Convention Application for a Patent

We, HOLLISTER INCORPORATED, a Corporation of the State of Illinois, United States of America,
63158/80

of 211 East Chicago Avenue, Chicago, Illinois 60611, United States of America,

hereby apply for the grant of a Patent

for an invention entitled "PROTECTIVE SEALING COMPOSITIONS IN MOLDED FORM FOR SURGICAL DRAINAGE OPENINGS"

which is described in the accompanying complete specification.

This application is a Convention application and is based on the application numbered 90,855 for a patent or similar protection made in United States of America on 2nd November, 1979; and application numbered 185,860 for a patent or similar protection made in United States of America on 8th September, 1980, respectively.

Our address for service is: CALLINAN AND ASSOCIATES Patent Attorneys, of 48-50 Bridge Road Richmond, State of Victoria, Australia.

Dated this 10th day of October 1980.

HOLLISTER INCORPORATED
By its Patent Attorneys:
CALLINAN AND ASSOCIATES
AUSTRALIA
Patents Act 1952-1973

Declaration in Support of
(a) A Convention Application
(b) An Application
for a Patent or Patent-of-Addition

In support of the Application/Convention Application made by
(c) Hollister Incorporated (hereinafter termed "said Company")

for a patent/patent-of-addition for an invention entitled:
"Protective Sealing Compositions in Molded
Form for Surgical Drainage Openings"

Sally Frances Malkasian
211 East Chicago Avenue,
Chicago, Illinois 60611,
United States of America
do solemnly and sincerely declare as follows:-

1. (a) I am/we are the applicant(s) for the patent/patent-of-addition
or
(b) I am/we are authorised by Hollister Incorporated
the applicant for the patent/patent-of-addition to make this declaration on its behalf.

2. (i) The basic application(s) as defined by Section 141 of the Act was made
in the United States on the 2nd day of November, 1979
by Wagdi Wadie Habib
and in the United States of America on the 8th day of September, 1980 by Wagdi Wadie Habib

3. (i) I am/we are the actual inventor(s) of the invention
or
(k) I am/we are the actual inventor(s) of the invention referred to in the basic application,
Wagdi Wadie Habib
1015 Borden Drive
Roselle, Illinois 60172
United States of America

4. The basic application referred to in paragraph 2 of this Declaration was the first
application made in a Convention country in respect of the invention the subject of the
application.

(a) Declared at Chicago, Illinois this 26th day of September, 1980
United States of America

SIGN
Sally Frances Malkasian

HERE

To: The Commissioner of Patents

Date: Chicago, Illinois
United States of America

Sally Frances Malkasian
Claim 1. A protective sealing composition in gelled and molded form, said composition including a mixture of a gellable, water-absorbing, particulate hydrocolloid gum and a non-toxic liquid polyhydroxy alcohol, wherein said composition has dispersed therein from 0.1 to 4.0% weight of colloidal silica.
BASE FORMULA

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Parts by Weight</th>
</tr>
</thead>
</table>

The following statement is a full description of this invention, including the best method of performing it known to us:
PROTECTIVE SEALING COMPOSITION IN MOLDED FORM FOR SURGICAL DRAINAGE OPENINGS

Protective sealing compositions in the form of molded rings or sheets for application around surgical fluid drainage openings are known. A common formulation for such compositions comprises a gelled mixture of karaya gum and glycerin. See, for example, United States Patents 3,302,647 and 3,954,105. As described in the first-cited patent, where the drainage opening is a stoma, the karaya-glycerin sealing composition may be used in the form of a molded ring which is placed around the stoma between the gasket of the ostomy appliance and the body of the wearer. The purpose of the ring is to provide a protective seal, that is, it is desired to prevent the intestinal fluid or urine being discharged from the stoma from leaking around the ring so that all of the discharged fluid is collected in the bag or pouch of the ostomy appliance. The sealing ring also performs the function of protecting the skin area around the stoma from the irritating urine or intestinal fluid, which in the case of ileostomies may include gastric juices. As illustrated by the second of the above-cited patents, the karaya-glycerin composition may also be used in the form of a sheet or blanket. Such blankets may also be used around stoma openings, or as described in patent 3,954,105, they may be used around drainage openings associated with a wound or surgical incision.

