

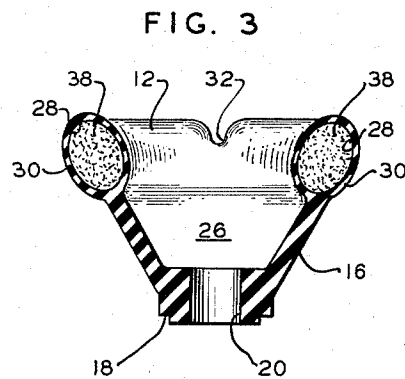
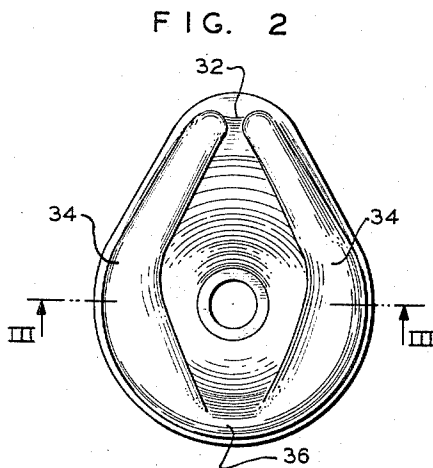
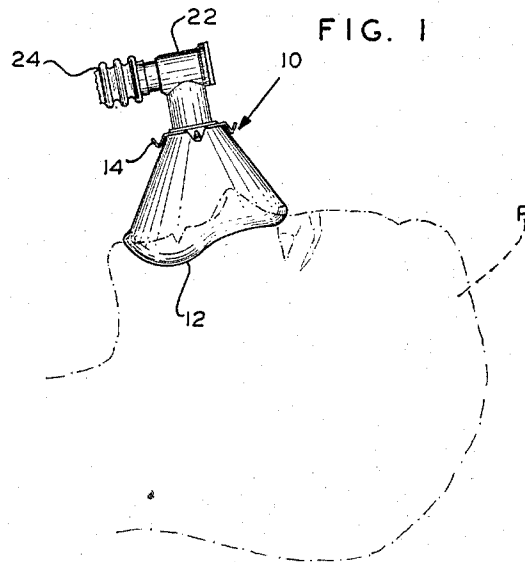
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FACE MASK AND SIMILAR DEVICES HAVING BODY-CONFORMING MEANS

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FACE MASK AND SIMILAR DEVICES HAVING BODY-CONFORMING MEANS

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20 Claims. (Cl. 128—141)

This invention relates to articles intended be placed against and conformed to the body of a wearer, and particularly to such articles used for medical purposes such as face masks and the like.

A face mask comprises, essentially, a hollow body, open along one side, which is adapted to be placed against a patient's face, such as to cover the nose and/or mouth of the patient, and thereby form a confined breathing chamber. The marginal face contacting portion of the mask is intended to form a substantially effective sealing engagement with the wearer's face to isolate the breathing chamber from the surrounding atmosphere. Suitable means are associated with the mask for delivering a gas or gas mixtures, to the breathing chamber for administration to the patient, such as oxygen or oxygen enriched atmosphere for oxygen therapy, or oxygen-anesthetic gas mixtures for anesthesia.

There has been considerable difficulty experienced heretofore in providing a face mask of practical construction which is capable of being comfortably accommodated against the wearer's face while at the same time affording an effective sealing engagement of the marginal rim. One type of mask has been equipped with an air cushion construction along the marginal mask rim to facilitate its conformance with the contour features of the wearer's face. Somewhat similar expediences have involved the use of sponge rubber and the like instead of an inflated cushion element. Although masks of such construction may conform to some limited degree with the facial contours, they do not comply to a sufficient extent with the more prominent irregularities, particularly, for example, around the bridge of the nose. Consequently in such masks the force applied to create sealing pressure is not distributed uniformly along the rim, and these masks must be pressed heavily against the patient for effective seating. As a result, discomforting stresses are produced in localized areas where the mask bears against the patient's face with excessive pressure.

