by providing a smoother, more even appearance and/or
20 feel; increasing the thickness of one or more layers of the skin; improving the elasticity or resiliency of the skin; improving the firmness of the skin; reducing the oily, shiny, and/or dull appearance of skin, improving the hydration status or moisturization of the skin, improving the appearance of fine lines and/or wrinkles, improving skin texture or smoothness, improving skin exfoliation or desquamation, plumping the skin, improving skin barrier properties, improving skin tone, and/or improving the brightness, radiancy, or translucency of skin. Some non-limiting
25 examples of cosmetic skin care compositions include skin creams, moisturizers, lotions, and products that leave color on the face, such as foundations and concealers.

“Dermatologically acceptable carrier” means any carrier that may be applied topically to skin tissue. The dermatologically acceptable carrier may be provided by a wide variety of materials and/or in a wide variety of forms including, but not limited to, simple solutions (e.g.,
30 water-based or oil-based), solid forms (e.g., gels or sticks) and emulsions (e.g., water-in-oil or oil-in-water).

“Non-porous” means a material, substrate or surface that: i) lacks passageways that permit a liquid from passing from one side of the material to the other side of the material, and/or

ii) does not absorb an appreciable amount of water over a one hour period of time at standard ambient temperature and pressure. In some embodiments, an appreciable amount of water is an amount greater than 5% by weight of the material, substrate, or surface.

“Surface roughness” refers to the 3D areal roughness of a surface and may be quantified by the parameters S_a , S_q , S_t , S_{tm} , etc., which are known in the art and defined in ISO 25178, the substance of which is incorporated herein by reference in its entirety. For example, S_a refers to the arithmetical mean height over a 3D surface. S_q refers to the RMS height over a 3D surface. S_t refers to maximum height difference between the highest and the lowest points on the profile, and S_{tm} refers to average of the S_t values (maximum height differences between the highest and lowest heights).

“Topical” and variations thereof refer to compositions that are intended to be applied directly to the outer surface of skin tissue.

Described hereafter are various embodiments of exfoliation devices and cosmetic skin care compositions suitable for use on facial skin. In some embodiments, the exfoliation device can provide a sufficient level of exfoliation adequate to enhance penetration of a cosmetic skin care agent of the skin care composition while still providing an aesthetically pleasing feel. Preferably, the exfoliation devices can provide these benefits even when used daily.

I. SURFACE CHARACTERISTICS OF SOME ABRASIVE MATERIALS

A wide variety of abrasive materials are known in the art. However, much is still not understood regarding the surface characteristics affecting both the aesthetics and the level of exfoliation provided by a material, particularly when utilized according to typical consumer practices. Four materials were investigated, including two materials formed from a plurality of fibers and two materials comprising abrasive particles bonded to a substrate. Referring to FIGS. 1, 2, 3 and 4, photographic images of the four tested materials are shown along with images generated by Optical Coherence Tomography (OCT) of the material surfaces. Material #1 (FIGS. 1A, 1B, and 1C) is a porous, nylon woven mesh formed by a plurality of fibers. The individual fibers appear to range in thickness from about 0.05 mm to about 0.08 mm. Material #2 (FIGS. 2A, 2B, and 2C) is a non-porous, sandpaper-like material comprising abrasive particles formed from diamond embedded in a binder on a thin polyethylene terephthalate (PET) film. Material #3 (FIGS. 3A, 3B and 3C) is a non-woven, porous cloth available under the tradename Exfolia from Beauty Cloth, Inc.. Material #4 (FIGS. 4A and 4B) is a non-porous, film

substrate to which are bonded cerium oxide particles. The cerium oxide particles have an average size of from about 0.25 microns to about 1 micron.

Example 1, which is described in more detail below, sets forth a methodology suitable for measuring surface roughness of a material. Surface roughness of a material may be characterized using an interferometric measurement device that utilizes light to measure a variety of surface area roughness parameters such as S_a , S_t , and S_{tm} . One such device is the DermaTop-Blue device available from Breuckmann GmbH (Germany), which utilizes a narrow-band, blue light source. Other test methods and devices may also be employed, as known in the art, to measure surface roughness parameters according to ISO 25178. Table 1 sets forth a summary of the average surface roughness values (in microns) measured for Materials #1 to #4.

TABLE 1

Material	S_a	S_q	S_t	S_{tm}
#1	187	253	3918	1491
#2	19	23	167	130
#3	19	24	178	113
#4	10	11	60	48

As illustrated in Table 1, Material #1 had the highest surface roughness values, while Material #4 had the lowest values.

15 II. IN VIVO TESTING

Referring to Example 2 below, Materials #1 to #4 were tested in vivo and the amount of protein removed by use of the materials was measured using a protein quantification assay. Protein removal is believed to be a proxy for measuring the amount of exfoliation achieved by a material. Protein quantification assays utilize a fluorogenic reaction between proteins and a reducing reagent to quantify the amount of proteins in the sample. The users applied small samples of the abrasive materials to dry forearm skin (e.g., without prior application of a skin care composition, which can act as a lubricant) by applying five strokes of the material over a two inch area of the forearm skin, after which the residual skin on the material surface was harvested and quantified using the protein quantification assay. In addition, comments were collected from the users about the skin feel of the abrasive materials.

The results from the in vivo testing of the four materials, including both the protein quantification values and an example of the user comments are summarized in Table 2 below.

TABLE 2

Material	Protein Removed ($\mu\text{g/ml}$)	Some User Comments
Material #1	247	Very rough
Material #2	120	Scratchy
Material #3	129	Very soft
Material #4	256	Excellent feel, abrasive yet soft

5 Surprisingly, while Materials #2 and #4 were both formed from abrasive particles bonded to a substrate, the user perception of the materials was quite different. While not intending to be bound by theory, the difference in user perception could be due to the higher surface roughness of Material #2 (see, e.g., Table 1) and/or a difference in the hardness and/or shape of the abrasive particles. Material #2 contained amorphous diamond particles, which have a Mohs hardness of 10, in contrast to Material #4 which contained cerium oxide particles, which have a Mohs hardness of 6. The lower surface roughness values and/or particle hardness of Material #4 appear to produce a more pleasing aesthetic benefit when rubbed against skin. Without intending to be bound by any theory, the disparate protein removal results between Material #2 and #4 might be explained by potential user self regulation, which may occur in instances where a user adjusts the amount of force applied to the exfoliating material to account for differences in material feel. 15 Notably, Material #4 also had the greatest amount of protein removal, followed closely by Material #1, despite the observed differences in surface roughness. Interestingly, the amount of protein removal by Material #4 was more than double that of Material #2 and almost double that of Material #3 despite Materials #2 and #3 having higher surface roughness values. With regard to Material #3, while it also had higher surface roughness values than Material #4, the higher surface roughness was apparently not sufficient to overcome the inherent flexibility provided by the fiber construction and this might have contributed to the lower protein removal value compared to Material #4. 20

III. IN VITRO PENETRATION OF SKIN CARE AGENTS

While Materials #1 and #4 may provide superior protein removal compared to Materials #2 and #3, this does not necessarily quantify the impact that this level of exfoliation may have on skin penetration of cosmetics agents. For example, the depth of localized protein removal and/or the amount of surface area removed can impact the amount of skin penetration of a cosmetic agent even though the total removed protein is about the same. Referring to Example 3, which is described in more detail below, samples of Materials #1 and #4 were also tested in vitro using human cadaver skin to assess the penetration of radio-labeled niacinamide into the skin following application of the abrasive materials. Penetration of the radio labeled niacinamide into the cadaver skin was assessed using a Franz diffusion cell system, which is a well known device in the art for measuring skin penetration of compounds. The abrasive materials were applied to the cadaver skin for 10 strokes (5 strokes in one direction and 5 strokes in reverse) using 50, 100, and 200 grams of force, which is within the range believed to be customary for consumer habits and practices, as discussed in Example 4 below. Table 3 summarizes the total percentage dose of niacinamide recovered from the epidermis, dermis, and the Franz cell receptor, twenty-four hours after application of Material #1 to six cadaver skin replicates, and the total percentage dose recovered for an untreated (i.e., not abraded) control tissue sample.

TABLE 3

Material #1	Control	50 grams	100 grams	200 grams
Sample #1	70.31	73.87	99.42	98.65
Sample #2	45.79	92.72	85.32	92.88
Sample #3	71.50	65.56	82.75	95.98
Sample #4	78.66	99.52	96.62	98.57
Sample #5		74.62	91.19	96.71
Sample #6		74.19	54.95	88.59
Avg	66.57	80.08	85.04	95.23
Stdv	14.33	13.05	16.06	3.88
p-value		0.160	0.100	0.0013

Table 4 summarizes the total percentage dose of niacinamide recovered from the epidermis, dermis, and the Franz cell receptor, twenty-four hours after application of Material #4 to six cadaver skin replicates, and the total percentage dose recovered for an untreated (i.e., not abraded) control tissue sample. While Material #4 did not perform quite as well as Material #1, it provided a more consistent level of skin penetration enhancement across the applied forces while importantly providing a more aesthetically pleasing skin feel in vivo than Material #1.

TABLE 4

Material #4	Control	50 grams	100 grams	200 grams
Sample #1	70.31	89.00	73.81	67.51
Sample #2	45.79	83.95	76.91	85.23
Sample #3	71.50	82.22	65.07	71.73
Sample #4	78.66	52.17	94.36	71.46
Sample #5		48.24	91.05	94.21
Sample #6		91.87	69.23	90.40
Avg	66.57	74.58	78.40	80.09
Stdv	14.33	19.23	11.83	11.27
p-value		0.499	0.190	0.132

Abrasion of the cadaver skin samples by Materials #1 and #4 increased the total average percentage dose of niacinamide recovered across applied forces compared to the untreated control. Skin samples abraded by Material #1 exhibited more niacinamide penetration than observed for skin samples abraded by Material #4.

The amount of protein removed by the abrasive materials from the cadaver skin samples was also quantified for three of the replicates using a protein quantification assay. Tables 5 and 6 set forth the quantity of protein measured.