Sealing compositions of the kind described pre-
ferably have an initial tackiness, usually referred to as "dry tack", so that they will provide an initial adhesive adherence to the skin around the drainage opening. It is particularly important that the compositions provide a high degree of adhesiveness while in contact with aqueous fluid. This is usually referred to as "wet tack".

The hydrocolloid in the composition, such as karaya, absorbs water which causes the hydrocolloid to swell and to increase in tackiness. However, with continued exposure to the aqueous fluid, especially where the fluid is urine or an intestinal discharge containing gastric juices, the composition tends to break down, losing mechanical strength, and eventually becomes ineffective for its desired protective sealing function. In application, such sealing rings or blankets must be frequently replaced. It has been desired to increase the mechanical and/or adhesive endurance of such rings or blankets, but heretofore no satisfactory means has been provided for accomplishing this result.

The present invention is based in part on the discovery that a new and surprising result is obtained by the incorporation of a small amount of colloidal silica, which is preferably in the form of fumed silica, in protective sealing compositions, which are composed of a mixture of hydrocolloid gum and polyhydroxy alcohol. More specifically, the resistance of such compositions in the form of molded rings or sheets to degradation by intestinal fluids and/or urine is markedly increased by
incorporating as small amount of fumed silica as 0.2%. At concentrations of silica above 4.0% the wet tack of the composition is reduced to such an extent that the composition is not effective. However, by limiting the amount of silica dispersed in the composition, the mechanical endurance of the composition can be increased without appreciably reducing its wet tack, and a satisfactory dry tack may also be obtained.

Accordingly the present invention provides a protective sealing composition in gelled and molded form, said composition including a mixture of a gellable, water-absorbing, particulate hydrocolloid gum and a non-toxic liquid polyhydroxy alcohol, wherein said composition has dispersed therein from 0.1 to 4.0% weight of colloidal silica. Based on present usage, the hydrocolloid gum is preferably karaya gum, but other gellable hydrocolloid gums can be used as a partial or complete substitute for the karaya. Such gellable hydrocolloid gums include ghatti, zedou, tragacanth, gelatin, dextran, pectin, xanthane, and similar natural gums. Synthetic gums may be used, including sodium carboxymethylcellulose and hydroxyethyl cellulose. Such hydrocolloid gums are characterized by being polysaccharides, by being hydrophilic and water-absorbing, and by being gellable in admixture with glycerin or other polyhydroxy alcohol.

For the purpose of the present invention, the hydrocolloid gums are used in a fine particulate form (viz. as powders). Karaya gum, for example, is usually employed in a sufficiently fine state of subdivision that
the powder will pass a 100 mesh or finer screen. The powdered gums as used are air-dry, that is, dry to the touch, but may contain some moisture, such as 10 to 18% by weight moisture.

The principal liquid component of the sealing composition is preferably a non-toxic liquid polyhydroxy alcohol. Based on present usage, glycerin is the preferred alcohol, but other polyhydroxy alcohols of similar properties can be used, such as, for example, propylene glycol, sorbitol, etc. Preferably, the polyhydroxy alcohol is not only non-toxic and non-irritating when applied to the skin, but, in addition, has a soothing or emollient action as provided by glycerin or similar emollient polyhydroxy alcohols.

