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(21) International Application Number: PCT/EP93/03358 (22) International Filing Date: 27 November 1993 (27.11.93) (30) Priority Data: 92311064.7 2 December 1992 (02.12.92) EP (34) <i>Countries for which the regional or international application was filed:</i> GB et al. (71) Applicant (for AU BB CA GB IE LK MN MW NZ SD only): UNILEVER PLC [GB/GB]; Unilever House, Blackfriars, London EC4P 4BQ (GB). (71) Applicant (for all designated States except AU BB CA GB IE LK MN MW NZ SD): UNILEVER N.V. [NL/NL]; Weena 455, NL-3013 AL Rotterdam (NL). (72) Inventors: BEE, Rodney, David; 10 Stevenson Court, Eaton Ford, St. Neots, Cambridge PE19 3LF (GB). NEEDHAM, David; 75 Whitefriars, Rushden, Northampton NN10 9PE (GB). (74) Agent: TONGE, Robert, James; Unilever plc, Patent Division, Colworth House, Sharnbrook, Bedford MK44 1LQ (GB).		(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>Without international search report and to be republished upon receipt of that report.</i>
(54) Title: COSMETIC COMPOSITION (57) Abstract A cosmetic or pharmaceutical composition suitable for topical application comprises stable gas cells having d _{3,2} average particle size below 20 _{μm} .		

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COSMETIC COMPOSITIONFIELD OF THE INVENTION

5 This invention relates to cosmetic and pharmaceutical compositions, in particular aerated pastes, creams and lotions intended for topical application to the skin, hair, mucosae and teeth.

10 BACKGROUND TO THE INVENTION

A problem encountered with many products, including cosmetic compositions, containing gas cells is the stability with time: this is because a gas cell dispersion
15 comprising large cells is vulnerable to creaming separation of the dispersion into discrete layers of different gas phase volume, the larger cells in the high gas phase volume layer will coalesce through film rupture, while the smaller gas cells, say under 100 μ m, are unstable with time, due to
20 disproportionation in favour of larger cells and this is in particular true if the gas cells become finer.

US4,588,582 (Lever Brothers Company) discloses modifying the appearance of toothpaste by incorporation therein of 10
25 to 20% of a gas in the form of discrete bubbles having a diameter in the range of from 10 to 30 microns to give stability.

EP 521 543 describes gas cells dispersed in a continuous
30 liquid medium in a stable condition, ie having a stability in excess of two weeks, the gas cells having a measured d_{3,2} average diameter of less than 20 μ m.

The boundary surface of each cell, that is the surface
35 separating the gas of each cell and the rest of the product, is preferably structured and comprises a multitude of adjacent domes. Specific stability is obtained if the

great majority of the domes have hexagonal and some pentagonal outlines. Usually, some irregularities, for example higher polygons, are present amongst the domed structures. These polygons can be of very irregular shape.

5

In the cases where the surfactant packs in an approximately planar film at the microcell surface, the regular domed surface is absent and may then be smooth or buckled.

10

Gas cells of a good stability with respect to creaming and disproportionation are obtained when the cells have diameters in the range from 0.1 to 20 μ m and more preferably from 0.5 to 3 μ m. Diameter throughout this description and claims refers to a measured $d_{3,2}$ (volume surface) average diameter. The expression "liquid medium" in this description and claims means any medium showing molecule mobility, ie including gels and viscous liquids.

15

A suitable method of preparing a multitude of gas cells in a liquid medium is also described in EP 521 543 and comprises whipping a liquid medium with a gas such that gas cells of the required dimension are formed while having a surface active agent contained in that liquid medium for stabilising the gas cells. For obtaining the gas cells of the required dimensions sufficient shear should be exerted on the larger gas cells that initially are formed. Factors influencing this shear are the type of mixer or beater or whisk, the viscosity of the liquid medium and the temperature thereof.

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In practice a high shear, mixer, such as a Kenwood Chef mixer, a colloid mill, an Oakes mixer, a cavity transfer mixer or a Silverson will be used. By increasing the viscosity and/or lowering the temperature of the liquid medium the size reducing effect of the mixer on the gas cells is increased. If a Kenwood Chef mixer is used at room temperature a suitable dynamic viscosity of the liquid

medium is preferably from 0.1 Pa.s to 20 Pa.s although the range of from 0.2 to 0.4 Pa.s is preferred.

5 Having obtained the gas cells in the form of a thick creamy foam, this foam is then aged. Stable gas cells may then be separated from part of the liquid medium used for preparing the cells. Separation can be achieved by centrifuging or using a dialysis membrane after modifying the liquid phase of the gas cell suspension such as by dilution with a
10 miscible fluid.

It has now been found that stable gas cells, prepared as a separate ingredient, for example as described above can advantageously be incorporated into cosmetic and
15 pharmaceutical compositions.

The use of this gas cells ingredient in the compositions of the invention provides improved creaminess in texture, a whiter more opaque product and, dependent on components,
20 enhanced fragrance, flavour, or improved skin or mouthfeel. Having similar particle size to an oil or fat emulsion, suspensions of gas cells prepared as described can be used to replace, or improve on, some of the attributes normally contributed by the oil/fat in cosmetic or pharmaceutical
25 emulsions.