More recently, a mask construction has been proposed in which the marginal face contacting rim comprises a hollow cavity containing a pliable filler material. The purpose of this construction is to allow the mask rim to be shaped and thus "tailor-fitted" to the individual wearer's facial contours for more effective accommodation. This type of construction is more effective generally than the prior masks and when new or first applied may be worn more comfortably. However, the masks of this type that have been proposed up to the present time still are not completely satisfactory or dependable, particularly for continuous use. In particular, the pliable materials that have been used or proposed as a filler for the hollow face contacting rims of these masks, dry out and become hardened in a relatively short period of time. Consequently, these masks may be used effectively only for a short duration, after which the rim portion loses its desirable, pliable qualities and is no longer effective or even usable. Such materials also are incapable of subjection to high temperatures, such as

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encountered in autoclave sterilization procedures, without hardening. Although sterilization of rubber articles, particularly conductive rubber, is usually accomplished by washing in germicidal solutions, autoclave sterilization is utilized, widely, after the use of masks in contagious cases. It is, therefore, desired that masks and the like withstand at least occasional sterilization without ruinous effect. In addition, the materials used as a filler for these masks are not stable under varying thermal conditions and have been found to lose their consistency at body temperatures. Consequently, after the mask has been in use a sufficient time to raise the temperature of the filler material to body temperature, the rim portion of the mask becomes fluid-like, the action of which is then similar, in effect, to that of the air, or sponge, cushion-type masks. As pointed out in connection with such masks, they are not effective in the desired uniform distribution of seating pressure and accommodation of prominent facial features. Some objection has also existed in connection with the relatively high density and excessive weight of the materials theretofore used.

Problems similar to those encountered in effective and comfortable seating of face masks, as described above, also are encountered in other types of articles that are worn or applied to the body of a patient during use. One such article, for example is a respirator shield used widely in the treatment of infantile paralysis where the respiratory power of the patient has been affected. The shield comprises a substantially rigid body which is placed over the chest of the patient to form a confined chamber. Pressure pulses then are delivered to the chamber for assisting the patient's breathing. The edges of the respirator shield body must be firmly and effectively engaged with the patient's body to prevent excessive leakage of the gases producing the pressure pulses. This invariably is uncomfortable to the patient and, up to now, no entirely satisfactory means has been devised for comfortably and effectively seating the shield.

It is an object, therefore, of the present invention, to provide an improvement in articles or devices which are intended to be placed against and to conform to the body of a patient or wearer, which will afford, in a simple manner, a more comfortable and effective seating engagement thereof.

It is another object of this invention to provide for such articles a pliable body engaging portion capable of being shaped or molded to conform as desired to body contours which will retain its pliability and moldable properties, indefinitely.

It is another object of this invention to provide such a body engaging portion which will be of substantially constant pliability and will not tend to become excessively softened at body temperatures.

It is a further object of the present invention to provide an improved face mask of the type having a pliable, peripheral portion adapted to be shaped and conformed to a wearer's facial contours, for more comfortable and effective seating engagement.

It is a further object of the present invention to provide such an improved face mask wherein the pliability of said peripheral portion will remain substantially constant indefinitely and will not vary significantly at body temperature.

It is another object of this invention to provide an improved face mask having a deformable hollow face contacting portion containing an improved, substantially stable, relatively light-weight, pliable filler material.

It is another object of the present invention to provide such an improved face mask wherein said improved filler material is non-toxic and therefore incapable of detrimentally affecting the wearer should said material come into contact with the wearer's skin.

It is a still further object of the present invention to provide an improved face mask of the type having an improved, pliable, face-contacting rim portion which is capable of subjection to autoclave sterilization without substantially altering the subsequent pliability or moldable qualities of said face-contacting rim portion.