In preparing the sealing composition, a sufficient amount of the polyhydroxy alcohol is employed to form a flowable mix, which can be formed or molded into the desired ring or sheet shape, and then set by gelation. The relative proportions of the polyhydroxy alcohol and the hydrocolloid can be varied while still achieving these general results. If too small an amount of the alcohol is present, the mix will be too stiff for flowing into the mold, while if too much of the alcohol is present, the molded composition will be too soft and insufficiently gelled. In accordance with present practice in relation to mixes of karaya gum and glycerin, approximately equal parts by weight of the gum and the alcohol give good results. However, a moldable mix can be prepared using more or less of the glycerin or other poly-
hydroxy alcohol. In general, the mix may contain from 35 to 55% of the karaya or other hydrocolloid, and from 35 to 55% of glycerin or other polyhydroxy alcohol.

As a more specific example, mixes can be prepared using portions within the range from 80 to 120 parts by weight of glycerin per 100 parts of karaya gum.

In accordance with the present invention, colloidal silica is incorporated in the sealing composition, the silica preferably being homogeneously dispersed therein. Fumed silica is preferred, although colloidal silica gel can also be used. The fumed silica is produced by flame hydrolysis of silicon tetrachloride. It can be obtained from various manufacturers, including the "Cab-O-Sil" products of Cabot Corporation, Boston, Massachusetts, and the "Aerosil" products of Degussa, Inc. New York, N. Y., U.S.A. These products are silicon dioxide in colloidal form having very high surface areas. For example, one suitable specific product is the Grade M-5 of Cab-O-Sil.

In the broadest aspect of this invention, colloidal silica is incorporated in the composition in an amount of from 0.1 to 4.0% by weight. (This and other stated percentages are based on the total weight of the composition, including the silica and all other ingredients of the finished product.) Within the stated range the endurance of the gel composition in contact with urine and/or intestinal fluids is markedly increased while the wet tack adhesive property remains adequate. However, it is preferable not to use over 1.5% silica.
(viz. from 0.1 to 1.5%) so that the dry tack and wet
tack properties are more fully retained.

To reduce the viscosity of the mix, and to
facilitate its molding or forming, it has been found
desirable to incorporate sodium carboxymethylcellulose (CMC)
in the mix. For example, from 2 to 15% of CMC may be
used. In representative formulations, from 3 to 8 parts
by weight of CMC is combined with 40 to 50 parts each
of karaya and glycerin, and from 0.5 to 1.2 parts of
fumed silica. Where the CMC is omitted, the optimum
amount of the fumed silica is somewhat lower, such as from
0.2 to 0.8% of the mix.

The compositions may include other minor ingre-
dients, such as preservatives or antibacterial agents.
For example, an alkyl para-hydroxy benzoate or a mixture
of such benzoates, may be used as the preservative. For
example, a mixture of methyl, ethyl, propyl, and butyl
parabens can be used. Where parabens are employed, such
as in amounts from 0.1 to 0.5%, it may be desirable to
first dissolve the parabens in propylene glycol or other
cosolvent with glycerin, in which the parabens are more
soluble than in glycerin. For example, from 2 to 10 parts
of propylene glycol can be used per 100 parts of glycerin.

In combining the ingredients to prepare the fluid
molding composition, the parabens may first be dissolved
in the small amount of propylene glycol, and then the
propylene glycol solution of the paraben mixed with the
larger amount of glycerin. The fumed silica can then be
dispersed in the combined polyhydroxy alcohols by mixing
In a presently preferred embodiment, a protective sealing composition is prepared in accordance with the
present invention using the following formula.

**FORMULA A**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) 2% fumed silica(^{(a)}) in glycerin blend(^{(d)})</td>
<td>50.0</td>
</tr>
<tr>
<td>(2) Karaya gum powder(^{(b)})</td>
<td>45.0</td>
</tr>
<tr>
<td>(3) Sodium Carboxymethylcellulose (CMC)(^{(c)})</td>
<td>5.0</td>
</tr>
</tbody>
</table>

100.0

\(^{(a)}\) Provides 1% fumed silica: Cab-O-Sil M-5 (Cabot Corporation, Boston, Massachusetts).

\(^{(b)}\) Minus 140 mesh; 10 - 18% moisture.

