

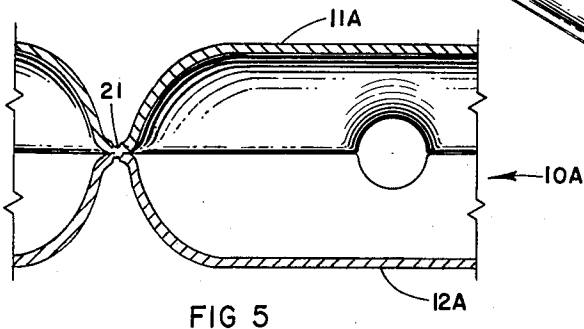
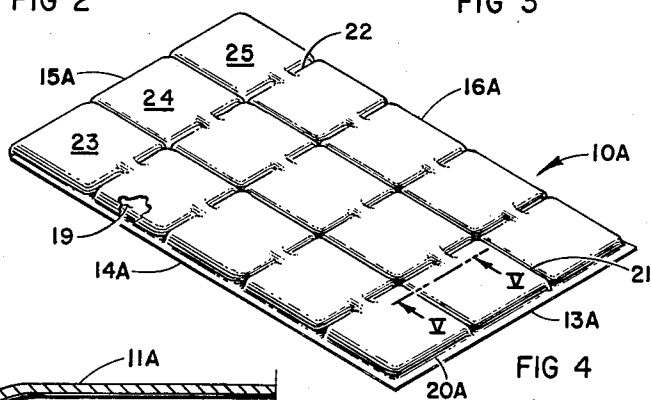
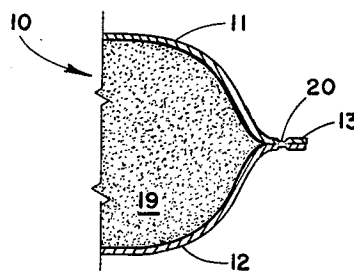
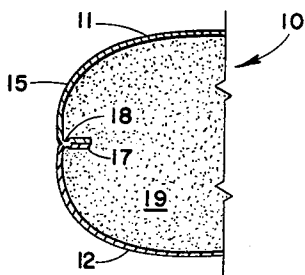
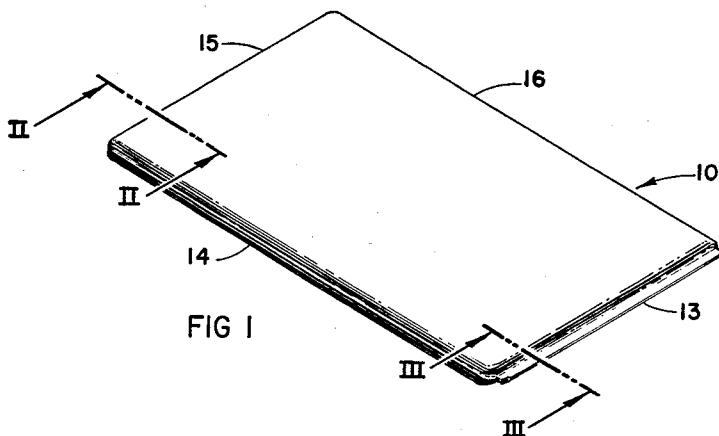
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THERAPEUTIC HEAT-TRANSFER DEVICE

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THERAPEUTIC HEAT-TRANSFER DEVICE
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This invention relates to devices for temperature control of a human body and more particularly to a device for such purpose and moldable to conform, over a wide range of temperatures, to the contours of the body part whose temperature is controlled thereby.

It previously has been recognized that, for most efficient temperature control of a part of a human body by an appliance such as an ice pack or hot water bottle, it would be desirable that as much area as possible of the temperature-controlled part be in contact with the surface of the appliance. While it has not been believed practically possible, however, to obtain this result in hot to moderately cold appliances, several devices have been proposed for providing a pack which is formable while very cold (i.e., from a few degrees below 32° F. and downwardly to still lower temperatures).

