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METHYL CELLULOSE SPONGE AND
METHOD OF MAKING

Nathan Millman, Somerville, and Roger E. Homm,
Neshanic, N.J., assignors to Ortho Pharmaceutical Cor-
poration, a corporation of New Jersey
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This invention relates to surgical sponges and, more particularly, to a methyl cellulose sponge that is absorbable by animal bodies.

Sponges are used in the practice of surgery to absorb fluids such as blood from the operating area. It is common practice to saturate such sponges with a coagulating agent before placing them in the incision. In this manner, the flow of blood is slowed and the presence of blood within the area of operation is minimized. Sponges for this purpose must be sterile and nontoxic. In addition, it is most desirable that the sponge be of a material that will be assimilated by the body since the danger that a surgical sponge may inadvertently be left in an incision is always present.

Gelatin sponges have been proposed for surgical sponges but such sponges are difficult to manufacture and are structurally weak as they will break up if subjected to any mechanical strain. It is another disadvantage that it will decompose at relatively low temperatures, which makes sterilization a problem.

Accordingly, the principal object of this invention is to provide a sponge-type substance which will be readily absorbable by the human body and which may be readily cut or formed into pieces that conform in size and shape to the contour of the area being treated.

It is a further object of this invention to provide a sponge characterized by a controlled and predictable absorption time.

It is a further object of this invention to provide a surgical sponge that will withstand sterilization temperatures as high as 190° C. without decomposition or deformation.

Still another object of this invention is to provide a sponge-like substance that may be manufactured in large volume by an economical process.

In practicing my invention, an aqueous solution of methyl cellulose is prepared and air is violently beaten into the solution with rapid agitation. A Waring Blendor, for example, will provide suitable agitation when working with a small quantity of methyl cellulose solution. After about 1 to 3 minutes of agitation, the methyl cellulose solution contains a large amount of occluded air that is uniformly dispersed in the form of small gas bubbles. Because of the appreciable viscosity of the methyl cellulose solution, the gas bubbles in the dispersed phase do not coalesce and the dispersion of air in the methyl cellulose solution is quite stable. This is true even though the dispersion be heated. Thus the product after agitation may be poured onto a hot surface or into a container of any size, shape or dimension. If the sponge is prepared by casting on a hot surface, the temperature of the surface should be maintained between 60° C. and 100° C., preferably the temperature is just below the boiling point of water. If the sponge is formed in a container, the container may be conveniently placed in an oven heated to 60–100° C.

The methyl cellulose that is used in preparing the aqueous solution has a methoxyl content of from 27.5 to 32.0%. This range produces a product having satisfactory water solubility. A lower degree of substitution forms a sponge that is soluble only in alkaline media,

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while a greater methoxyl content produces sponges that are soluble only in organic solvents.

The amount of methyl cellulose that is dissolved prior to the foaming step may vary from as little as 0.5% to as much as 12% by weight, depending upon the viscosity type of methyl cellulose used. Methyl cellulose is obtainable in a wide range of viscosities. In identifying the viscosity types of methyl cellulose in the present specification and claims the absolute viscosity (cps.) of 2% aqueous solutions at 20° C. is used. Viscosity types, from 10 to 700 cps. may be employed in producing sponges according to the present invention. In general, the low viscosity type methyl cellulose is used in higher concentration than the high viscosity type methyl cellulose. We find that entirely satisfactory sponges may be prepared from aqueous solutions containing 2% to 3% by weight of 4000 cps. methyl cellulose.

To increase the solubility and decrease the absorption time of methyl cellulose sponges other compounds may be added to the methyl cellulose solution before foaming. Urea, for example, when present in amounts up to 5% by weight will greatly increase the solubility of the methyl cellulose sponge. As little as 0.5% urea has an appreciable effect in reducing the time required for absorption. Aldehydes such as formalin and glyoxal (1 to 2.5% by weight of a 30% aqueous solution) will accomplish a similar result. When urea and formalin are combined with methyl cellulose in solution and heated, a urea formaldehyde resin is formed which decreases the solubility of the methyl cellulose sponge.

It is entirely unexpected that a foamed dispersion of air bubbles in an aqueous solution could be heated to temperatures that would drive off the water without coalescing the individual air bubbles and breaking down the foam. Since methyl cellulose reduces the surface tension of water, frothing or foaming might be anticipated if air were introduced into the solution during agitation. The heating of solutions is, however, a well-known method of expelling dispersed air bubbles. While we do not wish to be restricted to a particular theory, we believe that the exceptional characteristic of the aqueous methyl cellulose foams that permits heating the dispersion to elevated temperatures without breaking down the foam is due to the unique temperature-viscosity relationship of aqueous methyl cellulose solutions. In general, the viscosity of a solution will decrease as the temperature is raised. Aqueous methyl cellulose solutions, however, are peculiar in that the viscosity first decreases until a temperature of about 50° C. is reached and then increases sharply at higher temperatures. In addition, methyl cellulose differs from other well-known colloids in that its solutions gel on heating while those of other colloids gel on cooling. The simple process of making a sponge described above may be operated only because the methyl cellulose solutions when heated increase in viscosity thus making escape of the minute air bubbles more difficult. In addition, when at the concentration preferably employed (2% to 3%) methyl cellulose solutions will gel at about 55° C. Thus it is our belief that when the methyl cellulose foam is heated to temperatures of 60–100° C., the solution gels before the occluded gas may escape and therefore locks the minute gas bubbles in place. The gel so formed however is somewhat elastic and will permit expansion of the occluded gas on heating. During the heating or baking step, therefore, the air bubbles expand and the water content of the gel is vaporized. The resulting product is a uniformly porous sponge that has a density between 10 and 20 milligrams per cubic centimeter. Such sponges will absorb from 10 to 15 times their weight of water and may be sterilized at temperatures as high as 190° C. without discolorization or deformation. As mentioned

above, the solubility of the product may be quite closely controlled by additives.