TABLE 5

Material #1 Samples	Protein removed (mg/ml) 50 grams	Protein removed (mg/ml) 100 grams	Protein removed (mg/ml) 200 grams
1	171	217	243
2	176	209	245
3	172	207	234
Avg	173	211	241
Stdv	3.0	5.0	6.0

TABLE 6

Material #4 Samples	Protein removed (mg/ml) 50 grams	Protein removed (mg/ml) 100 grams	Protein removed (mg/ml) 200 grams
1	140	176	153
2	141	174	148
3	142	180	149
Avg	141	177	150
Stdv	1.0	3.0	2.0

- 5 The niacinamide recovery data of Tables 3 and 4 appear consistent with protein recovery data of Tables 5 and 6, wherein both the average niacinamide and protein recoveries for skin samples abraded by Material #4 showed a less pronounced increase with increasing force compared to skin samples abraded by Material #1.

IV. EXFOLIATING MATERIALS

From a review of the data in Tables 1 and 2, it appears there is a co-dependent interplay between material feel, material properties, and the amount of exfoliation produced in vivo. First with respect to fibrous Materials #1 and #3, Material #1 provided the best protein removal but had a negative aesthetic feel compared to Material #3. While Material #3 had a pleasing aesthetic feel, it did not provide the best protein removal in vivo. Thus, while these materials might be used for facial skin exfoliation, they did not provide the best combination of attributes. Comparing Materials #2 and #4, Material #2 provided neither the best protein removal nor the best aesthetic skin feel. As between all the tested materials, Material #4 provided the best combination of aesthetic skin feel and in vivo protein removal.

Comparing Tables 1 and 2, it appears that surface roughness alone does not characterize the exfoliation capability of Materials #2 and #4, as Material #2, which had the higher surface roughness values, provided a lower protein removal value in vivo compared to Material #4, contrary to what might have been intuitively expected beforehand. In contrast, Material #4, which had the lowest lower surface roughness values of all four materials generated the greatest amount of protein removal in vivo (Table 3). It is believed that, in instances where an exfoliating material comprises particles on a substrate, particle/material hardness in combination with surface roughness may be co-dependent properties affecting aesthetic feel and the level of skin exfoliation. As described above, Material #2 is formed from amorphous diamond particles (Mohs hardness = 10) compared to Material #4 which is formed from cerium oxide particles (Mohs hardness = 6). It is believed that the harder particles of Material #2 contributed to, at least in part, user self regulation that effectively limited the amount of exfoliation provided by Material #2 in vivo.

In order to provide exfoliation that quantitatively enhances penetration of a skin care agent while providing a pleasing aesthetic feel, it is believed that exfoliating materials comprising a substrate and particles having certain properties may be particularly useful in some instances. In some embodiments, these exfoliating materials have one or more of an arithmetical mean height of the surface (S_a) greater than 2, 4, 6, 8, 10 μm and/or less than 16, 14, 12, or 10 μm ; and/or a root mean square height of the surface (S_q) greater than 2, 4, 6, 8, 10 μm and/or less than 16, 14, 12, or 10 μm ; and/or a maximum height difference between the highest and the lowest points on the profile (S_t) greater than 20, 40, 60 μm and/or less than 140, 120, 100, or 80 μm ; and/or an S_{tm} value greater than 20, 40, or 60 μm and/or less than 100, 80, or 60 μm .

In some embodiments, the particles have an average Mohs hardness greater than 4, 5, 6, or 7 and/or less than 8, 7, or 6. Mohs hardness is an ordinal scale (1 to 10) that measures mineral hardness based on the ability of one mineral to scratch another. Talc is an example of a mineral with the lowest Mohs hardness (designated as 1), and a diamond has a Mohs hardness of 10 since it is one of the hardest minerals. The exfoliating material may also contain a mixture of a plurality of different particles (e.g., cerium oxide and diamond) having different Mohs hardness values. Some of the particles may have Mohs hardness values above and/or below what is described herein. If a mixture of particles is used, the average Mohs hardness of the combination of particles may be approximated by a weighted average based on the particle concentrations attached to or deposited on the substrate.

In some embodiments, the exfoliating material is non-porous (meaning both the exfoliating surface and the substrate are non-porous). In some embodiments, only the surface of the exfoliating material that is used to exfoliate the skin is non-porous, but the substrate may be porous. For example, the substrate may be provided as a porous woven or non-woven while the exfoliating surface formed by the binder and plurality of particles is non-porous and/or a solid surface. In some embodiments, the exfoliating surface is porous and the substrate is non-porous. In some embodiments, the exfoliating surface and/or substrate and/or the exfoliating material are devoid of fibers. In some embodiments, the exfoliating material, exfoliating surface, and/or substrate are provided in a flexible form to facilitate attachment to complex geometries of an exfoliation device.

A wide variety of rough materials comprising particles are suitable for use with the exfoliating devices described herein. While Material #4 is described herein as one example, it will be appreciated that other materials are equally suitable and are described herein. Referring to FIGS. 5 to 8, scanning electron microscopy images from a sample of Material #4 are shown at various magnifications. FIG. 5 shows a portion of the material at 50X magnification, while FIG. 6 shows a portion of the surface at 500X magnification. FIG. 7 is an 800X magnification of an agglomeration of particles on the material surface. FIG. 8 is a 10,000X magnification of a portion of the material surface. The material comprises irregularly shaped cerium oxide particles bonded to a substrate by an epoxy resin. Some of the particles are agglomerated into larger formations, one of which is shown in FIG. 7. The larger formations may have a size greater than 75 microns or from about 75 microns to about 150 microns. In some embodiments, there may be from about 1000 to about 50,000 agglomerated formations per 1 mm² of material surface area.

Some of the particles may range in size from 0.25 microns to about 1 micron. In some embodiments, a majority of the particles may range in size from 0.25 microns to about 1 micron.

While Material #4 comprises cerium oxide particles, other abrasive particles such as other oxides, diamonds, zirconium alumina, silicon carbide, garnet, emery, cubic boron nitride, nut shells, and combinations thereof may be substituted in whole or part. In addition, the particles may be solid, hollow, irregularly shaped or have a more defined geometrical shape (e.g., trapezoidal, spherical, etc.) than shown in the FIGS. 5 to 8. The abrasive particles may be randomly distributed or provided in a regular/repeating pattern. The abrasive particles may or may not be agglomerated into larger formations as shown by way of example in FIG. 7. In addition, at least some of the abrasive particles may have a particle size smaller than 0.25 or greater than 1 micron.

The abrasive particles may be cast, molded or otherwise attached to a substrate using a binder or adherent, as known in the art, thereby forming an exfoliating surface comprising peaks and valleys. Some methods which may be suitable for forming the exfoliating materials herein are described, for example, in USPNs 8,038,751; 7,947,097; 7,993,420; 7,811,342; 8,062,394; and U.S. Publication No. 2011/0162287. Some examples of binders which may be suitable for use include epoxy resins, polyester resins, acrylonitrile, cyanoacrylate, resorcinol, polysulfides, polypropylene, silicone, polyvinyl pyrrolidone, and polystyrene cement/butanone. Binders may be heat curing (e.g., epoxies, urethanes and polyimides), moisture curing (e.g., cyanoacrylate, urethanes) or thermosetting (e.g., epoxy, urethanes, cyanoacrylates and acrylic polymers). In some embodiments, the substrate may be a film formed from a polymer or mixture of polymers, paper, fabric, nonwovens, and combinations thereof. Some polymers suitable for forming a film include polyester or polypropylene. In some embodiments, the substrate may have a thickness greater than 0.02, 0.04, or 0.06 mm and/or less than about 0.5, 0.4, 0.3, 0.2, or 0.1 mm. In some embodiments, the exfoliating material is thin, for example having an overall thickness from about 0.01 mm to about 0.1 mm or from about 0.02 mm to about 0.05 mm.

V. EXFOLIATING DEVICES

Referring to FIGS. 9 and 10, one embodiment of an exfoliation device will now be described. The exfoliation device 10 comprises a body 12 and a facial skin contacting surface 14 formed at least partially from an exfoliating material 16. The exfoliating material 16 may be attached to a portion of the body 12 by any suitable means known in the art, including by use of an adhesive. A portion of the body 12 can be provided in the form of a disc, although it will be

appreciated that a wide variety of shapes and sizes for the body 12 may be provided. The body 12 may further comprise an elongate handle 18, which in one embodiment may be directed upwardly away from the disc shaped portion of the body 12. The handle 18 may be sized to be comfortably grasped by a hand so that the exfoliating device 10 may be hand held during use.

5 The exfoliating material 16 may be provided in the form of a substantially flat, thin sheet. In some embodiments, the exfoliating material 16 has a surface area from about 5 mm² to about 100 mm² or from about 10 mm² to about 50 mm², so as to provide a surface suitable for engaging a variety of facial skin surfaces. The exfoliating material 16 may be provided in a wide variety of shapes, circular being shown as one example in FIGS. 9 and 10.

10 Referring to FIG. 11, another embodiment of an exfoliating device is shown. The exfoliating device 100 comprises a body 120 and a three dimensional facial skin contacting surface 140 (as opposed to the substantially flat or planar contacting surface 14 illustrated in FIGS. 9 and 10). The facial skin contacting surface 140 may be provided in a partially rounded, cylindrical, or hemispherical shape. At least a portion of the facial skin contacting surface 140
15 has a plurality of abrasive particles 144 attached thereto to form peaks and valleys. In some embodiments, the facial skin contacting surface 140 comprises a flexible and/or resilient material such as, for example, a foam material. The abrasive particles 144 may be applied to at least a portion of the facial skin contacting surface 140 using a variety of processes. In one method, an adhesive, such as a cyanoacrylate glue, may be applied to the substrate and the abrasive particles
20 144 may be electrostatically deposited onto the surface. The exfoliating material properties may be varied by controlling the abrasive particles 144 sizes (e.g., via sieving), the electrostatic charge and/or the deposition time. In some embodiments, the abrasive particles 144 may be cerium oxide. In other embodiments, a 3D exfoliating surface may be provided by adhering a flexible exfoliating material to a 3D surface, such as the surface 140 shown in FIG. 11.