\(^{(c)}\) CMC 7HOX8F (Hercules, Incorporated, Wilmington, Delaware).

\(^{(d)}\) Glycerin blend: 94.795% glycerin, 4.839% propylene glycol, 0.161% methylparaben, 0.028% propylparaben, and 0.177% butylparaben.

In compounding the above ingredients, the glycerin blend with the fumed silica uniformly dispersed therein is mixed with the karaya gum powder and the sodium carboxymethylcellulose until a uniform gellable mixture is obtained. This mixture, prior to gellation, is poured into molds for forming rings or sheets, and is cured in the molds to produce the ring or sheet product. The curing may be obtained by leaving the composition in the molds overnight at ambient room temperature. Alternatively, the curing may be accelerated by applying heat from infrared...
lights or by microwave radiation. Microwave heating is preferred.

To improve dry tack, if desired, a small amount of a suitable pressure sensitive adhesive is deposited in the bottoms of the molds before filling them with the mix. For example, the adhesive may be the "H49" vinyl acrylic medical pressure-sensitive adhesive of U.S. Adhesives, Chicago, Illinois, U.S.A.

EXAMPLE II

In another embodiment, a protective sealing composition is prepared in accordance with the present invention using the following formula.

FORMULA B

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Propylene glycol (USP)</td>
<td>2.25</td>
</tr>
<tr>
<td>(2) Methylparaben</td>
<td>0.075</td>
</tr>
<tr>
<td>(3) Propylparaben</td>
<td>0.013</td>
</tr>
<tr>
<td>(4) Butylparaben</td>
<td>0.082</td>
</tr>
<tr>
<td>(5) Glycerin (USP, 99%)</td>
<td>46.58</td>
</tr>
<tr>
<td>(6) Fumed silica</td>
<td>0.50</td>
</tr>
<tr>
<td>(7) Karaya gum powder</td>
<td>50.50</td>
</tr>
</tbody>
</table>

In compounding the above ingredients, ingredients (2) to (4), the parabens, are dissolved in ingredient (1), the propylene glycol. This solution is added to ingredient (5), the glycerin, and mixed until uniform.
Ingredient (6), the fumed silica, is then dispersed in the liquid solution of the preceding ingredients, and the dispersion is mixed until uniform. The karaya powder, ingredient (7), is then added with mixing continued until a uniform gellable mixture is obtained. This mixture, prior to gellation, is poured into molds for forming rings or sheets, and is cured in the molds to produce the ring or sheet product. The curing may be obtained by leaving the composition in the molds overnight at ambient room temperature. Alternatively, the curing may be accelerated by applying heat from infrared lights or by microwave radiation.

In the foregoing example, the fumed silica is Cab-O-Sil M-5 (Cabot Corporation, Boston, Massachusetts). The gum karaya is in the form of a powder passing a 140 mesh screen, and may contain from 10 to 18% moisture.

EXAMPLE III

A composition is prepared as described in Example II except that algin powder is substituted on an equal weight basis for the karaya gum powder. The algin is supplied by Kelco Company, Clark, New Jersey.

EXAMPLE IV

Using the compounding procedure described in Example II, a protective sealing composition is prepared according to the following formula.
**FORMULA C**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Propylene glycol (USP)</td>
<td>2.88</td>
</tr>
<tr>
<td>(2) Methylparaben</td>
<td>0.098</td>
</tr>
<tr>
<td>(3) Propylparaben</td>
<td>0.017</td>
</tr>
<tr>
<td>(4) Butylparaben</td>
<td>0.105</td>
</tr>
<tr>
<td>(5) Glycerin (USP, 99%)</td>
<td>56.4</td>
</tr>
<tr>
<td>(6) Fumed silica</td>
<td>0.5</td>
</tr>
<tr>
<td>(7) Xanthan gum</td>
<td>40.0</td>
</tr>
</tbody>
</table>

In the foregoing formula, the xanthan gum is a food grade product supplied by Kelco Company, Clark, New Jersey.