Typical, previously proposed devices of this character have included a bag with thin, flexible walls and containing a liquid consisting of water to which has been added enough of a freezing point depressant to bring about the transformation of the liquid, at a temperature below 32° F., into a slushy mass. The bag, lowered to this temperature, can be pressed against a body part which it cools and thus is molded to a shape generally conforming to the part where it contacts the same. The slush, which contains many small grains or crystals, tends to retain the molded shape and thus improves the uniformity and rate of cooling of the therapeutically treated part.

While constituting genuine advances in the art, these devices have had serious shortcomings and disadvantages which have greatly curtailed their benefits and usefulnesses. The slush-forming additive to the water has been a freezing-point depressant such as glycerine, various glycols and alcohols, glycol ethers, etc.

Many of these additives have had annoying disadvantages which tend to limit their desirability. All, for example, are liquids and, when combined with the water filling the cold-pack bag, readily leak from any small rupture which may be present in the bag. Glycerine, in particular, exhibits a tendency to leak out of very small cracks and orifices through which water would not ordinarily pass.

More seriously limiting the usefulness of these devices and even rendering them dangerously injurious for some usages is the narrow temperature range within which the materials employed are formable and the relatively extreme coldness of the appliance when within that range. The range over which even butyl and amyl alcohols form a slush is excessively narrow, and this range is even more restricted in the case of ethyl and methyl alcohols. When the latter are added in moderate amounts to water, the resulting liquid forms a slush which melts at a temperature below 32° F. but which, if cooled further, becomes a hard, unyielding mass at 5 or 10 degrees below the freezing point of water. The remaining additives cited above, if added in sufficient quantity, remain slushy at lower temperatures and are formable even down to 0° F.; all, however, continue to melt at a temperature well below the freezing point of water.

One of the best of these solutions, containing water with propylene glycol, forms slush at around 27° F. and is still slushy at 0° F. This range, in terms of degrees Fahrenheit, is very narrow and inadequate in comparison with the range over which temperature control of a body member, for various therapeutic purposes is desir-

able. While extremely cold applications well below freezing are occasionally needed, many conditions occur in which it is desirable to keep a body member warm or even as hot as may be tolerated. The sole advantage of the previous devices over a bag of cold water, except in the rare cases where extreme cold is actually of most benefit, lies in their formability, within the slushing range, for close conformity to the part treated. The range of formability is too cold, however, for treatment of many conditions (i.e., circulatory embarrassments, etc.) and in all cases extreme care and caution must be employed to avoid frostbite of the treated part. Though moderate cold (i.e., above 32° F.) is most commonly of most benefit where cold is needed, the slush has melted in this range and the therapeutic device has become a mere cold-water bag with no ability of its contents to retain an impressed shape. The same is true, of course, throughout the wide range of "warm" and "hot" up to the limits of human endurance, in which range the prior devices are capable of no result beyond that of an ordinary hot water bottle.

In many cases where temperature control of an affected part is required, it would be more convenient or comfortable to the patient to form the therapeutic device to the contour of the treated part while the device is at room or body temperature and hence before bringing the device to the temperature of treatment. This clearly is impossible in the case of the previously employed slushing devices, which are formable only below the freezing point of water. In addition, the slush after being formed to the affected part tends to flow or creep and thus is inclined to lose its initial conformity to the treated body part.

In addition, the specific heat, in the previously known devices, is undesirably low and thus limits the extent of temperature control which can be exerted per unit weight as well as volume of the cold pack. Water being the material of highest known specific heat, it would be desirable for maximum efficiency that the bag contents be pure water. To acquire more than a token range of formability of the device, however, it has been necessary to employ so much additive in the water that the specific heat of the device is reduced to an undesirably large degree. Though acquired at expense of a significant loss of efficiency of the device, the widened range of formability so achieved is still very narrow since it does not extend into the wide and important range lying above 32° F.