25 Referring to FIG. 12, yet another embodiment of an exfoliating device 200 is shown. The exfoliating device 200 comprises a body 220 and a facial skin contacting surface 240. The exfoliating device 200 is the same as the exfoliating device 10 shown in FIGS. 9 and 10, except that the handle 18 is replaced by one or more flexible straps 218 thru which a user may insert one or more fingers to retain the exfoliating device 200 about the finger(s) during use.

30 In yet another embodiment, the exfoliating device 300 may be provided in the form of a hollow cylinder or tube (FIG. 13) into which at least one finger may be inserted. The hollow

cylinder may be closed at one end 310 and have an opening 312 at the opposite end. An exfoliating material 314 may be attached to or otherwise formed adjacent the end 310.

The exfoliating devices may be formed from a wide variety of materials according to any appropriate forming process, as known in the art. For example, in some embodiments, all or a portion of the exfoliating device may be formed from a polymeric material by injection molding. The exfoliating devices may or may not include an electrical power source (such as a battery) and/or an electric motor for moving the exfoliating material. In some embodiments, however, the exfoliating material may provide sufficient exfoliation without the need for an electric motor, for example, through manual movement by a user. While exfoliating devices 10, 100, 200 and 300 have been described as some examples suitable for use with the exfoliating materials and surfaces described herein, it will be appreciated that other exfoliating devices may be equally well suited for use with these materials and surfaces.

VI. COSMETIC SKIN CARE COMPOSITIONS

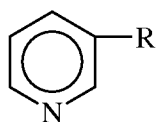
The exfoliating devices described herein may be used in combination with one or more cosmetic skin care compositions suitable for topical application to a facial skin surface. The cosmetic skin care composition may comprise one or more cosmetics agents and a dermatologically acceptable carrier.

The cosmetic skin agents may be any agent that provides an efficacious and/or consumer desirable skin benefit. A wide variety of cosmetic agents may be included in the cosmetic skin care compositions, as known in the art. Some suitable agents may include, but are not limited to, sugar amines, vitamins, oil control agents, moisturizers, photosterols, hexamidine compounds, skin tightening agents, anti-wrinkle agents, flavonoids, hydroxyl acids, N-acyl amino acid compounds, retinoids, peptides, anti-cellulite agents, desquamation agents, anti-acne agents, anti-oxidants, radical scavengers, anti-inflammatory agents, skin lightening agents, botanical extracts, antimicrobials, antifungal agents, antibacterial agents, and combinations thereof. Examples of these materials are provided in U.S. Patent Publication Nos. 2007/0185038; 2006/0275237; 2004/0175347; and 2006/0263309. The cosmetic skin care composition may comprise from about 0.0001%, 0.001%, 0.01%, 0.05%, 0.1%, 0.5%, 1%, 2%, or 3% to about 30%, 25%, 20%, 15%, 10%, 7%, 5%, 3%, 2%, or 1%, by weight based on the weight of the composition, of one or more skin care agents.

Examples of sugar amines that are useful herein include glucosamine, N-acetyl glucosamine, mannosamine, N-acetyl mannosamine, galactosamine, N-acetyl galactosamine, their isomers (*e.g.*, stereoisomers), and their salts (*e.g.*, HCl salt).

“Vitamins” means vitamins, pro-vitamins, and their salts, isomers and derivatives. Non-limiting examples of suitable vitamins include: vitamin B compounds (including B1 compounds, B2 compounds, B3 compound, B5 compounds, such as panthenol or “pro-B5”, pantothenic acid, pantothenyl; B6 compounds, such as pyroxidine, pyridoxal, pyridoxamine; carnitine, thiamine, riboflavin); vitamin A compounds, and all natural and/or synthetic analogs of Vitamin A, including retinoids, retinol, retinyl acetate, retinyl palmitate, retinoic acid, retinaldehyde, retinyl propionate, carotenoids (pro-vitamin A), and other compounds which possess the biological activity of Vitamin A; vitamin D compounds; vitamin K compounds; vitamin E compounds, or tocopherol, including tocopherol sorbate, tocopherol acetate, tocopherol succinate, other esters of tocopherol and tocopheryl compounds; vitamin C compounds, including ascorbate, ascorbyl esters of fatty acids, and ascorbic acid derivatives, for example, ascorbyl phosphates such as magnesium ascorbyl phosphate and sodium ascorbyl phosphate, ascorbyl glucoside, and ascorbyl sorbate; and vitamin F compounds, such as saturated and/or unsaturated fatty acids.

In certain embodiments, the cosmetic skin care compositions may comprise a vitamin B3 compound. As used herein, “vitamin B3 compound” means a compound having the formula:



wherein R is - CONH₂ (*i.e.*, niacinamide), - COOH (*i.e.*, nicotinic acid) or - CH₂OH (*i.e.*, nicotinyl alcohol); derivatives thereof; and salts of any of the foregoing.

As used herein, “peptide” refers to peptides containing ten or fewer amino acids and their derivatives, isomers, and complexes with other species such as metal ions (*e.g.*, copper, zinc, manganese, magnesium, and the like). Peptide refers to both naturally occurring and synthesized peptides. Also useful herein are naturally occurring and commercially available compositions that contain peptides. The peptides may contain at least one basic amino acid (*e.g.*, histidine, lysine, arginine). Peptide derivatives useful herein include lipophilic derivatives such as palmitoyl derivatives. In one embodiment, the peptide is selected from palmitoyl-lys-thr-thr-lys-ser, palmitoyl-gly-his-lys, their derivatives, and combinations thereof.

Polyphenolic compounds include flavonoids such as those broadly disclosed in U.S. Patent Nos. 5,686,082. Exemplary flavonoids include one or more flavones, one or more isoflavones, one or more coumarins, one or more chromones, one or more dicoumarols, one or more chromanones, one or more chromanols, isomers (*e.g.*, *cis/trans* isomers) thereof, and mixtures thereof.

In certain embodiments, the cosmetic compositions herein may include one or more suitable dermatologically acceptable carriers. The carriers may be provided in a wide variety of forms. In some embodiments, the carrier comprises water and/or water miscible solvents. The carrier may be present at an amount of from 1% to 95% by weight, based on the weight of the composition (*e.g.*, from 1%, 3%, 5%, 10%, 15%, 20%, 25%, 30%, 35%, 40%, 45%, 50%, 55%, 60%, 65%, 70%, 75%, 80%, or 85% to 90%, 85%, 80%, 75%, 70%, 65%, 60%, 55%, 50%, 45%, 40%, 35%, 30%, 25%, 20%, 15%, 10%, or 5%). Suitable water miscible solvents include monohydric alcohols, dihydric alcohols, polyhydric alcohols, glycerol, glycols, polyalkylene glycols such as polyethylene glycol, and mixtures thereof. When the cosmetic composition is in the form of an emulsion, the water and/or water miscible solvents are typically associated with the aqueous phase of the emulsion.

The dermatologically acceptable carrier may also comprise one or more suitable oils. The oils may be volatile or nonvolatile oils. Volatile oils suitable for use herein may have a viscosity ranging from 0.5 to 5 centistokes (cSt) at 25°C. Volatile oils may be used to promote more rapid drying of the skin care composition after it is applied to skin. Nonvolatile oils may be included to provide emolliency and protective benefits to the skin. In certain embodiments, the cosmetic compositions may include one or more suitable silicone oils such as, for example, one or more polysiloxanes. Other silicone oils that may be suitable for use in the cosmetic compositions herein include cyclic silicones. In certain embodiments, hydrocarbon oils (*e.g.*, straight, branched, or cyclic alkanes and alkenes) may be included in the present cosmetic compositions. Other suitable oils include amides (*e.g.*, compounds having an amide functional group while being liquid at 25°C and insoluble in water) and ethers.

The dermatologically acceptable carrier may also comprise an emulsifier. An emulsifier may be desirable when the composition is provided in the form of an emulsion or if immiscible materials are being combined. The cosmetic compositions herein may include from 0.05%, 0.1%, 0.2%, 0.3%, 0.5%, or 1% to 20%, 10%, 5%, 3%, 2%, or 1% emulsifier. Emulsifiers may be nonionic, anionic or cationic. Linear or branched type silicone emulsifiers may also be used.

Emulsifiers also include emulsifying silicone elastomers. Suitable silicone elastomers may be in the powder form, or dispersed or solubilized in solvents such as volatile or nonvolatile silicones, or silicone compatible vehicles such as paraffinic hydrocarbons or esters. Silicone gums are another oil phase structuring agent. Another type of oily phase structuring agent includes
5 silicone waxes. Silicone waxes may be referred to as alkyl silicone waxes and are semi-solids or solids at room temperature.

Optionally, the cosmetic skin care composition may further comprise a sunscreen active. Sunscreen actives include both sunscreen agents and physical sunblocks. Sunscreen actives may be organic or inorganic. A wide variety of conventional sunscreen actives may be used. Sagarin,
10 et al., at Chapter VIII, pages 189 et seq., of *Cosmetics Science and Technology* (1972), discloses numerous suitable actives. The sunscreen active may be present at an amount of from 1% to 20%, or from 2% to 10% by weight based on the weight of the composition. Exact amounts may vary depending upon the sunscreen chosen and the desired Sun Protection Factor (SPF).

The skin care compositions may be generally prepared by conventional methods such as
15 known in the art of making compositions and topical compositions. Such methods typically involve mixing of ingredients in or more steps to a relatively uniform state, with or without heating, cooling, application of vacuum, and the like. Typically, emulsions are prepared by first mixing the aqueous phase materials separately from the fatty phase materials and then combining the two phases as appropriate to yield the desired continuous phase.