**EXAMPLE V**

A protective sealing composition is prepared using the compounding and molding procedure of Example II, as applied to the following formula.

**FORMULA D**

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Propylene glycol (USP)</td>
<td>2.37</td>
</tr>
<tr>
<td>(2) Methylparaben</td>
<td>0.079</td>
</tr>
<tr>
<td>(3) Propylparaben</td>
<td>0.014</td>
</tr>
<tr>
<td>(4) Butylparaben</td>
<td>0.087</td>
</tr>
<tr>
<td>(5) Glycerin (USP, 99%)</td>
<td>46.45</td>
</tr>
<tr>
<td>(5A) Sorbitol (USP, 70%)</td>
<td>5.0</td>
</tr>
<tr>
<td>(6) Fumed silica</td>
<td>1.5</td>
</tr>
<tr>
<td>(7) Gum zedou powder</td>
<td>44.5</td>
</tr>
</tbody>
</table>

100.000
In mixing the foregoing ingredients, ingredients (5) and (5A), the glycerin and sorbitol, are combined as described for the glycerin, ingredient (5), in the procedure of Example I.

EXAMPLE VI

A protective sealing composition is prepared according to the compounding procedure of Example II using the formula set out below.

FORMULA E

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Propylene glycol (USP)</td>
<td>3.05</td>
</tr>
<tr>
<td>(2) Methylparaben</td>
<td>0.10</td>
</tr>
<tr>
<td>(3) Propylparaben</td>
<td>0.02</td>
</tr>
<tr>
<td>(4) Butylparaben</td>
<td>0.11</td>
</tr>
<tr>
<td>(5) Glycerin (USP, 99%)</td>
<td>59.72</td>
</tr>
<tr>
<td>(6) Fumed silica</td>
<td>2.0</td>
</tr>
<tr>
<td>(7) Sodium Carboxymethylcellulose</td>
<td>35.0</td>
</tr>
</tbody>
</table>

The sodium carboxymethylcellulose is CMC 7HOXF, supplied by Hercules, Incorporated, Wilmington, Delaware. The molded rings or sheets are preferably cured by microwave heating.

EXAMPLE VII

A protective sealing composition was prepared according to the following formula.
FORMULA F

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Propylene glycol (USP)</td>
<td>2.71</td>
</tr>
<tr>
<td>(2) Methylparaben</td>
<td>0.09</td>
</tr>
<tr>
<td>(3) Propylparaben</td>
<td>0.020</td>
</tr>
<tr>
<td>(4) Butylparaben</td>
<td>0.1</td>
</tr>
<tr>
<td>(5) Glycerin (USP, 99%)</td>
<td>53.08</td>
</tr>
<tr>
<td>(6) Deionized water</td>
<td>3.0</td>
</tr>
<tr>
<td>(7) Fumed silica</td>
<td>1.0</td>
</tr>
<tr>
<td>(8) Sodium Carboxymethylcellulose</td>
<td>15.0</td>
</tr>
<tr>
<td>(9) Gum karaya powder</td>
<td>25.0</td>
</tr>
<tr>
<td></td>
<td>100.000</td>
</tr>
</tbody>
</table>

In compounding the above ingredients, the same mixing procedure is used as described in Example II with reference to ingredients (1) to (5). Ingredient (6), the deionized water is then added, and the mixing is continued to produce a uniform mixture. Ingredient (7), the fumed silica, is then dispersed in the liquid solution to form a uniform dispersion. Ingredient (8), the sodium carboxymethylcellulose is then added with continued mixing, and ingredient (9), the karaya is added last, and the mixing continued until a uniform gellable composition is obtained. The molding and gelling procedure is the same as described in Example II.