In accordance with the present invention there is provided an article adapted to be placed against and conformed to the body of a wearer having a hollow, deformable, body contacting portion and a stable, non-setting compliant filler material therein, said material comprising a mixture of a viscous, non-polymerizable water-soluble, organic liquid dispersant having a boiling temperature at least higher than 100° C., and a finely-divided, insoluble, organic polymer characterized by being inert to said dispersant and non-fusible at temperatures up to at least 100° C. The constituents comprising the filler are mixed in proportions which produce any desired consistency. At the consistency preferred for the purposes of this invention the composition is characterized by possessing a reproducible, stable degree of compliance over the range of room temperatures to body temperature. The desired rheological properties exhibited by the preferred composition include definite, low-yield values together with a relatively high resistance to further deformation beyond a certain initial deformation. To afford a wider latitude of rheological properties, the filler mixture may include smaller amounts of a soluble organic polymer as a thickening agent additive.

Other objects and advantages of the present invention may be better understood by referring to the following description of a preferred embodiment thereof and the accompanying drawings, in which:

Fig. 1 is a side elevation view showing an anesthetic mask embodying a preferred form of the invention, illustrating the manner in which the mask is worn by a patient;

Fig. 2 is an end view of the face mask shown in Figure 1 looking into the interior thereof as it would be viewed by a person putting on the mask; and,

Fig. 3 is a sectional view taken longitudinally through the body of a face mask, along the line 3—3 in Figure 2, looking in the direction of the arrows, showing the deformable, hollow body-contacting rim and the pliable filler composition contained therein.

Referring now to the drawings, a face mask, representative of the type of mask and body conforming article which may be employed in carrying out the present invention, is designated by the numeral 10. As shown in Fig. 1, the face mask 10 which is of the oro-nasal type, is placed against the face of a patient shown at P, such that its marginal rim portion 12 forms a sealing engagement. The mask may be manually held in place or may be secured to the patient's head such as by means of an elastic strap attached to a hook ring 14 on the mask and passed around the back of the patient's head. Preferably, the mask is made of rubber, either natural or synthetic, or some similar flexible material which is capable, at least, of withstanding steam sterilization without ruinous effect. Frequently the rubber compositions used also contain conductive ingredients, such as graphite, which avoid the accumulation of static electrical charges. Usually the mask is preshaped, or molded, in the form of a hollow body, which may be of a generally conical, self-retaining shape as illustrated at 16 in Fig. 3 of the drawings, the side walls of the body 16 being of sufficient thickness to give some degree of form rigidity. At the apex of the conical mask body 16 is formed a substantially thick-walled shoulder 18 having an opening 20 therein adapted to receive a connector fitting such as the connector 22 seen in Fig. 1. A flexible hose 24, Fig. 1, is attached to the connector fitting for the delivery of a respirable gas mixture to a breathing chamber 26 formed within the hollow body of the mask, which is isolated from the atmosphere when the mask is in place. The respirable gases may be, for

example, a mixture of ether vapor and oxygen, such as when the mask is used for anesthesia.

The mask rim 12 as may best be seen in Fig. 3 comprises a peripheral, hollow-section, or cavity 28, defined by a relatively thin-walled membrane 30, which is a part of the mask body. Such a construction may be accomplished in a manner well-known to those skilled in the art. Preferably the mask body and rim are designed and constructed, as is conventionally done, so that the open side of the mask has a peripheral outline that corresponds in a general way with the principal facial features. Thus, a notch 32 is included in the original molded shape of the mask rim to facilitate the seating of the mask over the bridge of the nose. Similarly, side portions 34, Fig. 2, extend further, rearwardly when the mask is worn, to conform in a general way to the hollows of the cheek, and a bottom portion 36 of the rim is arranged slightly forward thereof to correspond to the relative contour of a wearer's chin on which this portion rests. It will be understood, of course, that such permanent pre-shaping of the mask rim cannot provide effective seating for all wearers due to the wide variations in detailed facial characteristics, and serves only to approach the general facial outline. The exact conformity of the mask rim to the wearer's face is achieved by manually shaping the pliable rim 12 which contains a filler material 38 comprising an improved, non-setting pliable mixture in accordance with the present invention. The mixture preferably has a wetting action on the wall membrane 30, which is relatively thin, such that this wall has little tendency to spring away from the filler material and will tend to assume the shape of the filler.