The cosmetic skin care composition may be provided in a package sized to store a
20 sufficient amount of the composition for a treatment period. The size, shape, and design of the package may vary widely. Certain package examples are described in USPNs D570,707; D391,162; D516,436; D535,191; D542,660; D547,193; D547,661; D558,591; D563,221; 2009/0017080; 2007/0205226; and 2007/0040306. In addition or alternatively, the exfoliating
25 devices described herein may be packaged as a kit with one or more cosmetic skin care compositions suitable for use on a facial skin surface with the exfoliating device.

VII. METHODS OF USE

The exfoliating devices disclosed herein may be applied to one or more facial skin
30 surfaces as part of a user's routine involving the application of one or more cosmetic skin care compositions thereto. Additionally or alternatively, the exfoliating devices and cosmetic skin care compositions herein may be used on an "as needed" basis. In some embodiments, the exfoliating device may be applied to the facial skin surface before application of one or more

cosmetic skin care compositions. In other embodiments, the cosmetic skin care composition may be applied to the facial skin surface using the exfoliating device. For example, the cosmetic skin care composition might be applied to the exfoliating material and then the exfoliating material and the cosmetic skin care composition might be simultaneously applied to the facial skin surface. In still other embodiments, the cosmetic skin care composition may be dispensed by the exfoliating device onto the facial skin surface during use. In some embodiments, particular areas of the facial skin may be identified as being in need of a skin care benefit that can be provided by topical application of a cosmetic skin care composition, and it is then desirable to apply an exfoliating device to the skin area in need of treatment in order to enhance penetration of a cosmetic agent in the cosmetic skin care composition.

In some embodiments, the exfoliating device may be applied to the facial skin surface at least once per day, twice per day, or three times per day for a period of 7, 14, 21, or 28 days or more. During each use, one or more facial skin surfaces may be exfoliated using the device, wherein the facial skin surface is subjected to a plurality of repetitive motions of the exfoliating device across the facial skin surface. In certain embodiments, the exfoliating device may be applied to the facial skin surface between 2 and about 10 strokes during each use.

VIII. EXAMPLES AND TEST METHODS

The following are non-limiting examples and/or test methods relating to various aspects of the methods, devices, and kits described herein. The examples are given solely for the purpose of illustration and are not to be construed as limiting the invention, as many variations thereof are possible.

EXAMPLE 1 - SURFACE ROUGHNESS MEASUREMENTS

This Example describes a method for measuring the surface roughness of a material. Other suitable methods and devices may be employed, as known in the art. In this example, a DermaTop-Blue device, available from Breuckmann GmbH (Germany), was utilized for measuring the surface roughness of Materials #1 to #4 described above. The DermaTop-Blue device has a measurement field of 40 mm x 30 mm, a depth of measuring volume of 20 mm, a resolution of 1280 x 1024 pixels, a depth resolution of 4 μ m, a lateral resolution of 15 μ m, and a measurement points distance of 30 μ m. The software version was DermaTop Ver. 3.1.09. The following parameters were selected for the measurements.

[APPLICATION]
TYPE=Wrinkles
LPC=NO
Align_TASK=Global
5 check_Expression=Yes
Enhance=NO
Sorting_Mode=SOI
Par_Rotation_Side_link =YES

10 [ACQUISITION]
ZOOM=1
AUTOEXPOSURE=Yes
AOI-MASK=Square
Visualization-3D=2
15 REPLICA-MASK=None
Sensor-Volume=No
Help_PopUp =Yes

[PROCESSING]
20 PROCESS_FILTER=Hair
Filter_Weight=Medium
Levelling=POLYNOM 3.ORDER
Extract-Eyebag= No
SOI_INVERT=NO
25 SOI_XSIZE=10
SOI_YSIZE=10
XOffset=0
YOffset=0
Rotation=0
30 Rotation_link=NO
SnapShot_SOI=Single
Save_Texture =NO
SOI_ASCII-EXPORT=NO

35 [EVALUATION]
SOI-Filter =Low
CUTOFF-FILTER =Gauss
CUTOFF=2.5
Save-Cutoff-SOI=NO
40

ROUGHNESS-2D=YES
TARGET-2D=Original
PROFILE-TYPE=PARALLEL
Profile-Dir=Auto
45 NB-PROFILES=50

ROUGHNESS-3D=YES
TARGET-3D=Original

A 10 mm x 10 mm square area of each of Materials 1 to 4 was measured for the surface profile. Average values for S_a , S_q , S_t , and S_{tm} were calculated by the software for the sampled areas of each Material. The average values (in microns) are summarized in Table 1 above.

EXAMPLE 2 – IN VIVO TESTING OF FOUR MATERIALS

5 In this Example, samples of Materials #1 to #4 were tested by six test subjects. Each test subject treated a small forearm area (dry, without the addition of a topical composition) with approximately a 12 mm diameter sample of the abrasive material for 5 strokes using a device similar to that shown in FIGS. 9 and 10 along a 152 mm x 25 mm area of the forearm. The skin exfoliated by the material was harvested and the amount of protein quantitated using a protein
10 assay. Table 2 above sets forth the results of the protein assay.

The following protein assay procedure was used to generate the results set forth in Table 2. First, the exfoliated skin was harvested from the surface of the abrasive material by placing the abrasive surface in a 1.5 mL Eppendorf tube containing 1.5 mL of saline. The samples were vortexed for 3 minutes. The harvested samples were placed in a 16 mL centrifuge tube with
15 saline added. The sample was agitated with a Vortex mixer and centrifuged at 20,000 RPM for 30 minutes. The supernatant was then removed and discarded leaving the bottom 2 ml in the tube along with the skin sample. The skin sample was then washed with 50/50 MeOH/H₂O by adding 4mL of 50/50 MeOH/H₂O, vortexing to mix and then adding another 8mL to fill tube. The skin sample was then centrifuged for another 30 minutes at 20,000 RPM. This process was
20 repeated 3 times. The sample was then transferred to a 2 mL centrifuge vial and centrifuged for 30 minutes at 13,000 RPM. The supernatant was then removed and discarded leaving the bottom 0.5 mL in the tube along with the sample. This process was repeated until the original centrifuge tube was clean of all samples. The sample was then dried in an oven set at 60 °C overnight. When dry, 1 mL of 0.1N NaOH was added to each sample vial and digested at 95 °C overnight.
25 The sample was centrifuged at 13,000 RPM for 30 minutes and 25 µl of the sample pipetted in triplicate to 96-well plate for the protein assay.

The protein assay can be performed using any suitable quantitation kit, as known in the art. One example is the AnaLyte OPA Protein Quantitation Kit (Catalog # 71015) available from AnaSpec, Inc. of San Jose, CA, USA. This kit is designed to detect protein concentration using
30 o-phthalaldehyde (OPA) as a sensitive fluorimetric indicator. OPA in the presence of a reducing agent reacts with an α -amino acid to form an intense blue fluorescent product, which can be read by fluorescence microplate reader or fluorometer (e.g., SpectraMax Plus 384 available from

Molecular Devices, LLC of CA, USA) capable of detecting emission at 440-480 nm with an excitation at 335-345 nm. The quantity of protein in the assay solution may be determined from the fluorescence, as known in the art.

EXAMPLE 3 – IN VITRO MEASUREMENT OF NIACINAMIDE PENETRATION

5 This Example describes the measurement of niacinamide penetration thru human cadaver skin using a Franz diffusion cell assay following abrading of six replicate skin samples by Material #1 and six replicate skin samples by Material #4. Split-thickness human cadaver skin (Allosource, Englewood, CO) was thawed at ambient conditions, cut into appropriately sized sections resulting in six test samples plus six control samples. A 20 to 25 cm² cadaver skin sample
10 was fixed at each end and each abrasive surface (31.75 mm diameter circle) was placed against the skin with a 50, 100 or 200 gm weight. The weighted abrasive surface was dragged across the cadaver skin for five strokes in one direction and then five strokes in the perpendicular direction. This was repeated for six skin samples, one for each of the six samples of Material #1 and the six samples of Material #4. 1 cm² cadaver skin plugs were cored out of the treated skin samples and
15 mounted in standard Franz-type diffusion cells (0.79 cm² surface area) maintained at about 37 °C. The receptor compartments were filled with 5 mL phosphate buffered saline (PBS - pH 7.4) that included 1% polysorbate-20 and 0.02% sodium azide, and the skin was allowed to equilibrate for two hours. The cells were randomized to treatment group based upon ³H₂O flux through the mounted skin (150 µL of ³H₂O applied for five minutes, removed and followed by
20 collection of receptor fluid after 60 minutes). Diffusion cells were randomized by ranking each cell according to water flux and distributing cells across treatment legs such that each group included cells across the range of observed water flux. Each treatment group typically had 6 replicates.

 Aliquots of the test products/formulations were spiked with ¹⁴C-niacinamide with
25 approximately 3 µCi per 300 mg product aliquot, mixed and assayed for total radioactivity in triplicate using Ultima Gold (available from Perkin-Elmer) liquid scintillation cocktail (LSC) and liquid scintillation counting (Tri-Carb 2500 TR Liquid Scintillation Analyzer, PerkinElmer, Boston, MA). The skin samples were topically dosed with 5 µL of the radio labeled niacinamide product using a positive displacement pipette. The product was gently spread over the surface of
30 the skin samples (0.79 cm²) using the pipet tip. The receptor solution was collected and replaced at various time points following application every 6 hrs with a final collection at 24 hours. After the final receptor collection, each skin sample was wiped two times with Whatman filter paper

soaked with PBS/Tween 20 and once with 70%/30% ethanol/water to remove unabsorbed (residual) product. The epidermis was separated from the residual dermis by dissection. The skin sections were dissolved in 0.50 - 1.25 mL Soluene-350 (Perkin Elmer, Boston, MA) at 60 °C overnight, and all receptor collections, filter paper wipes, and solubilized tissue sections were counted using liquid scintillation counting. Disintegrations-per-minute (dpm) for each compartment of each cell were blank corrected and summed to obtain a total recovered radiolabel value for a given cell. The dpm of each compartment were then normalized to the total recovered radiolabel value to obtain a “percent recovered radiolabel” parameter for each compartment (individual receptor collections, epidermis, dermis, and wipes for mass balance). Cumulative receptor values for each collection time point were calculated as the sum of the individual collections to that time point, with the total receptor value as the sum of all individual collections. The total skin value was the sum of the epidermis (including stratum corneum) and dermis values, and the total permeated value the sum of total skin and cumulative receptor values. Tables 4 and 5 summarize the niacinamide recovery results. In addition to niacinamide recovery, protein recovery from three samples of Material #1 and Material #4 was also measured using generally the same procedure described in Example 2. A summary of the protein recovery data is provided in Tables 5 and 6.