DEFINITION OF THE INVENTION

Accordingly, the invention provides a cosmetic or
30 pharmaceutical composition comprising a preformed gas cells ingredient comprising a surfactant, in which the gas cells have a $d_{3,2}$ average particle size of less than $20\mu\text{m}$ and a stability in excess of 2 weeks.

DISCLOSURE OF THE INVENTION

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The invention is founded on the preparation of an

ingredient comprising a large number of very stable gas cells of very small size. When such cells are present in bulk they will form about 10^8 to about 10^{10} per ml. On incorporation of this ingredient into a cosmetic or pharmaceutical composition, it is preferably distributed throughout the mass in the form of discrete cells so as to provide the benefits associated with their presence. However it must be expected that the cells are likely to form flocculates in the composition. The stable gas cells, whether present in discrete form or as flocculates, are distinguished from any gas cells of a larger size that may be present. The latter is not in the form of stable cells, but contributes most of the volume.

Usually the gas cell number concentration in the composition will be above about 10^6 per ml, preferably above 10^7 per ml, with the number and size selected to provide the desired benefit.

The particle size of the gas cells is less than $20\mu\text{m}$, more preferred 0.1 to $10\mu\text{m}$, most preferred from 1 to $6\mu\text{m}$.

The gas cells ingredient for use in compositions of the invention have a stability in excess of 2 weeks. With this is meant that upon storage for 2 weeks at 4°C more than 90% by number of the gas cells in the composition still remain intact. Especially preferred are compositions, wherein the stability of the gas cells is more than 4 weeks, most preferably more than 8 weeks.

The gas cells ingredient can be prepared from a cosmetically acceptable surface active material suitable for the making of gas cells with structured surfaces, that is a surfactant whose head group does not carry a substantial charge, compared to that of an ionised anionic or cationic surfactant, and whose head group also occupies a similar surface area to that of the tail group, such that

the tail group is capable of crystallising at the storage temperature of the composition. Preferably, the tail group of the surfactant is saturated and has a carbon chain of at least 14, preferably from 16 to 22 carbon atoms, for products to be held at room temperature or slightly higher. Suitable surfactants are nonionic or virtually so in character, for example mono-, di- or tri-long chain fatty acid esters of sucrose or distearoyl or dipalmitoyl phosphatidylcholine or mixtures thereof.

10

If desired any suitable thickener may be present in the system while forming the stable gas cells. Suitable thickener materials are for example sugars, (hydroxy-alkyl) celluloses, hydrolysed starches and mixtures thereof.

15

For preparing compositions containing the gas cells in accordance to the invention, it is desirable to prepare the gas cells in bulk separately and add these as an ingredient to the composition during or after its preparation.

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A suitable method of pre-preparing the gas cells ingredient involves the preparation of an aqueous solution of the desired viscosity (for example by using a thickener material at a suitable level) and containing 0.1 to 20 wt% of surfactant(s). In this context it is believed to be within the ability of the skilled person to select those thickeners that will be capable of contributing to the desired viscosity of the aqueous solution. The selection of the surfactant is critical to the subsequent stability of the gas cells. It is restricted to those providing the surface characteristics as described earlier. Gas cells are mechanically incorporated into the aqueous solution and then comminuted by suitable agitation, preferably at high shear, until a system is formed wherein the average particle size of the gas cells is within the limits as herein before described. By taking the appropriate surfactant phase with water or other solutes at low levels,

gas cells according to the invention can if desired be manufactured without the use of a separate component to contribute the principal part of the viscosity.

5 The cosmetic or pharmaceutical compositions of the invention into which the gas cells are incorporated, as a separate ingredient can be any composition which is suitable for topical application to the skin, hair, mucosae or the teeth. The ingredients of such composition in
10 addition to the gas cells, will be those that are conventionally employed by manufacturers and formulations of cosmetic and pharmaceutical compositions.

According to a particularly preferred embodiment of the
15 invention, the gas cells can be employed to enhance delivery, during topical application, of active materials that can benefit the skin, hair, mucosae or teeth.

For example, it has been shown that co-surfactants
20 containing suitable lipid chains may be incorporated into the structured gas cell surface. In this state, the co surfactant is molecularly dispersed within the interface. The stable gas cells therefore provide a favourable vehicle both to hold and to deposit beneficial surface active
25 species onto a surface. For example species such as ceramides may be included into and deposited from such structures.

When the composition is in liquid or semi liquid form, the
30 gas cells can be employed to enhance the appearance of the composition. Thus, because of their size (of the order of the wavelength of light) and the refractive index difference between the gas phase and the supporting liquid, gas cells of the present invention scatter light very
35 effectively. Consequently, a concentrated suspension for example, greater than 10^7 cells ml^{-1} when present in a suitable support medium can be used as a barrier to light

radiation. Such cells can be used to replace or augment organic sunscreens or solid inorganic pigments, such as ultra fine titanium dioxide, which are currently used in sunscreen creams and lotions.

5

The amount of gas cells that can usefully be incorporated into compositions in accordance with the invention, as a preformed gas cells ingredient is from 0.001 to 80%, preferably from 0.1 to 10% by volume of the composition.

10

ILLUSTRATION OF THE GAS CELLS

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Accompanying Figures 1 to 6 show electron micrographs of domed and differently structured gas cells which feature in the composition according to the invention, each shown at a different magnification factor.