The insoluble organic polymers that may be used for the purposes of the filler composition according to the present invention are the addition and condensation polymers which, when in the form of discrete particles, do not fuse to a homogeneous mass at temperatures up to at least 100° C., and are insoluble in the dispersing medium. Examples of these are vinyl type polymers from polymerizable unsaturated monomers, such as the polymers and copolymers of vinyl chloride, acrylonitrile, styrene, diallylphthalate and vinylidene chloride; ether polymers, such as cured epoxy resins; polyesters, such as polyethylene terephthalate polymers and cured polypropylene maleate-styrene copolymers; polyamides, such as polyhexamethylene sebacamides, and polyamides from omega-aminoundeconoic acid, aldehyde condensate polymers, such as cured phenol-formaldehyde and cured melamineformaldehyde resins; polyurethanes, such as the polyurethane from hexamethylene diamine and the dichloroformate of 1,4-butanediol, and polyester-urethane copolymers; and, polycyclic polymers, such as cuprene.

Preferably the addition and condensate polymers used herein are in the form of finely-divided, discrete particles, preferably in the range of one-half to ten microns diameter. When particles outside of this range are used, particularly sizes above ten microns, the composition does not possess the desired rheological properties which are preferred for use in the present invention. Mechanical attrition methods such as afforded in a ball-mill or the like may be used to produce particles of fine particle size from the solid or larger particle sizes of the resin, although this method is not entirely satisfactory. It is preferable to obtain the insoluble polymer or copolymer material used herein, by aqueous, emulsion, or modified-emulsion, polymerization, for example, as described in the United States Patents Nos. 2,625,539 and 2,729,627. The resin particles produced by such polymerization techniques are extremely minute and, generally, within the preferred range of sizes for use herein. Emulsion polymers of average particle size much below ½ micron are less satisfactory. Such very fine emulsion polymers in aqueous dispersions may be spray dried or heat-treated in order to improve their physical dimensions and properties for

the purpose of the present invention. Of somewhat less convenience but also useful in facilitating obtaining particles of the desired sizes are the suspension, bulk, or solution polymerization methods in which the product separates as a free polymer during the polymerization. The polymers that may readily be prepared in the desired particle sizes by the above emulsion, or modified-emulsion polymerization techniques are preferably used. These include vinyl type polymers made from polymerizable unsaturated monomers, such as the polymers and copolymers of vinyl chloride, acrylonitrile, styrene and vinylidene chloride, and the polyurethanes obtained from hexamethylamine and the dichloroformate of 1,4-butanediol. The most preferred insoluble polymers for the purposes of the present invention are vinyl chloride polymers such as polyvinyl chloride and copolymers of vinyl chloride with minor proportions of other monomers. Such resins have a preferred uniform particle size such that 0.03% maximum is retained on a 200 mesh screen (within the range of 0.5 to 10 microns) and none is retained on a 100 mesh screen. When used as described herein, the filler compositions made therefrom afford exceptionally desirable physical properties without setting, even after prolonged periods of more than one year, and without the tendency, appreciably, to lose consistency at body temperature. Such compositions are also stable at sterilizing temperatures.

The dispersant employed herein is a viscous, non-polymerizable organic, liquid which is inert, or non-injurious, to rubber, either natural or synthetic, as is consistent with its miscibility with water, and will not evaporate during sterilization of the mask or of other articles containing the pliable composition, under normal procedures. The liquid polyhydric alcohols are suitable for this purpose, including, for example, glycols, such as ethylene glycol, propylene glycol, and 1,2-propanediol; polyethylene glycols, such as diethylene glycol; and, glycerin. Glycerin which has a desired viscosity and possesses other desired properties to a high degree, is preferred as the dispersant.