It is apparent that it is highly desirable to provide a therapeutic device of improved operation and benefits and not subject to the disadvantages and limitations which heretofore have been inherent in devices for temperature control of a part of a human body.

Accordingly, it is a major object of the present invention to provide a device, for temperature control of a part of a human body, which is moldable and form-retaining throughout a greatly increased range of temperatures.

Another object is to provide a therapeutice heat-controlling device which is moldable and shape-retaining at temperatures above the freezing point of water and up to temperatures at and even beyond the limits of human tolerance.

A further object is to provide a therapeutic heat-controlling device which successfully maintains an initial shaping into conformity with a body part whose temperature is controlled thereby throughout a much wider range of temperatures than previously has been possible and without cooling of the device to a temperature so low as to evoke the danger of frostbite of the temperature-controlled part.

A further object is to provide a therapeutic heat-controlling device whose specific heat is of the general order or better than that of previous heat-controlling devices

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and whose formability and shape retention is maintained over a much greater range of temperatures.

An additional object is to provide a device of the character thus far stated and which is much less subject to leakage at temperatures above freezing.

Yet another object is to provide a device of improved comfort to the patient and which is easily and inexpensively made.

Other objects and advantages will be apparent from the specification and claims and from the accompanying drawing illustrative of the invention.

In the drawing:

FIGURE 1 is a perspective view of an embodiment of the invention;

FIGURE 2 is a partial, longitudinal sectional view taken as at line II—II of FIGURE 1;

FIGURE 3 is a similar view taken as at line III—III of FIGURE 1;

FIGURE 4 is a perspective view of a modification of the embodiment shown in FIGURE 1; and

FIGURE 5 is a partial, cross-sectional view taken as at line V—V of FIGURE 4.

With initial reference to FIGURES 1, 2, and 3, the device for temperature control of a part of a human body comprises a bag 10 having front and rear walls 11, 12 made of a flexible, pliable plastic which is thin enough to conform readily to the contour of a part, such as a hand, facial area, etc. with which it is brought into contact. Besides enabling the walls 11, 12 to conform readily to the temperature-controlled part, a material which is softly pliable is preferred since it is more comfortable and agreeable to the patient. A thermoplastic film preferably is employed as the material of the walls 11, 12, polyvinyl chloride films and polyethylene films being exemplary of suitable materials. The front and rear walls 11, 12 may be separate sheets, or, as in the preferred mode of construction, a single, rectangular sheet folded to place the free edges of the front and rear walls in register and in faying relation with each other about three sides 13, 14, 15 of the bag, the fold occurring at the fourth side 16, which thus is initially closed. The free edges of the front and rear walls, 11, 12 are turned inwardly of the bag along one side 15 of the latter, as shown in FIGURE 2, and heat is applied to bring about a local melting and fusion of the thermoplastic material of the front and rear walls 11, 12 which produces a weld which seals the bag along the entire side 15. The edges of the front and rear walls 11, 12 preferably are turned inwardly and welded together, as shown at 17 in FIGURE 2, along the entire length of the adjoining side 14 of the bag as well. Since the material of which the bag 10 is made is folded along the side 16 and since the two sides 14, 15 are sealed by welding as described, the bag 10, before placing the thixotropic material therein, is sealed along three sides 14, 15, 16 and open along its fourth side 13.

A convenient way of making the bag with wall edges turned inwardly (as in FIGURE 2) along the two sides 14, 15 is to fold the plastic sheet, from which the bag is made, along the side 16 to bring the edges of the upper and lower walls 11, 12 into register and faying relation with each other along the bag sides 13, 14, 15. With all the edges of the two walls 11, 12 extending outwardly of the bag, a weld is made along the entire length of the two sides 14, 15 of the bag. The wall edges at each side 14, 15 thus will appear as in FIGURE 3, the difference in orientation being taken into consideration in each case. The bag then is turned inside-out to turn the wall edges, along the two sides 14, 15, inwardly of the bag as shown in FIGURE 2. A major linear portion of the free edges of the two walls 11, 12 thus is welded together as at 18 (FIGURE 2) and turned inwardly; and the result is a neat and attractive closure of the bag 10 along the sides 14, 15. The welding of the bag material preferably is performed with a metallic strip some-