EXPERIMENTS

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Experiments 1 to 4 illustrate the preparation of the gas cells ingredient for subsequent incorporation into compositions of the invention.

Experiment 1

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An aqueous solution was prepared containing 70% by wt of maltodextrin 63DE and 2% by wt of sucrose mono stearate ester. Using a Kenwood chef mixer this solution was whipped with air for 1 hour at speed 5. A thick creamy foam resulted.

35

This foam showed an air phase volume of 0.6 and the great majority of the gas cells had a diameter of the order of $2\mu\text{m}$ and below. On standing for 40 days little visible change had occurred in these cells.

Electron microscopy photographs showed (see Figures 1 and

2) that the air cells had surfaces compartmentalised into domes, most of the domes having a hexagonal and some pentagonal outline. Few showed a differently polygonal outline: See in particular, Figure 2. A representation showing part of a domed surface and made with the largest magnification factor is shown in Fig 3.

The foam as prepared could be diluted 1000 times with water resulting in a white milky liquid. The same result was obtained on 1000 times dilution with a 30% by wt aqueous maltodextrin 63DE solution. Though no longer suspended/dispersed in a thick viscous aqueous liquid the gas cells with diameters less than 5-10 μ m remained in suspension, although with some creaming. This creaming could be reversed by simple stirring or swirling. No significant change took place over 20 days.

Even though some flocculation of cells occurred over extended times (normally greater than several days depending on ionic concentration) the cells remained essentially stable with respect to disproportionation. Flocculation did however cause an increase in the rate of creaming of the gas cell suspension. When not flocculated the cells smaller than 10 μ m can be seen to be strongly under the influence of Brownian motion, showing that the stability of these cells does not result from the cells being constrained in a rigid matrix.

The gas cells could be concentrated again to a gas phase volume of 0.4 by centrifuging the diluted liquid in a centrifuge at a speed of 2500 rpm for 5 minutes. As expected, the rate of concentration of the gas cells by centrifugation could be manipulated by varying the viscosity of the suspending phase and by the magnitude of the applied gravitational force.

The thick foam prepared by the method just described was

diluted with distilled water to air phase volumes ϕ of 0.1, 0.01 and 0.001 respectively. After standing for 14 days, gas cell size determinations were made both with a Coulter Counter (aperture size $70\mu\text{m}$) and a Malvern Zetasizer.

5

For the Coulter Counter determination, samples of each of the three amounts of diluted foams were taken after gently shaking and these samples were diluted with distilled water to a dilution suitable for the determination.

10

The results were as follows:

Phase volume $\phi 0.1$

	size μm	vol %	population (000s)
	<1.00	9.5	75
5	1.25	16.2	65.1
	1.58	24.3	51.3
	1.99	23.9	28.2
	2.51	13.6	8.1
	3.16	6.0	1.8
10	3.98	3.1	0.5
	5.02	1.5	0.1
	6.32	0.3	0
	7.96	0.2	0
	10.03	0.6	0
15	12.64	0.1	0
	15.93	0	0
		TOTAL	230

20 Phase volume $\phi 0.01$

	size μm	vol %	population (000s)
	<0.79	-	-
	1.00	17.2	65.2
25	1.25	16.8	30.8
	1.58	15.1	14.0
	1.99	11.6	5.9
	2.51	7.6	1.9
	3.16	4.0	0.5
30	3.98	2.4	0.1
	5.02	4.0	0.1
	6.32	4.4	0.1
	7.96	7.0	0
	10.03	2.6	0
35		TOTAL	119

Phase volume $\phi 0.001$

	size μm	vol %	population (000s)
5	<0.79	-	-
	1.00	22.4	96
	1.25	24.5	52.1
	1.58	18.8	20.8
	1.99	13.0	7.6
10	2.51	6.4	1.9
	3.16	3.1	0.4
	3.98	2.2	0.1
	5.02	1.5	0.1
	6.32	2.2	0
15	7.96	1.1	0
	10.03	0	0
		TOTAL	179

20 A blank gas cell size determination of distilled water resulted in a total background count from particulate impurities of 600.

25 An amount of the original foam was diluted with distilled water to an air phase volume of 0.05 and dialysed against distilled water overnight to reduce the maltodextrin in the liquid phase.

30 After suitable dilution the following data were obtained for gas cell size distribution using a Malvern Zetasizer.

12

	gas cell size class nm	relative number of gas cells %
	below 353.9	0.0
	353.9 - 414.6	0.8
5.	414.6 - 490.4	4.7
	490.4 - 577.2	10.8
	577.2 - 679.3	19.1
	679.3 - 799.6	27.7
	799.6 - 941.2	20.2
10	941.2 - 1107.8	10.8
	1107.8 - 1303.9	4.7
	1303.9 - 1534.8	1.1
	over 1534.8	0

15

The same dialysed sample, gently sonicated in an ultrasonic cleaning bath, was subjected to a particle size determination in a Malvern Zetasizer, giving the following data:

20

	gas cell size class nm	relative number of gas cells %
	below 241.4	0
	241.4 - 278.1	1.2
25	278.1 - 320.5	4.5
	320.5 - 369.3	8.6
	369.3 - 425.5	14.5
	425.5 - 490.3	20.4
	490.3 - 564.9	19.2
30	564.9 - 650.9	15.1
	650.9 - 750.0	9.8
	750.0 - 864.2	5.1
	864.2 - 995.8	1.6
35	over 995.8	0

These gas cells sizes and distributions are all confirming that the major amount of gas cells is well under 10 μ m size.