Table I summarizes a series of tests in adult rats on methyl cellulose sponges that have been modified with urea, formalin, glyoxal, or mixtures of urea with formalin.

Twenty-one examples of methyl cellulose sponges prepared from aqueous solutions containing from 1.3 to 5% by weight methyl cellulose (4000 cps. viscosity type) are summarized in Table II. All of the compositions listed in Table II gave satisfactory surgical sponges by the process described above.

Table I

Foam	Percent MC	Percent Urea	Percent Formalin	Percent Glyoxal	Density, mg./cc.	Size Tested in Abdominal Cavity	No. of Rats	Absorption Time, days
Fo56-6-14	3	1	1	-----	20	7 cm. x 2 cm. x 1 cm.	2	15-28
Fo56-6-14B	3	2	2	-----	20	7 cm. x 2 cm. x 1 cm.	8	15-34
Fo56-8-21	3	0.5	0.5	-----	18	7 cm. x 2 cm. x 1 cm.	3	20-50
Fo56-8-23	3	0.75	0.75	-----	20	7 cm. x 2 cm. x 1 cm.	3	20-50
Fo56-8-23A	3	1	1	-----	20	7 cm. x 2 cm. x 1 cm.	3	<19
Fo56-8-23C	3	1.5	1.5	-----	20	7 cm. x 2 cm. x 1 cm.	3	19-60
Fo56-8-28	3	-----	-----	-----	10	7 cm. x 2 cm. x 1 cm.	3	10
Fo56-8-28A	3	-----	0.5	-----	10	7 cm. x 2 cm. x 1 cm.	2	<15
Fo56-8-28C	3	-----	2.5	-----	10	7 cm. x 2 cm. x 1 cm.	2	<15
Fo56-8-30	3	-----	-----	0.48	15	7 cm. x 2 cm. x 1 cm.	3	<12
Fo56-6-14C	3	0.5	-----	-----	15	7 cm. x 2 cm. x 1 cm.	1	<10

Limitations:

	Range, percent	Ideal, percent
Methyl Cellulose	0.5-12.0	3.0
Urea	0.0-5.0	0.5
Formalin	0.0-4.0	0.5
Glyoxal	0.0-2.5	1.0

Table II

Foam	Percent MC	Percent Urea	Percent Formalin	Percent Glyoxal
Fo54-12-23A	2.0	-----	-----	0.15
Fo54-12-27B	3.0	-----	-----	2.5
Fo54-12-27C	4.0	-----	-----	2.5
Fo55-2-28C	4.0	-----	-----	-----
Fo55-2-28D	5.0	-----	-----	-----
Fo55-3-3	1.3	-----	-----	-----
Fo56-3-8A	3.0	0.5	-----	-----
Fo56-3-8B	3.0	1.0	-----	-----
Fo56-4-10A	2.0	1.25	-----	-----
Fo56-4-10B	2.0	2.5	-----	-----
Fo56-4-10C	2.0	3.75	-----	-----
Fo56-4-10D	2.0	5.0	-----	-----
Fo56-6-14A	3.0	-----	1.00	-----
Fo56-6-14C	3.0	2.0	-----	-----
Fo56-6-19A	3.0	4.0	4.00	-----
Fo56-6-21A	3.0	0.25	0.25	-----
Fo56-8-21B	3.0	0.125	0.125	-----
Fo56-8-23B	3.0	1.25	1.25	-----
Fo56-8-28C	3.0	-----	2.5	-----
Fo56-8-30A	3.0	-----	-----	0.33
Fo56-8-30B	3.0	-----	-----	0.18

The use of a large container to prepare surgical sponges of large size presents no unusual difficulties. It is also possible to build up a large sponge by sealing together a large number of similar sponges. Two sponges may be firmly united by moistening the surface of each and pressing the moistened surfaces together until dry.

It will be apparent to those skilled in the art that the

principal objects of this invention have been accomplished and that numerous and various changes and modifications may be made in the embodiments of the invention herein described and that the invention is capable of use and has advantages not specifically described herein. It will therefore be appreciated that the present disclosure is to be construed in the nature of illustration only, and that the invention is to be limited or delineated only by the appended claims.

What is claimed is:

1. A water permeable methyl cellulose surgical sponge

30 capable of absorbing 10 to 15 times its weight of water, and having a methoxyl content of from about 27.5 to 32.0%.

2. A water permeable surgical sponge having a matrix essentially of methyl cellulose and characterized by substantially complete biological absorbability in a living animal body in between about 10 and about 60 days, and having a methoxyl content of from about 27.5 to 32.0%.

3. A water permeable surgical sponge according to claim 2, the matrix of which contains a minor quantity of formaldehyde.

4. A water permeable surgical sponge according to claim 2, the matrix of which contains a minor amount of glyoxal.

5. A water permeable surgical sponge according to claim 2, the matrix of which contains a minor amount of urea.

6. A water permeable surgical sponge according to claim 2, the matrix of which contains a minor amount of urea and formaldehyde.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

Patent No. 3,005,457

October 24, 1961

Nathan Millman et al.

It is hereby certified that error appears in the above numbered patent requiring correction and that the said Letters Patent should read as corrected below.

Column 1, line 31, for "sponge-type" read -- sponge-like --; column 2, line 10, for "700" read -- 7000 --.

Signed and sealed this 17th day of April 1962.

(SEAL)

Attest:

ESTON G. JOHNSON

Attesting Officer

DAVID L. LADD

Commissioner of Patents