EXAMPLE 4 – CONSUMER PRACTICES

This Example describes the investigation of consumer habits and practices for applying cosmetic skin care compositions. In order to identify exfoliating materials that are suitable for frequent use while still providing a sufficient level of exfoliation to enhance penetration of skin care agents, it is useful to understand consumer habits and practices with regard to the application of skin care products. Understanding how skin care products are applied in daily practice informs how (e.g., number of strokes, pressure, etc.) an exfoliating device might be used by a typical user, which is useful, in turn, for assessing the in vitro effects of various abrasive materials. Seven female test subjects were monitored while applying a skin care composition to their faces using four different application methods. The methods included applying the composition using their fingers, applying the composition using a cotton surface, applying the composition using a hand held applicator, and applying the composition using a powered applicator. The number of strokes used during each application method, and the number of strokes used in various regions of the face (e.g., cheeks, forehead, and chin) were observed. The amount of pressure applied by the user was also measured using a pressure sensitive glove. From this study, it was found that consumer's typically utilize from 2 to 10 strokes at a pressure from

50 g/cm² to 400 g/cm² when applying a skin care composition to facial skin surfaces. In some instances, the number of strokes is from 7 to 10 and the pressure is from 100 g/cm² to 300 g/cm².

The dimensions and values disclosed herein are not to be understood as being strictly limited to the exact numerical values recited. Instead, unless otherwise specified, each such
5 dimension is intended to mean both the recited value and a functionally equivalent range surrounding that value. For example, a dimension disclosed as “40 mm” is intended to mean “about 40 mm.”

Every document cited herein is hereby incorporated herein by reference in its entirety unless expressly excluded or otherwise limited. In addition, U.S. Provisional App. No.
10 61/623,466 is incorporated by reference herein in its entirety. The citation of any document is not an admission that it is prior art with respect to any invention disclosed or claimed herein or that it alone, or in any combination with any other reference or references, teaches, suggests or discloses any such invention. Further, to the extent that any meaning or definition of a term in this document conflicts with any meaning or definition of the same term in a document
15 incorporated by reference, the meaning or definition assigned to that term in this document shall govern.

While particular embodiments of the present invention have been illustrated and described, it would be obvious to those skilled in the art that various other changes and modifications can be made without departing from the spirit and scope of the invention. It is
20 therefore intended to cover in the appended claims all such changes and modifications that are within the scope of this invention.

CLAIMS

What is claimed is:

1. A hand-held exfoliation device (10) suitable for repeated use on a facial skin surface, comprising:
 - a. a body (12); and
 - b. an exfoliating material (16) attached to the body (12), the exfoliating material (16) being sized for application to the facial skin surface and including a substrate and a plurality of particles attached to the substrate to form peaks and valleys thereon, wherein the exfoliating material has an arithmetical mean height over a three dimensional surface S_a of from about 2 μm to about 16 μm and the particles have an average Mohs hardness of from about 4 to about 8.
2. The exfoliation device (10) of claim 1, wherein the plurality of particles have an average size from about 0.25 μm to about 1 μm .
3. The exfoliation device (10) of any preceding claim, wherein some of the plurality of particles are agglomerated into larger formations.
4. The exfoliation device (10) of any preceding claim, wherein the exfoliating material (16) has a root mean square height over a three dimensional surface S_q of from about 2 μm to about 16 μm .
5. The exfoliation device (10) of any preceding claim, wherein the particles are bonded to the substrate by a bonding means selected from the group consisting of a binder and an adhesive.
6. The exfoliation device (10) of claim 5, wherein the exfoliation material (16) comprises an exfoliation surface that includes the particles and binding means.
7. The exfoliation device of claim 6, wherein the exfoliating surface is non-porous.
8. The exfoliation device (10) of any preceding claim, wherein the substrate includes a polymeric film.
9. The exfoliation device (10) of any preceding claim, wherein the plurality of particles comprise oxide particles, diamond particles, zirconium alumina particles, silicon carbide particles, garnet particles, emery particles, cubic boron nitride particles or nut shell particles and combinations thereof, preferably cerium oxide particles.

10. A skin care kit, comprising an exfoliation device (10) according to claim 1 and a packaged skin care composition comprising a cosmetic skin care agent and a dermatologically acceptable carrier.
11. A method of improving penetration of an agent into a facial skin surface, comprising:
 - a. contacting the facial skin surface with the hand-held exfoliation device (10) of claim 1; and
 - b. applying a cosmetic skin care composition to the facial skin surface contacted by the hand-held exfoliation device (10), wherein the cosmetic skin care composition comprises a skin care agent and a dermatologically acceptable carrier.
12. The method of claim 11, wherein contacting the hand-held exfoliating device (10) to the facial skin surface occurs before applying the cosmetic skin care composition to the facial skin surface.
13. The method of claim 11 or 12, wherein the hand-held exfoliating device (10) is contacted with the facial skin surface by applying a pressure of from about 20 g/m² to about 400 g/m² for from 1 to about 10 strokes.
14. The method of any of claims 11 to 13, wherein the hand-held exfoliating device (10) is contacted with the facial skin for from 3 seconds to about 60 seconds.
15. The method of any of claims 11 to 14, wherein the hand-held exfoliation device (10) is contacted with the facial skin surface at least once per day for at least 7 days.