Experiment 2

5

An aqueous solution containing 1.5% (w/w) hydroxy-ethylcellulose and 6% (w/w) sucrose ester, S-1670 Ryoto Sugar Ester ex Mitsubishi Kasei Food Corporation, which is a mixture of predominantly sucrose mono and distearates was aerated in the bowl of a planetary mixer using a fine wire whisk. After 30 minutes the concentration of sucrose esters was increased by 2% by the addition of a more concentrated aqueous solution (25% w/w). Subsequent identical additions were made during whipping at 10 minute intervals until the sucrose ester concentration reached 12% w/w on the total. The overall viscosity of the aerated matrix was maintained approximately constant by the addition of an appropriate amount of water. Optionally, gas cell suspensions prepared in this manner could be processed through a colloid mill to remove quickly the larger gas cells.

20

Two gas cell suspensions so formed were allowed to stand for 1 hour and subsequently for 1 day. After 100 fold dilutions of both samples no change could be recorded over time in the gas cell size distribution as measured by light microscopy. Observed in this way, gas microcells had typical diameters in the range 1 to 10 μ m. By light microscopy the microcells could be seen to be freely mobile both in the flowing liquid on the microscope slide and to be moving under the influence of Brownian motion. By increasing the surfactant concentration in this way, an increased proportion of gas microcells relative to larger cells could be formed. After dilution to a viscosity which allowed removal of cells larger than the required size (in this case 20 μ m) and separation by creaming, the gas cell suspension had a phase volume of gas of ~0.4 and contained

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in the region of 10^9 cells per ml. If required, excess surfactant could be removed by dialysis.

5 Gas microcells prepared in this way could be mixed with solutions containing a gelling or a viscosity imparting agent with appropriate yield strength properties to produce a suspension of known phase volume which is substantially stable to creaming of the cells. With suitable microbiological precautions the gas cell suspension
10 remained unchanged over a period of many weeks.

Experiment 3

15 Gas microcells have been prepared using a mixture of two types of surfactants having different head group sizes but the same or very similar saturated hydrophobic chains. This experiment illustrates that microcells of substantial stability can be prepared by the addition of various amounts of co-surfactant(s) in which the characteristic
20 surface dome features can be expanded such that the radius of the dome is modified to become more (or less) similar to that of the gas cell surface. This can be illustrated by transmission electron micrograph (Figure 4). The sample was prepared by the procedure of Experiment 1 but from a
25 composition of surfactants of sucrose ester (1.3 w/v) and stearic acid (0.07% w/v). In such microcells the regular pattern is disturbed. Whilst the cell surface remains curved and separated into domains, these are no longer regular. An otherwise identical preparation, but this time
30 containing 1.3% w/v sucrose ester and 0.7% stearic acid, produced gas microcells containing essentially smooth surfaces with only a few lines or discontinuities separating the curved surfaces. Many cells showed no separate regions. After ageing for 13 days and separation
35 of the microcells by 10 times dilution and removal of the larger cells by creaming, the microcells, in two separate determinations of size distribution gave a $d_{3,2}$ of 1.19 and

1.25 μ m for the dispersion. Microcells in these experiments showed stability characteristics analogous to those microcells described above.

5 Experiment 4

Defatted and fully hydrogenated phosphatidylcholine (PC) (98% pure and containing 1% lysophosphatidylcholine plus other phospholipids as impurities (Emulmetec 950 ex Lucas Meyer)) was used in a small scale preparation of gas
10 microcells. 0.5g PC was heated to 65°C in 10g of 60% maltodextrin solution. A homogenous dispersion was prepared by stirring whilst controlling the temperature for 1 hour. Further dispersion using an ultrasonic probe was
15 used in a second run with similar results. The suspension was aerated at room temperature for 1 hour using a microscale whipping apparatus comprising a cage of stainless steel wires driven by a variable speed motor. A phase volume of typically 0.7 was obtained in the initial
20 aeration step. After ageing for 24 hours the foam comprising microcells could be stripped of the larger cells by creaming. The microcells when viewed by transmission electron microscopy had surfaces characterised by the presence of waves or wrinkles (Figure 6) and frequently
25 deviated substantially from an overall spherical (Figure 5). Cells in the range 1 to 20 μ m could be harvested by standard separation techniques.

EXAMPLES

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The invention is illustrated by Examples 1 and 2 which define skin cream compositions, each containing a preformed gas microcell suspension prepared as described in Experiment 1.

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Example 1

This example illustrates an oil-in-water skin cream in accordance with the invention.