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what longer than the side 14 or 15 being welded and maintained at a temperature at which, during the time it is in contact with the material of the bag 10, will effect the necessary fusion of the walls 11, 12 without burning or otherwise damaging the bag material. The heated strip is placed along the side 14 or 15 of the bag at or somewhat inwardly of the extreme margins of the faying edges of the walls 11, 12, is held in place until the walls have fused together, and then is removed to allow cooling and setting of the weld. Other techniques are possible, and since the welding together of thermoplastic sheets is widely known and practiced, the details of the welding operation will not be further elaborated.

The thixotropic mixture 19 is water with a relatively small percentage of a filler added thereto. The filler is a material substantially insoluble in water and divided into particles small enough to form, with the water, a thixotropic colloidal mixture. Materials which have yielded excellent results are titanium dioxide, magnesium silicate, and the naturally occurring rock or clay known as bentonite; carbon also is suitable as a filler material and gives good results although it is more difficult to wet than the other materials listed. The chosen material is divided into particles less than 3 microns in diameter, and particles of approximately 1 micron in diameter are employed in the preferred embodiment. Enough of the filler is mixed with the water to form a mixture which readily yields and flows upon the application of a light pressure but which stands without creeping or flowing following removal of the pressure. The total content, by weight, of the filler in the mixture is less than 8%, mixtures containing 5% of the filler by weight having been found to be of an entirely satisfactory consistency. When much less filler than 5% is employed, the mixture loses its ability to retain its form upon removal of a molding pressure, while over 8% of filler in the mixture is inclined to produce too thick a mixture. For greatest thermal efficiency of the device, as little filler as possible for obtaining a desired consistency should be employed in order that as high a percentage as possible of the mixture will be water, the latter having the highest specific heat of any known material.

Admixture of the filler into the water and rapid formation of the thixotropic mixture 19 is greatly facilitated by adding a small quantity of a wetting or dispersing agent to the admixed water and filler. The octylphenol-ethylene oxide condensates (for example, "Triton X-100" marketed by the Rohm & Haas Co. of Philadelphia, Pa.) are satisfactory dispersing agents, as are the alkali metal salts of sulfonated naphthalene complexes (such as "Tamol N," also marketed by the Rohm & Haas Co.).

The thixotropic mixture 19 resulting from combining ingredients as described above is introduced into the bag 10 to fill it to a desired thickness and shape, and the bag walls 11, 12 preferably are pressed about the mixture they contain to expel substantially all air, whereupon the bag's fourth side 13 is sealed by producing along its length a weld 20 which joins the bag's front and rear walls 11, 12 near or at their free edges as shown in FIGURES 1 and 3. All the free, faying edges of the two walls 11, 12 thus are sealingly joined to seal the thixotropic mixture in the bag 10, the major portion of the faying edges being joined as already described along the bag sides 14, 15 and a minor linear portion extending outwardly along side 13 and welded as shown in FIGURE 3 to complete the sealing of the aqueous mixture 19 in the bag 10.

While the thixotropic mixture 19 made as already described yields excellent results, an important modification of the invention employs a thickener which permits the use of much less filler than specified above without loss of the desired thixotropic characteristic. The thickener is a water-swelling, colloidal, organic material of which sodium alginate is a preferred example. Less than 1% by weight of the thickener is employed in the mixture 19.

An excellent thixotropic mixture is obtained by adding sodium alginate to the water to the extent of $\frac{1}{2}\%$ of the total weight of the mixture. After mixing the water and thickener, 3% (by weight) of filler is added and given a preliminary mixing. The dispersing agent then is added and the ingredients are mixed until the thixotropic state is fully attained. It will be noted that, by virtue of the presence of the thickener, the total percentage of additives in the water is much reduced, thus increasing the percentage of water present in the mixture 19 and further increasing its already thermal efficiency, which already is very superior in a material having formability over as wide a range of temperatures, as will be further discussed.