The consistency of the filler mixture and the rheological properties thereof may be adjusted by varying the proportions of the dispersant and the insoluble organic polymers, or by appropriate selection of the dispersing medium. For example, in the latter case, the use of equivalent amounts of polyethylene glycol instead of ethylene glycol or glycerin tends to give a more viscous mixture. The physical characteristics of the filler may also be varied by the use of relatively high molecular weight, soluble polymers as additives to the filler mixture which are particularly useful in affording a wide latitude of rheological properties. Polymers which may be used for this purpose are stable, relatively high molecular weight, polymers soluble in the dispersing medium and include, for example, a number of polyvinyl alcohol polymers and copolymers and various water dispersible cellulose derivatives such as hydroxyethyl cellulose and alkali methyl cellulose carboxylates. These additives, of which polyvinyl alcohol is the most preferred, are used in relatively small amounts compared to the other ingredients. For example, 6 parts by weight of a completely hydrolyzed polyvinyl alcohol together with 350 parts polyvinyl chloride and 250 parts glycerin provides a mixture suitable for the purposes of the invention. The substitution of a less saponified polyvinyl alcohol, for example, 80 percent saponified polyvinyl acetate facilitates solvation of the thickening agent and increases the viscosity of the mixture.

A preferred filler composition for use in accordance with the present invention is prepared by adding six parts of polyvinyl alcohol to 250 parts of glycerin, and mixing. To the glycerin phase, 350 parts by weight of finely-divided, emulsion polymerized, polyvinyl chloride, having the preferred particle size (0.03% maximum retained on 200 mesh screen) are added and the constituents thor-

oughly mixed. When provided with this composition as a filler material, a face mask such as shown in the present drawings affords the desired pliability, enabling the mask rim to be pressed to a desired contour for substantially exact conformity with the face of any patient. The rim retains such shape as long as desired and may be removed if desired without loss of the fitted shape, thus permitting the mask to be replaced readily, without difficulty or exertion. The filler material is stable and will not harden upon aging. Thus, the mask rim retains such pliability indefinitely. It can undergo steam sterilization treatment without harmful effect to the filler and, furthermore, is not significantly softened at body temperature.

A similar composition, also preferred for use herein, was prepared in the manner described above and tested with a Tinius-Olsen plastometer to characterize its rheological behavior. The composition consisted of 6 parts by weight of polyvinyl chloride, of the same particle size given above, and 4.5 parts glycerin. 10 grams of the dispersion mixture, having a putty-like consistency, were tamped into a short length of glass tube and this cylindrical plug pushed out onto aluminum foil supported by a smooth glass surface. The extruded plug was $\frac{7}{8}$ inch in diameter and $\frac{1}{16}$ inch high. In the plastometer incremental forces were applied upon the cylindrical plug of the test mixture and the separation of the plastometer surfaces recorded at each increment, 1 minute and 5 minutes after contacting the plug (the plug was protected above and below by aluminum foil). The gauge reading was zero with the two foils in place. The following tabulated data shows the percent of the initial height of the plug observed 5 minutes after applying each increment of force, in which time it was observed that cold flow, from each incremental load, had substantially ceased.

TABLE

Deformation under incremental loads

Force, kg.	Percent of Initial Height	Force, kg.	Percent of Initial Height
0.0.....	100.00	2.5.....	63.1
0.5.....	100.00	3.0.....	48.9
1.0.....	98.2	3.5.....	48.3
1.5.....	90.5	4.0.....	47.9
2.0.....	82.1		

As indicated in the above data, the cylindrical plug did not change its shape appreciably under a force of 0.5 kg., but yielded readily under forces in the range of 2 to 3 kg. Higher forces in the range of 3.0 to 4.0 kg. caused little further deformation. This test illustrates the desired rheological properties of the preferred filler compositions of the present invention, which it is seen possess a definite low yield value, i.e., do not cold flow of their own volition but are readily pliable under the influence of moderate pressures, and are relatively resistant to deformation beyond a certain limit. It will be seen that the rim of a face mask provided with such a filler composition may be readily shaped to a desired impression. However, when the filler material has been initially stressed in the fitting of the mask it becomes more firm and offers greater resistance to the additional forces applied for sealing the rim of the mask, thus enabling the mask rim to accommodate and distribute these greater forces more effectively.