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An oil-in-water cream emulsion having the following formulation was prepared:

	<u>% w/w</u>
10 Mineral oil	4
Gas microcell suspension (Experiment 1)	10
Ceramide	0.01
Brij 56 ⁽¹⁾	4
15 Alfol 16RD ⁽²⁾	4
Triethanolamine	0.75
Butane-1,3-diol	3
Xanthan gum	0.3
Preservative	0.4
20 Perfume	qs
Butylated hydroxy toluene	0.01
Water	to 100

(1) Brij 56 is cetyl alcohol POE (10)

25 (2) Alfol 16RD is cetyl alcohol

Example 2

This example illustrates a suncare cream in accordance with the invention. The suncare cream had the following formulation:

		<u>% w/w</u>
	2-hydroxy-n-octanoic acid	1
10	Gas microcell suspension (Experiment 1)	20
	Silicone oil 200 mPas	7.5
	Glycerylmonostearate	3
	Cetosteryl alcohol	1.6
	Polyoxyethylene-(20)-cetyl alcohol	1.4
15	Xanthan gum	0.5
	PARSOL 1789 ⁽³⁾	1.5
	PARSOL MCX ⁽⁴⁾	7
	Perfume	qs
	Colour	qs
20	Water	to 100

(3) PARSOL 1789 is 4-(1,1-dimethylethyl)-4'-methoxydibenzoylmethane

25 (4) PARSOL MCX is octyl methoxycinnamate

CLAIMS

1. A cosmetic or pharmaceutical composition comprising a preformed gas cells ingredient comprising a surfactant, in
5 which the gas cells have a d_{3,2} average particle size of less than 20 μ m and a stability in excess of 2 weeks.
2. A composition according to claim 1, wherein the d_{3,2} average particle size of the gas cells is from 0.1 to 10 μ m.
10
3. A composition according to claim 1, wherein the d_{3,2} average particle size of the gas cells is from 0.5 to 3 μ m.
4. A composition according to claim 1, 2 or 3, in which
15 the surfactant is chosen from those whose head group does not carry a substantial charge, compared to that of an anionic or cationic surfactant.
5. A composition according to any preceding claim, in
20 which the surfactant is chosen from those whose head group occupies a similar surface area to that of the tail group.
6. A composition according to any preceding claim, in
25 which the surfactant is chosen from those whose tail group is capable of crystallising at the storage temperature of the composition.
7. A composition according to any preceding claim, in
30 which the tail group has a carbon chain of at least 14 carbon atoms.
8. A composition according to claim 7, in which the carbon chain comprises from 16 to 22 carbon atoms.
- 35 9. A composition according to any preceding claim in which the surfactant is a nonionic surfactant.

10. A composition according to any preceding claim, in which the surfactant is a mono-, di-or tri-long chain fatty acid ester of sucrose.
- 5 11. A composition according to any of claims 1 to 9, in which the surfactant is chosen from distearoyl phosphatidylcholine, dipalmitoyl phosphatidylcholine and mixtures thereof.
- 10 12. A composition according to any preceding claim, in which the preformed gas cells ingredient further comprises a thickener.
- 15 13. A composition according to claim 12, in which the thickener is chosen from sugars, (hydroxyalkyl) cellulose, hydrolysed starches and mixtures thereof.