While for many therapeutic uses formability at temperatures below the freezing point of water will not be required, occasions will conceivably arise in which a very low temperature of the device will be desired and at which temperatures the device must be formable. Low-temperature formability is attained (without loss of the ability to retain an impressed form upon the device having risen above the freezing point of water) by the addition of a freezing-point depressant to the mixture. The function of the depressant is to cause the water in the mixture to form many small, relatively free crystals when below its freezing point and thus to leave the mixture formable. Many materials suitable for depressing the freezing point of water to cause the water to form a slush rather than ice when below 32°F . are known, and a number are named and their use for this purpose described in U.S. Patent 2,366,989 to Robertson and U.S. Patent 2,378,087 to Kearney. Ethylene and propylene glycol, for example, are both satisfactory in this capacity. As taught in the Kearney patent, a mixture of 5% to 10% (by volume) of propylene glycol in water begins to freeze above 27°F . but is still a yielding, slushy mass of crystals even at 0°F . A similar amount of propylene glycol yields the same result when added to the thixotropic mixture, about 3% to 5% by volume generally being adequate for preventing hard freezing.

Whereas a mixture composed of water and a freezing-point depressant retains an impressed form only while far enough below the freezing point of water to be slushy, the thixotropic mixture of the present invention is moldable and form-retaining at temperatures so high as even to be beyond the range of human tolerance. While without the freezing point depressant the thixotropic mixture freezes to a hard solid at or very near 32°F ., it is formable and form-retaining from about 32°F . to beyond the highest temperature (for example, 135°F .) at which it will ordinarily be employed for therapeutic purposes. This wide range of temperatures throughout which the mixture is moldable and shape-retaining permits highly efficient temperature control of an affected member at moderately cold temperatures (32°F . and above) or, where required by the condition treated, at as high a temperature as desired. Because of the pliability of the film of which the bag is made and because of the thixotropic nature of the mixture with which the bag is filled, a slight pressure forcing it against the affected part causes it to assume the contours of the part and to retain the same, even at high temperatures, when the pressure is removed. Surface contact between the device and body part is thus readily effected over the widest possible area and easily maintained since the mixture does not melt or lose its formed shape upon a change in temperature.

Where sub-freezing temperatures are desired, however, the device is readily employable. The body part to be treated is pressed against the device to mold it into close conformity with the contours of the part, and this is accomplished with the device at room temperature or any other convenient above-freezing temperature. The device then is carefully removed and, without disturbing its formed shape, cooled to as low a sub-freezing temperature as desired. Upon freezing, the device becomes hard

and solid but still retains the impressed shape so that it fits the body part perfectly when again placed upon it. The temperature range of form retention of this version of the temperature controlling device thus is even wider than and includes the already wide range of formability.

By addition, where desired, of the freezing-point depressant, the thixotropic mixture does not freeze hard and is still formable at temperatures as low as, if desired, 0°F . Because the thixotropic mixture will not of itself run through pinholes, etc. in the bag but must be actually forced before it will pass through such an opening, leakage is no problem even though glycerine be employed as the freezing-point depressant. Though only a minor item in comparison with the benefits pointed out above, this nonetheless is obviously an important advantage, in itself, over previous devices employing glycerine or other freezing-point depressants to prevent hard freezing below 32°F .

FIGURE 4 shows a form of the device in which the bag front and rear walls 11A, 12A are made from separate sheets and thus have free, faying edges at all four sides 13A, 14A, 15A, 16A of the bag 10A. These edges all extend outwardly of the bag 10A and are joined, to seal the mixture in the bag, by welding in the manner shown at 20 in FIGURE 3. While the appearance of the bag of FIGURE 1 wherein there are no outwardly turned free edges except at side 13 will be preferred by some, the bag 10A of FIGURE 4 is nonetheless neat and attractive in appearance and somewhat simpler to manufacture. The use of a single sheet to form both walls 11A, 12A, thus placing a fold at one of the sides (as at the side 16 in FIGURE 1) is of course readily possible where all free edges of the walls 11A, 12A are turned outwardly as in FIGURE 4. Further, a cylindrical material may readily be employed, thus eliminating free edges of the walls 11A, 12A at two sides (e.g., the sides 14A, 16A of the bag) and thus necessitating welds at only the two remaining sides 13A, 15A.