1/13

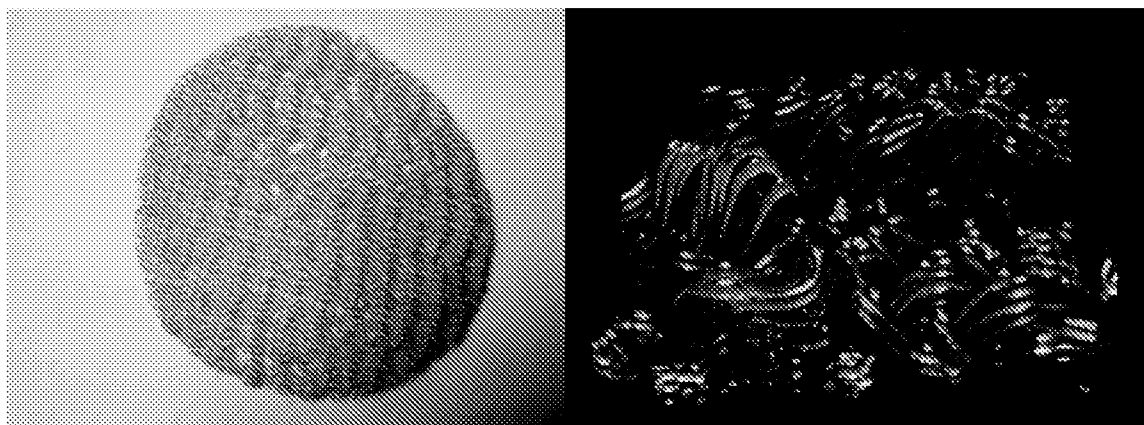


Fig. 1A

Fig. 1B

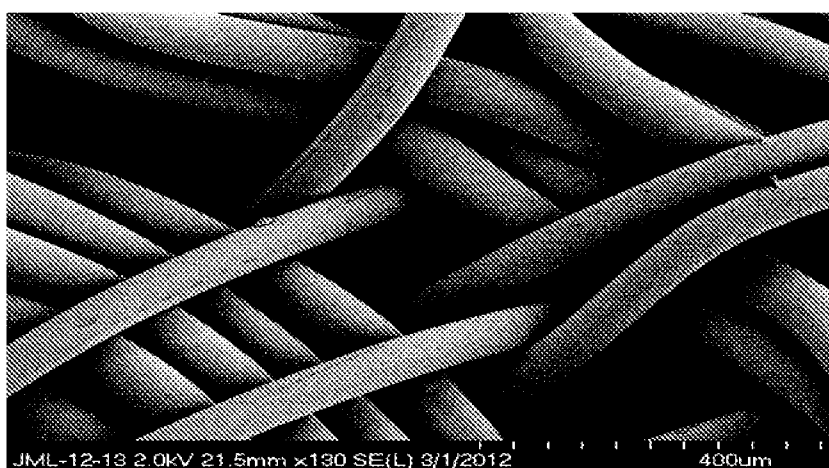


Fig. 1C

2/13

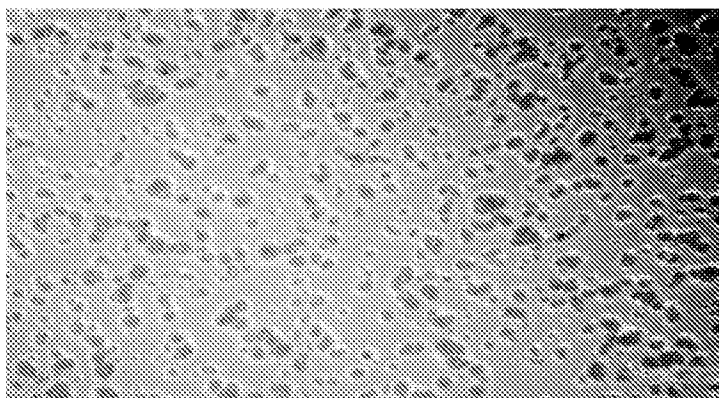


Fig. 2A

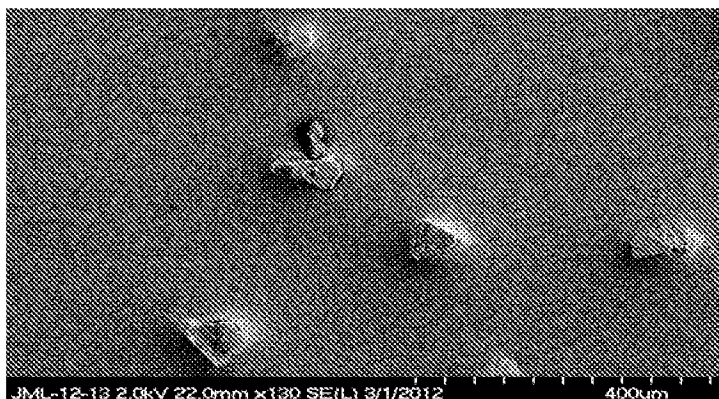


Fig. 2B

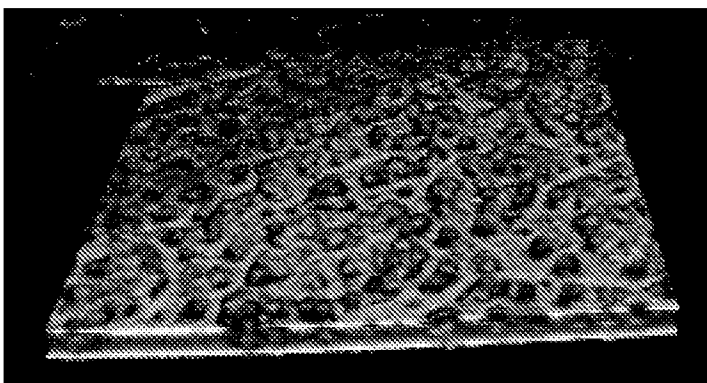


Fig. 2C

3/13

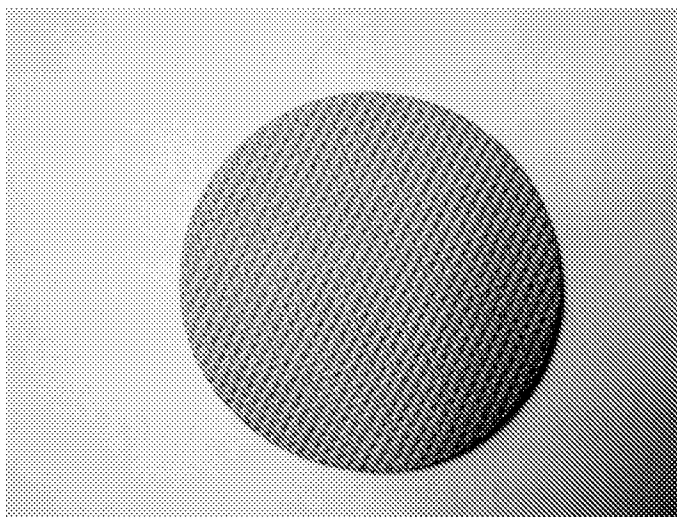


Fig. 3A