1 / 6

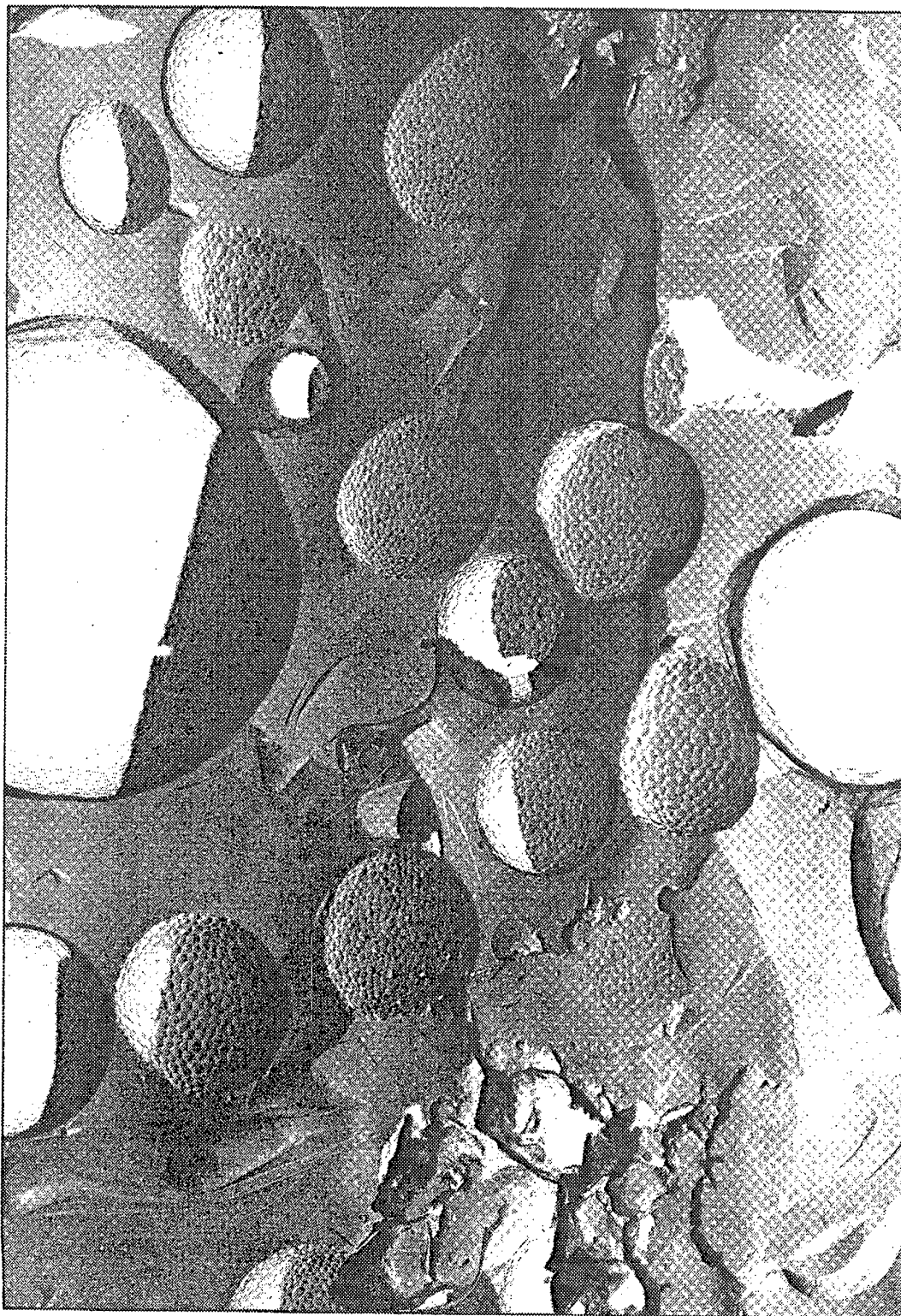


Fig. 1

1 μm

2 / 6

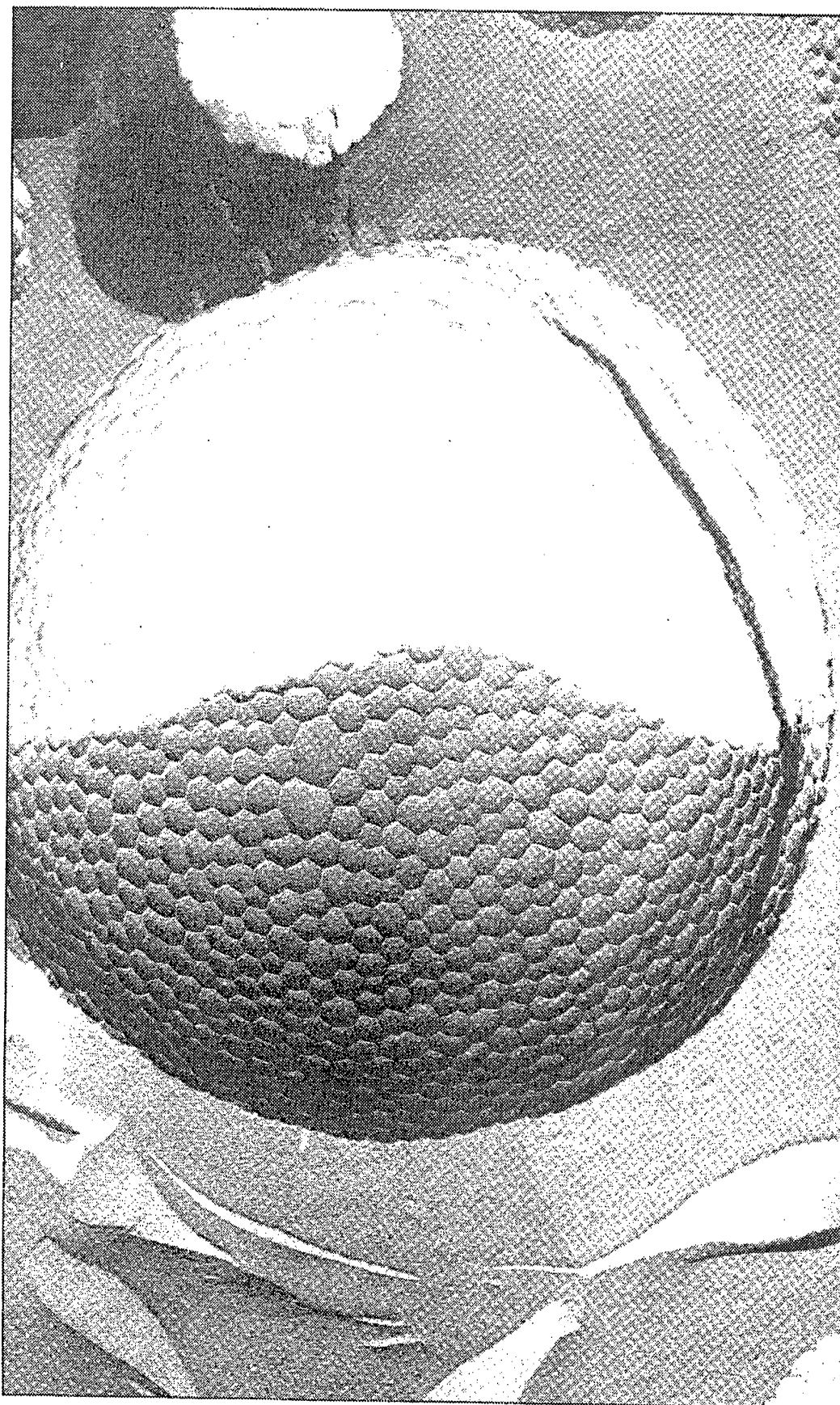


Fig. 2