Although, for ease of illustration and explanation, a rectangular bag has been shown and described, it will be understood that bags of any other polygonal form are readily made according to the invention, the bag preferably being made to correspond to the general size and shape of the part whose temperature it is to control.

FIGURE 4 shows an additional feature which is especially valuable where the area of the device must be quite large, as, for example, where it must cover most of the entire dorsal or ventral surface of a human body. In such case, some difficulty may be experienced in evenly distributing the thickness of the thixotropic mixture and in avoiding pushing or squeezing too much of it to one location to the loss of sufficient material in another. Such difficulty is prevented by a plurality of welds placed in criss-crossed lines across the main body of the bag 10A to divide it into a plurality of compartments. The sides 14A, 15A, 16A of the bag first are sealed by edge-welds, then the spaced, longitudinal welds such as weld 21 are applied. Each of these extends the length of the bag and sealingly joins the front wall 11A to the rear wall 12A, as where the two walls are joined by the weld 21 (FIGURE 5). The bag end 15A opposite the as yet unsealed end 13A then is filled with the thixotropic mixture, and the front and rear walls are joined by the transverse weld 22 which thus seals the introduced mixture into a plurality of end compartments 23, 24, 25. Thixotropic mixture again is introduced to fill the bag adjacent this last-applied weld 22, whereupon a second transverse weld, spaced from the first, is applied to form another plurality of mixture-filled compartments. In similar fashion, the entire bag is filled and compartmented, the final compartments being closed by the end weld 20A. The thixotropic mixture 19 is omitted from the view presented in FIGURE 5 in order

that the details of construction of the bag 10A may be better shown.

While the front and rear walls of the bag, for example the walls 11, 12 of FIGURE 1, have been spoken of as made of a thermoplastic material and their free edges sealingly joined together by welds, as described, for sealing the bag, it will be understood that a thermosetting material may be used, where preferred, for the front and rear walls 11, 12 or 11A, 12A and their free, faying edges sealingly joined, by known technics, by means of a cement. Examples of thermosetting materials suitable for making the front and rear walls include the various terephthalic polyester films such as, to specifically point out one, the "Mylar" material marketed by E. I du Pont de Nemours & Co. (Inc.), Wilmington, Delaware.

Under conditions of use wherein there is the possibility of spoilage of the thixotropic mixture because of, for example, fermentation of the thickener, the device may be pasteurized after the mixture 19 is sealed in the bag; alternatively, a small amount of boric acid or other preservative may be added to the mixture during its preparation.

Because of its close conformity to (and hence, maximum surface contact with) the temperature-controlled member, a lower temperature of the contents of the bag, for example, the bag 10 of FIGURE 1, may be employed while still achieving as much elevation of the over-all temperature of the part as in a less efficient device at much higher temperature. As a consequence, the patient finds the device much more comfortable, as is also the case where the part must be cooled to a low temperature, the device not having to be made so cold to achieve a given degree of over-all cooling. The lack of any pressure needed for maintaining conformity of the device to the treated part also contributes greatly to patient comfort, as does the entire absence of filler caps or stems or thick patches covering an opening through which the bag has been filled. Meanwhile, the material of the bag and the water for the mixture are quite inexpensive, as is the manner of making the device, and the low percentages of the ingredients other than the water in the thixotropic mixture render the quantities required quite low in cost. The device, therefore, is both easily and inexpensively made, and, as seen from the foregoing, is convenient and is provocative of no special problems in use.