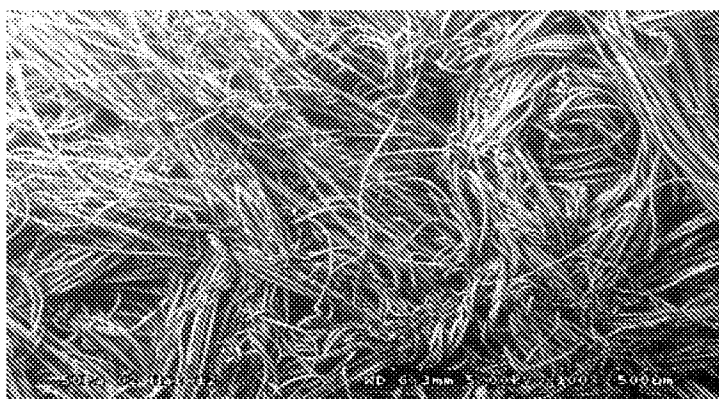


Fig. 3B

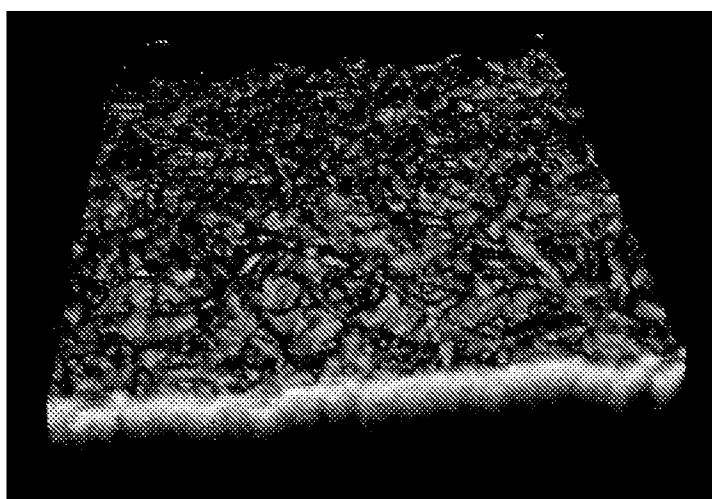


Fig. 3C

4/13

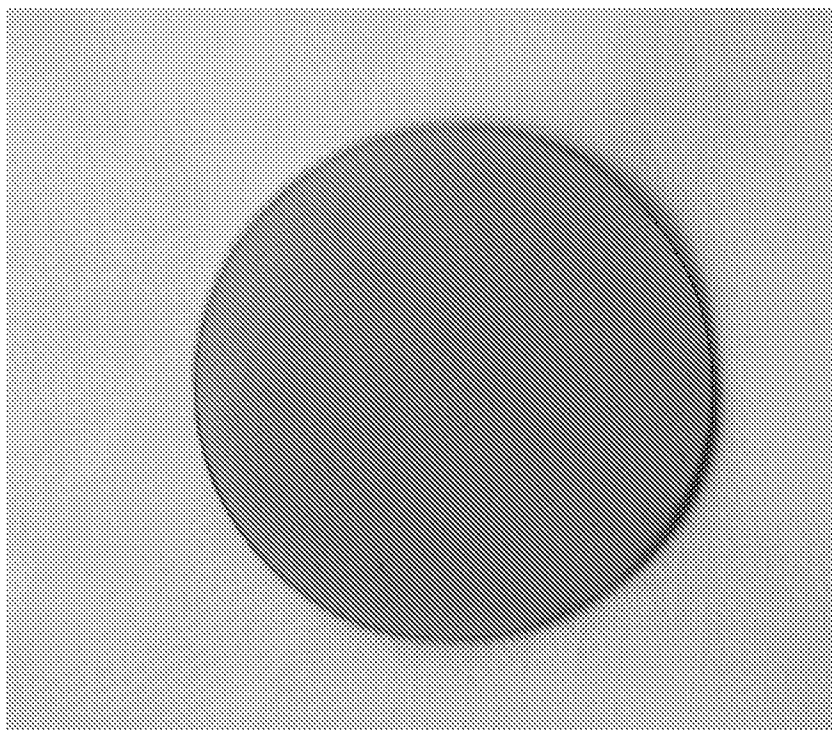


Fig. 4A

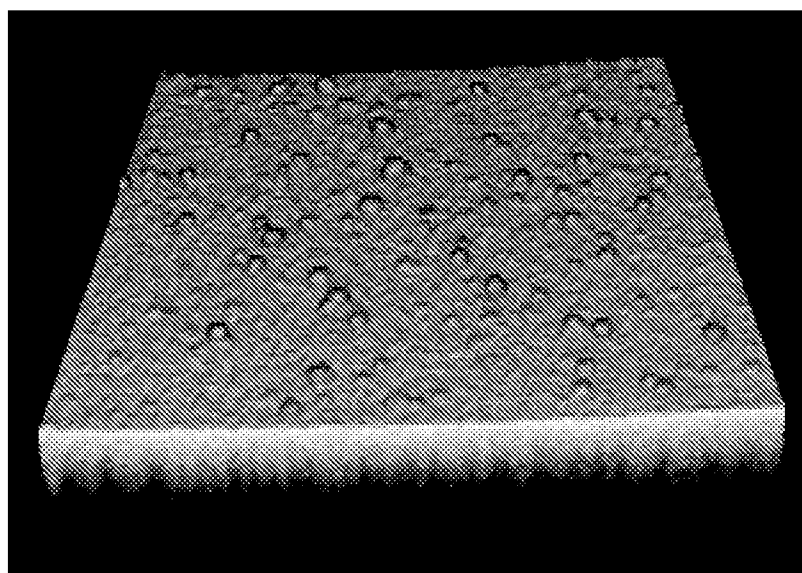


Fig. 4B

5/13

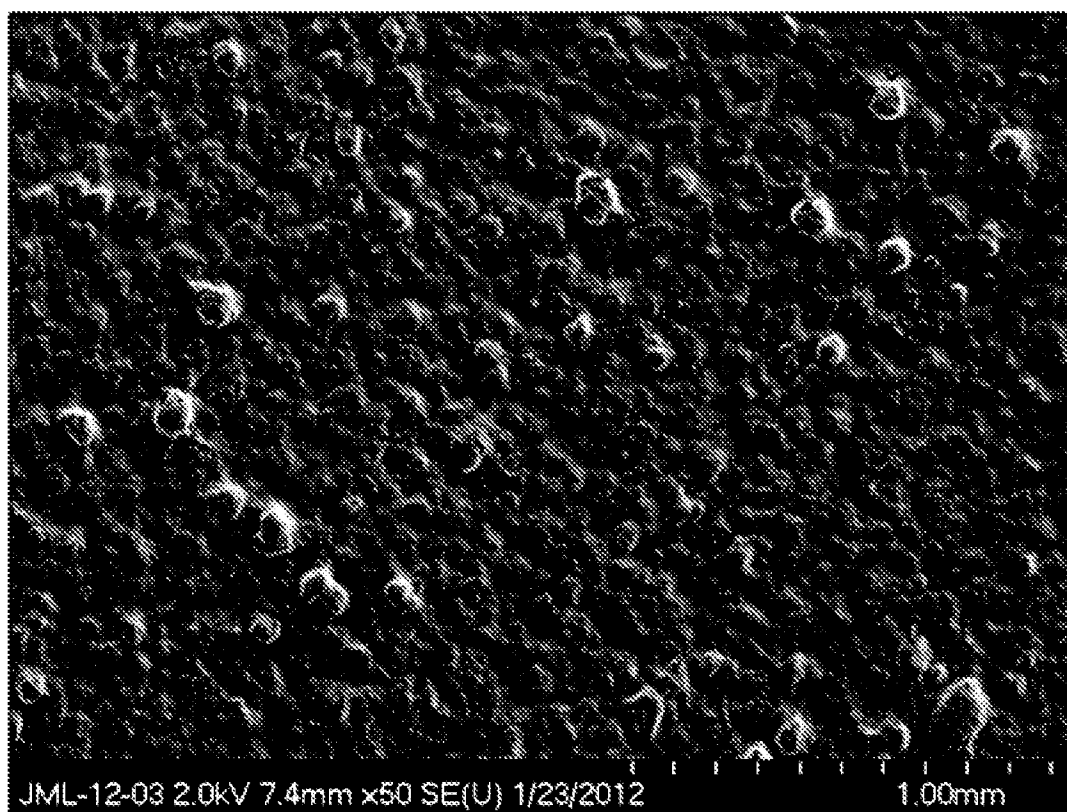


Fig. 5

6/13

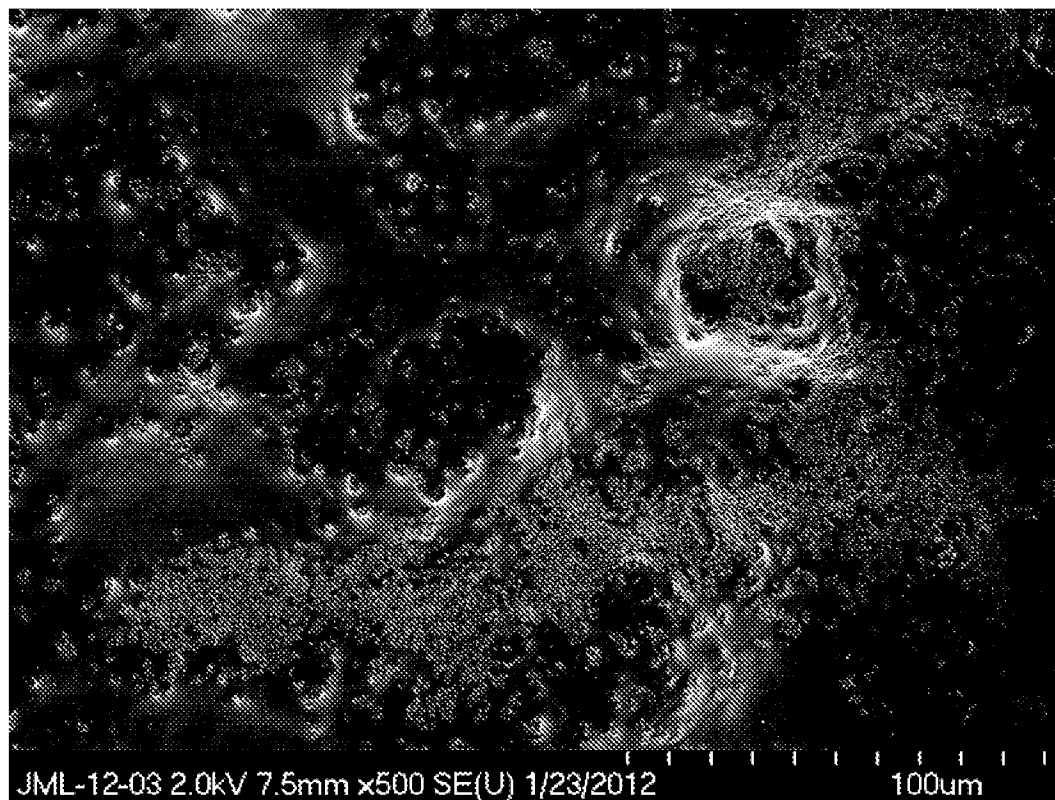


Fig. 6

7/13

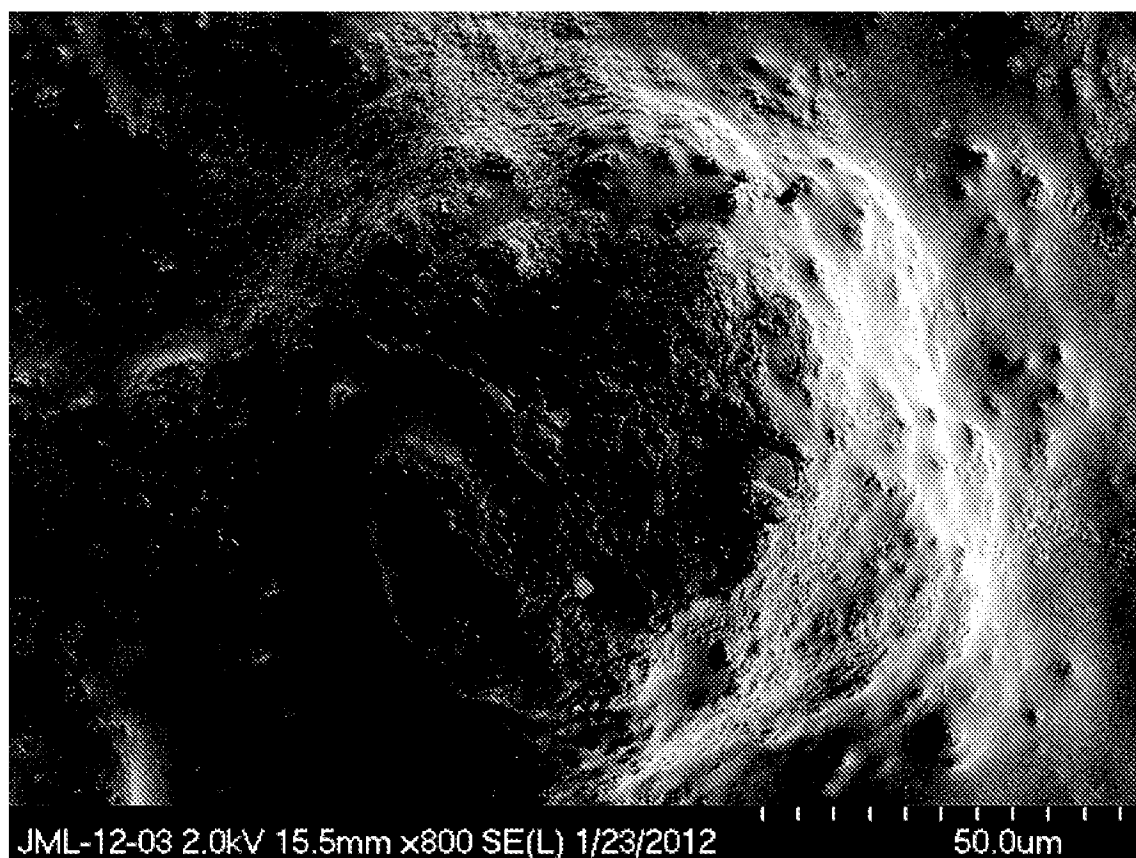