500 nm

3/6

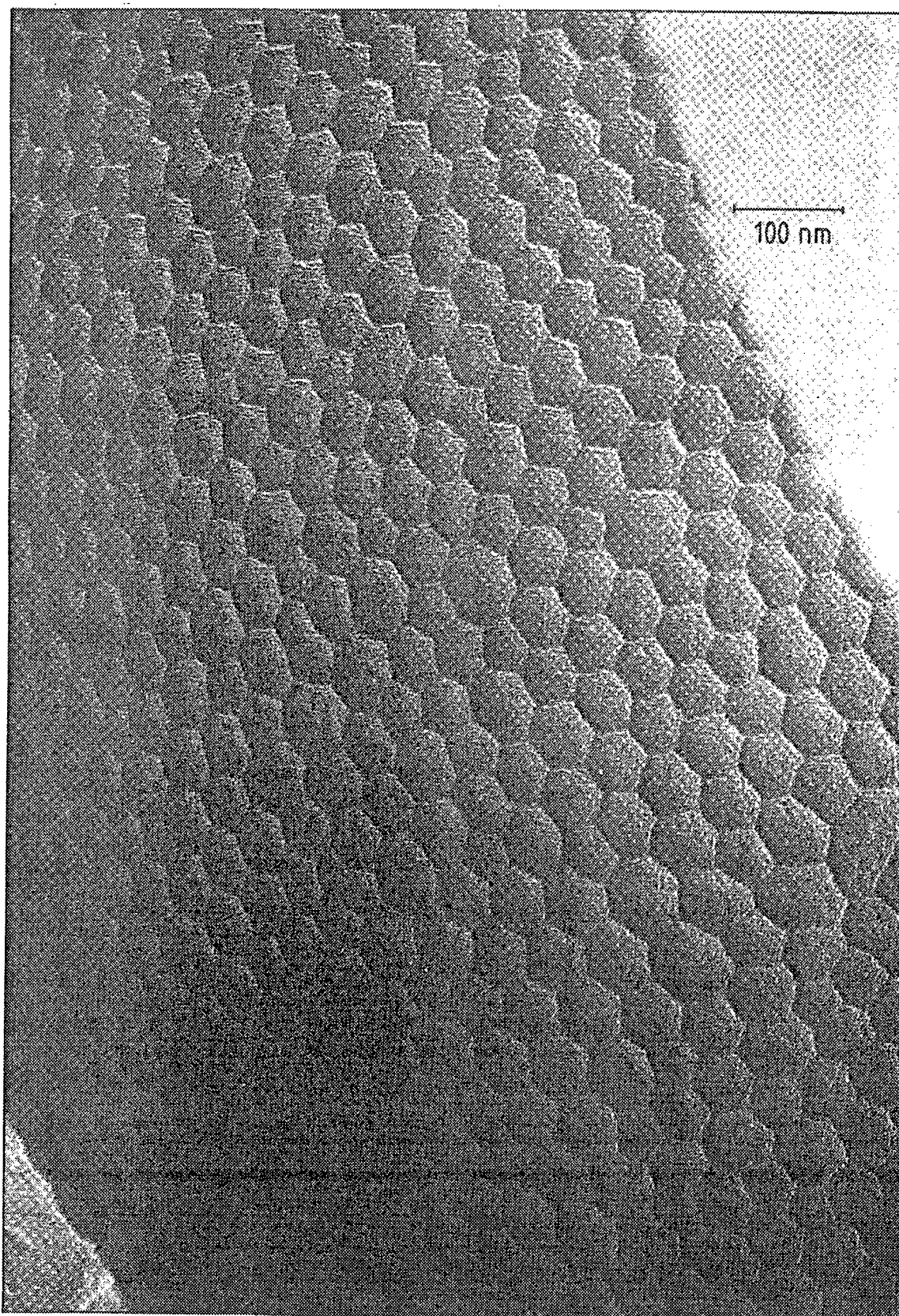


Fig. 3

4/6



Fig. 4

100 nm

5/6

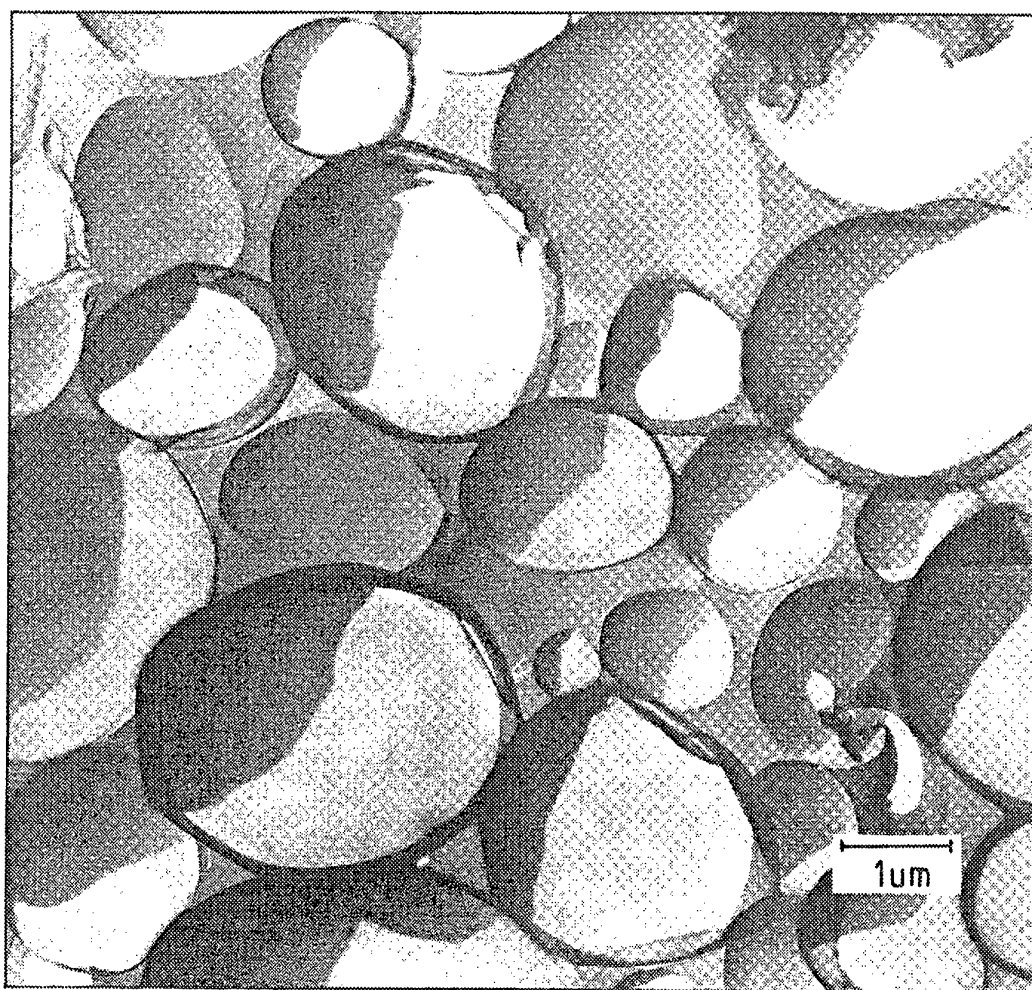