It will be understood that the invention is not limited to the specific embodiments herein described and that various modifications thereof are possible. The invention may be utilized and practiced by those skilled in the art in other ways, without departing from the spirit or scope thereof, as defined by the following claims.

This is a continuation of our co-pending application Serial No. 565,352.

We claim:

1. An article adapted to be placed against and conformed to the body of a wearer comprising a deformable,

hollow, body-contacting portion having a stable, non-setting, compliant filler material therein characterized by possessing a substantially uniform degree of compliance over the range of room temperature to body temperature, said filler material comprising a cohesive, nonsetting mixture of a viscous, nonpolymerizing, organic liquid dispersant having a boiling temperature above 100° C., and a finely-divided solid which is insoluble in said dispersant and nonfusible at temperatures up to at least about 100° C.

2. An article according to claim 1 wherein said dispersant is a liquid polyhydric alcohol having a boiling temperature above 100° C.

3. An article according to claim 2 wherein said dispersant is glycerin.

4. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising a vinyl type polymer from polymerizable unsaturated monomers.

5. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising a cured epoxy resin.

6. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising a polyester selected from the group consisting of polyethylene terephthalate polymers and cured polypropylene maleate-styrene copolymers.

7. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising a polyamide selected from the group consisting of polyhexamethylene sebacamides and polyamides from omega-aminoundeconoic acid.

8. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising an aldehyde condensate polymer selected from the group consisting of cured phenol-formaldehyde resin and cured melamine-formaldehyde resin.

9. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising a polyurethane selected from the group consisting of the urethane from hexamethylene diamine and the dichloroformate of 1,4-butanediol and polyester-urethane copolymers.

10. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising cuprene.

11. An article according to claim 1 wherein said finely-divided solid is an organic polymer of a particle size in the range of 1/2 to 10 microns.

12. An article according to claim 1 wherein said finely-divided solid is an organic polymer comprising an emulsion-polymerized polymer having a particle size in the range of 1/2 to 10 microns.

13. An article according to claim 12 wherein said emulsion-polymerized polymer is selected from the group consisting of vinyl polymers and polyurethanes from hexamethylene and the dichloroformate of 1,4-butanediol.

14. An article according to claim 13 wherein said dispersant is a liquid polyhydric alcohol having a boiling temperature above 100° C.

15. An article according to claim 14 wherein said dispersant is glycerin.

16. An article according to claim 1 wherein said dispersant comprises glycerin, and said insoluble, finely-divided solid is an organic polymer comprising finely-divided polyvinyl chloride.

17. An article according to claim 16 wherein said finely-divided polyvinyl chloride is of a particle size in the range of 1/2 to 10 microns.

18. An article adapted to be placed against and conformed to the body of a wearer comprising a deformable, hollow, body-contacting portion having a compliant filler material therein comprising a mixture of 350 parts by weight of polyvinyl chloride, 250 parts by weight of glycerin and 6 parts by weight of polyvinyl alcohol.

19. An article according to claim 18 comprising a face mask defining a breathing chamber and wherein said body-contacting portion comprises a marginal face-contacting rim adapted to engage the face of the wearer and form an effective seal preventing escape of gases from said breathing chamber to the atmosphere.

20. A face mask made of rubber comprising a hollow body defining a breathing chamber and a flexible, hollow rim forming a face-contacting portion of said body, said rim being adapted to be deformed to accommodate the facial features of the wearer for effecting a substantially gas-tight sealing engagement, and said rim containing a compliant filler composition comprising a mixture of polyvinyl chloride and glycerin proportioned to give said filler a consistency effective to render said rim pliable and shape-retaining.

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