Fig. 7

8/13

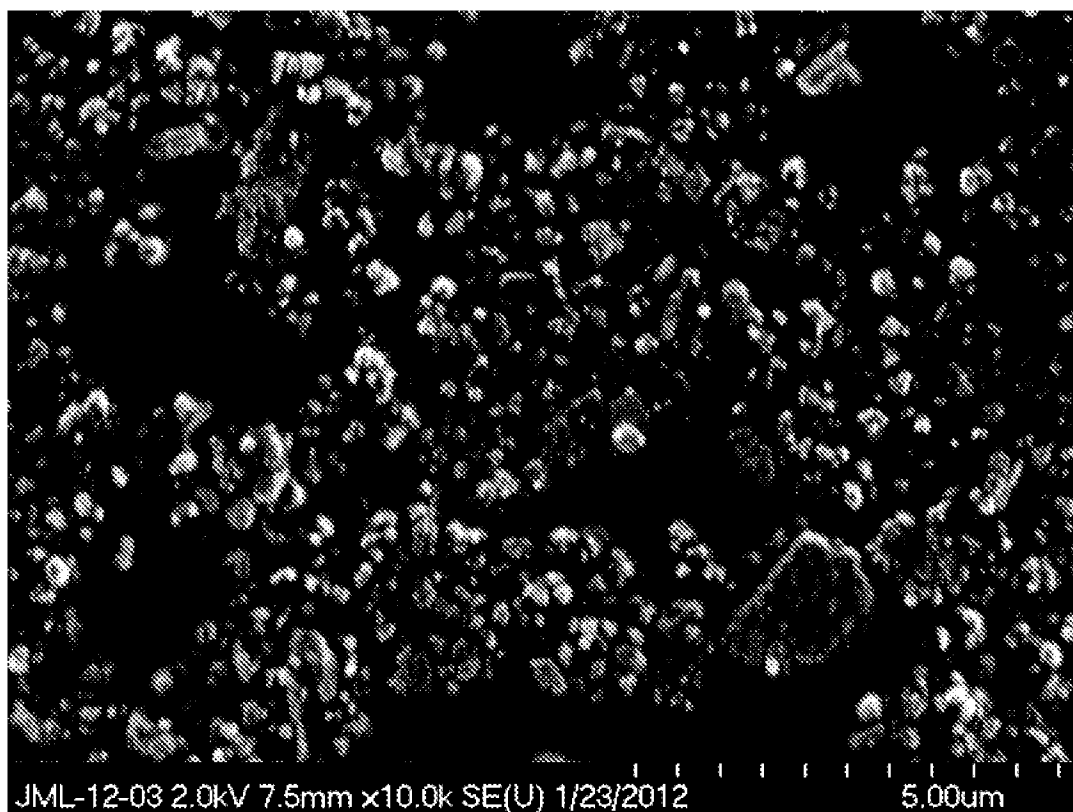
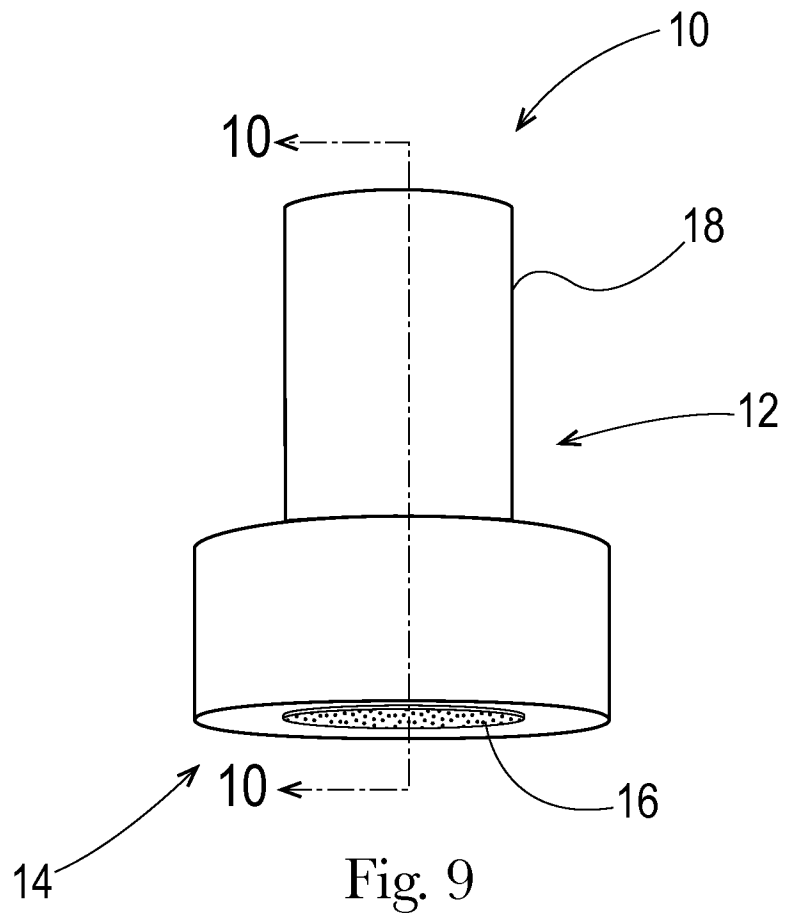
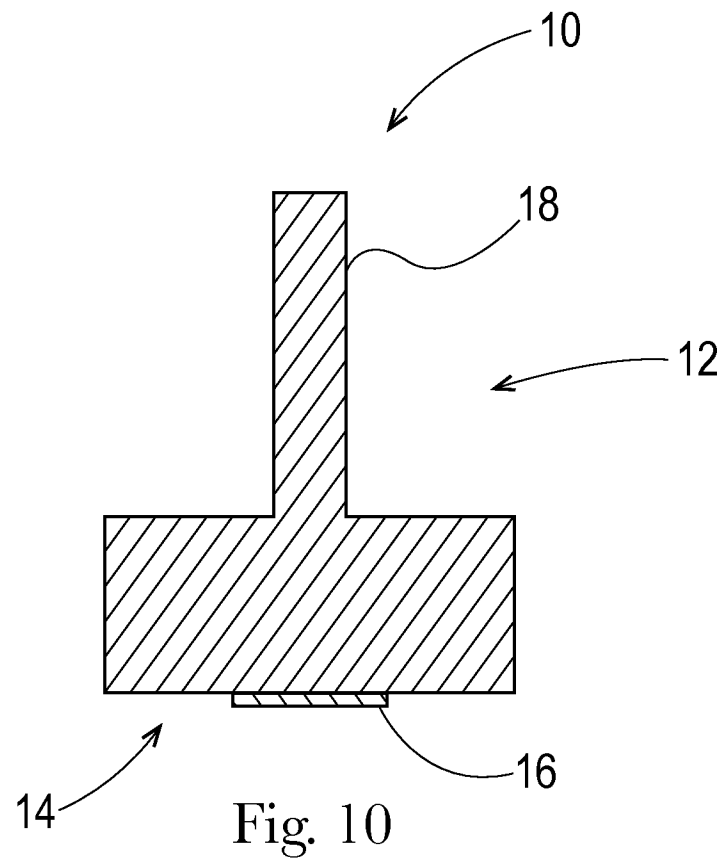


Fig. 8

9/13



10/13



11/13

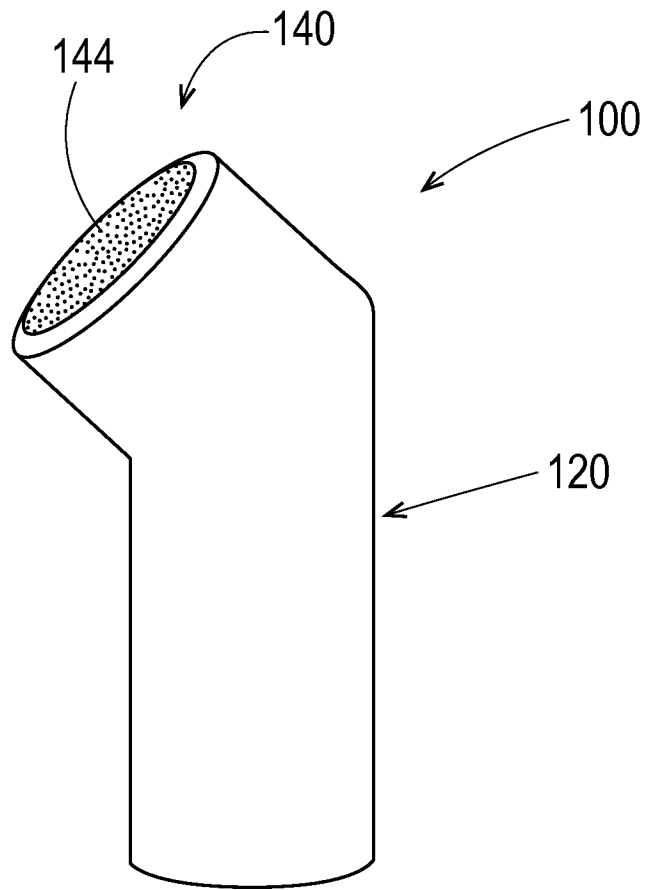
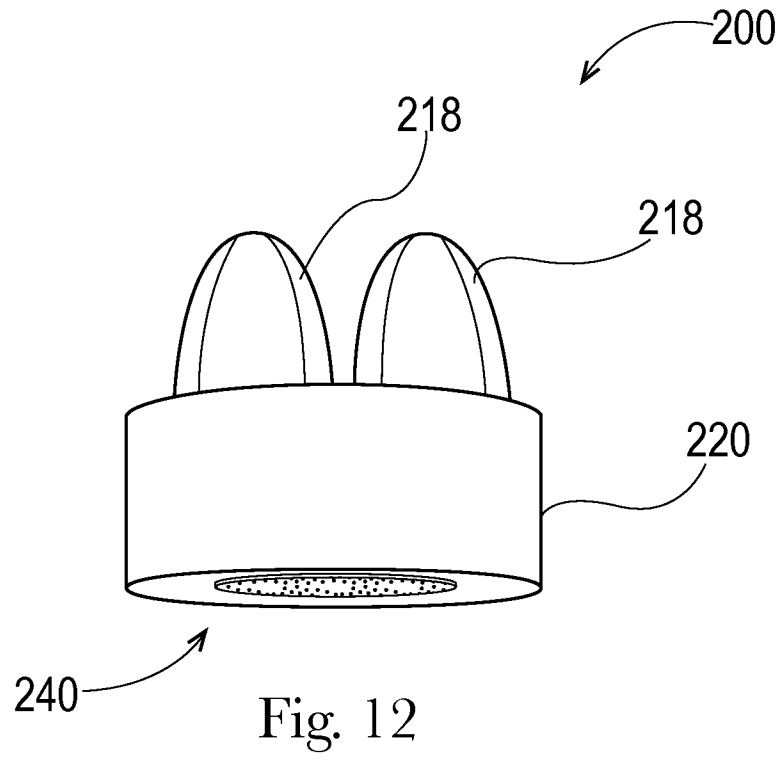


Fig. 11

12/13



13/13

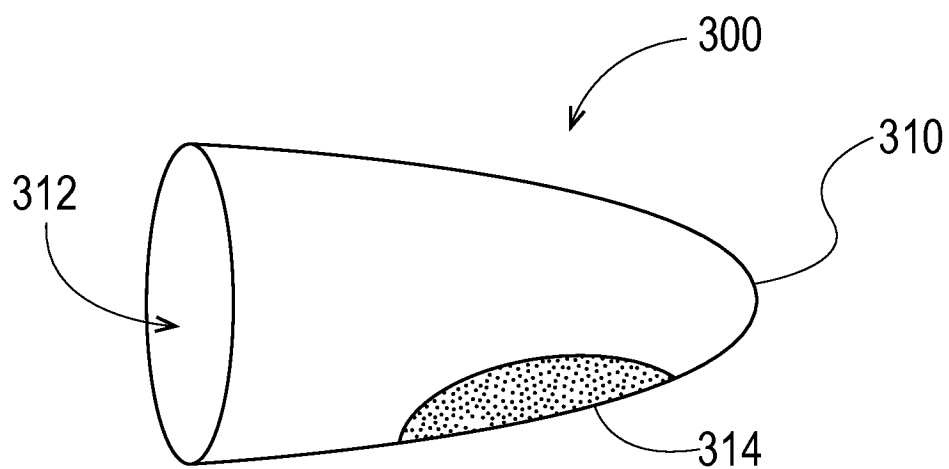


Fig. 13