Fig. 5

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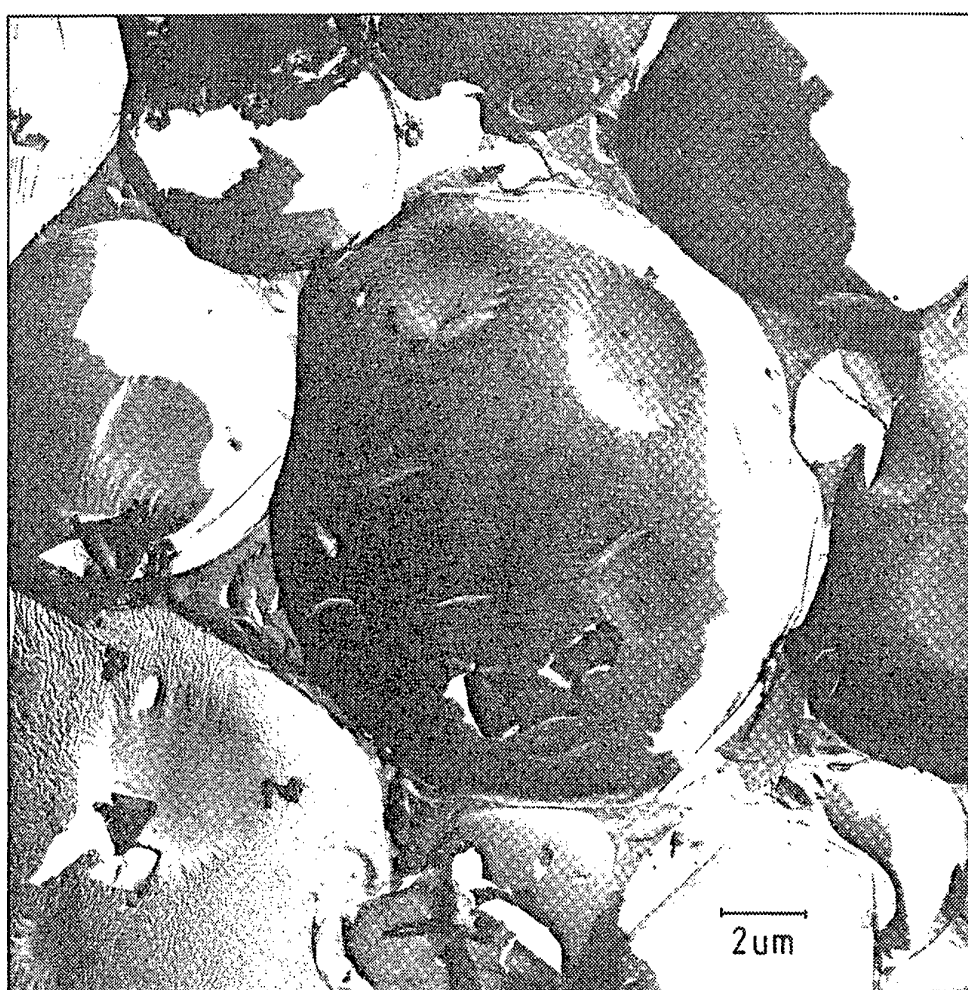


Fig. 6