As employed throughout the specification, including the description and claims, the term "sealed" is broadly synonymous with "closed." The two modes of sealing described above have been chosen to provide specific examples, but it is not intended that the scope of the invention be taken as restricted thereto; and it will be understood that the bag may be sealed by any other closure means including but not restricted to the use of a closure member, tying off one or more ends or sides of the bag, etc.

While only one embodiment of the invention together with several modifications thereof has been shown and described herein, it will be evident that further modifications are possible in the elements of the device for temperature control of a part of the human body without departing from the scope of the invention.

I claim:

1. A device for controlling the temperature of a portion of a human body, said device comprising: a sealed bag made of a flexible plastic; and a yieldably formable, thixotropic mixture contained within the bag.

2. The device claimed in claim 1, the thixotropic mixture comprising water and a filler including a material substantially insoluble in water and divided into particles of less than approximately three microns in diameter.

3. The device claimed in claim 1, the thixotropic mixture comprising water, a filler including a finely

divided material substantially insoluble in water, and a dispersing agent.

4. The device claimed in claim 1, the thixotropic mixture comprising water, a filler including a finely divided material substantially insoluble in water, and a water-swelling, colloidal thickener.

5. The device claimed in claim 1, the thixotropic mixture comprising water, a filler including a finely divided material substantially insoluble in water, a water-swelling, colloidal thickening material, and a dispersing agent.

6. A device for temperature control of a portion of a human body comprising a sealed bag made of a thin, flexible, plastic, and a yieldably formable, thixotropic mixture contained within the bag, said mixture comprising: water; and a filler in sufficient quantity to form a thixotropic mixture with the water, the filler including an inorganic, finely divided material substantially insoluble in water.

7. The device recited in claim 6, the inorganic, finely divided material being chosen from the group including magnesium silicate, titanium oxide, carbon, and bentonite.

8. The device recited in claim 7, the total content of said inorganic, finely divided material in the thixotropic mixture being less than 8%.

9. A device for temperature control of a portion of a human body comprising a sealed bag made of a thin, flexible, plastic, and a yieldably-formable, thixotropic mixture contained within the bag, said mixture comprising: water; an organic, water-swelling, colloidal thickening material; and a filler in sufficient quantity to form a thixotropic mixture with the water and thickening material, the filler including an inorganic, finely divided material substantially insoluble in water and present in larger quantity than the thickening material.

10. The device set forth in claim 9, the thickening material being a metallic alginate and the content of the thickening material in the thixotropic mixture being less than 1% by weight.

11. A device for temperature control of a portion of a human body comprising a sealed bag made of a thin, flexible, plastic, and a yieldably-formable, thixotropic mixture contained within the bag, said mixture comprising: water; a freezing-point depressant added to the water; and a filler added to the water and depressant in sufficient quantity to form a thixotropic mixture, the filler including an inorganic, finely divided material forming less than 8% by weight of the thixotropic mixture.

12. A device for temperature control of a portion of a human body comprising a sealed bag made of a thin, flexible, plastic, and a yieldably-formable, thixotropic mixture contained within the bag, said mixture comprising: water; a freezing-point depressant in the water in quantity sufficient to lower the freezing point of the water to a desired value; a water-swelling, colloidal, organic thickening material in quantity less than 1% by weight of the thixotropic mixture; an inorganic filler material substantially insoluble in water and divided into particles less than 3 microns in diameter, the inorganic filler material being present in a quantity less than 6% by weight of the thixotropic mixture; and a dispersing agent.

References Cited in the file of this patent

UNITED STATES PATENTS

65	2,101,843	Factor	Dec. 14, 1937
	2,174,455	Bates	Sept. 26, 1939
	2,593,002	Bernhardt	Apr. 15, 1952
	2,595,328	Bowen	May 6, 1952
70	2,606,005	Poux	Aug. 5, 1952
	2,697,424	Hanna	Dec. 21, 1954
	2,710,008	Jensen	June 7, 1955

FOREIGN PATENTS

75	990,265	France	June 6, 1951
----	---------	--------	--------------