EXAMPLE VIII

Endurance and tack tests were conducted using the base formula set out below and amounts of fumed silica (Cab-O-Sil M-5) from 0 to 2.5%.
BASE FORMULA

Ingredients                        | Parts by Weight
---                                | ---
(1) Propylene glycol (USP)         | 0.735
(2) Methylparaben                  | 0.098
(3) Propylparaben                  | 0.029
(4) Butylparaben                   | 0.049
(5) Glycerin (USP, 99%)            | 49.04
(6) Fumed silica                   | 0 to 2.5
(7) Karaya gum powder              | 50.0

For the endurance tests, the simulated intestinal fluid was prepared as described in U.S.P. XIX "Intestinal Fluid, Simulated, TS," pg. 765 (1974). The simulated urine was prepared as described in Remington's Pharmaceutical Sciences, "Urine," pg. 598-9, Ed 15 (1975). The dry and wet tack tests were conducted by a modification of the ASTM Method 02979-71, using a probe of 0.5 cm diameter.

The endurance test apparatus includes a tank for containing the simulated intestinal fluid or urine, and a plurality of tripod testing fixtures, which may be placed in the tank in contact with the solution. The testing fixture has a platform at the top with a sample-receiving recess. The center portion of the recess is cut-out to provide an opening through the platform. When placed in test position, the test samples bridge the openings. U-shaped weights are then placed over the samples. These weights are in the form of steel hooks weighing approximately 7.4 grams. In use, the hooks are placed over the
samples so that when the hooks break through the samples they would fall freely through the openings in the platforms. Nylon strings are attached to the upper cross-arm portions of the inverted U-shaped hooks and the strings are attached to the operating levers of micro switches, the lengths of strings being selected so that when the sample is broken, the micro switch will be activated, and a timing clock for the particular sample will be stopped. In starting the test, after the samples have been placed in the tank and the strings attached to the micro switch levers, the simulated urine or intestinal fluid is added to the tanks to a level above the position of the samples, and the timing clocks for each sample are started. The elapsed time for breakthrough of each sample is thereby automatically recorded.

The samples for the endurance tests were cut sections of rings molded from the formulas varying fumed silica content. Each test sample has a weight of approximately 1.0 grams, and had an elongated shape. The center portions of the samples engaged by the weighted hooks had dimensions of approximately 0.15 by 0.3 inches. The measured time for breakthrough was corrected by multiplying the measured time by 1.0 grams of the sample divided by actual weight of the sample. For the tack tests, cut sections of the rings were applied to test discs having a center opening through which the tack probe extends. Dry tack was determined with the surface of the sample in dry condition, and wet tack was determined after the sample had been contacted with water. The force required to separate the probe from
the sample was measured in grams, and recorded as grams per centimeter of probe diameter, which was 0.5 cm. Replicate tests were conducted on each sample, and the values compiled as averages of five identical samples.

The results obtained by the endurance and tack tests are summarized below in Table A.

**TABLE A**

<table>
<thead>
<tr>
<th>% Fumed Silica</th>
<th>Endurance time in simulated Urine</th>
<th>Endurance time in simulated Urine</th>
<th>Tack (gms/0.5 cm) Dry</th>
<th>Tack (gms/0.5 cm) Wet</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>2.0 hrs.</td>
<td>1.5 hrs.</td>
<td>216</td>
<td>324</td>
</tr>
<tr>
<td>0.25%</td>
<td>Over 24 hrs.</td>
<td>16.0 hrs.</td>
<td>342</td>
<td>406</td>
</tr>
<tr>
<td>0.5%</td>
<td>18.75 hrs.</td>
<td>Over 24 hrs.</td>
<td>338</td>
<td>428</td>
</tr>
<tr>
<td>1.0%</td>
<td>Over 24 hrs.</td>
<td>Over 24 hrs.</td>
<td>246</td>
<td>312</td>
</tr>
<tr>
<td>1.75%</td>
<td>Over 24 hrs.</td>
<td>Over 24 hrs.</td>
<td>164</td>
<td>270</td>
</tr>
<tr>
<td>2.5%</td>
<td>Over 24 hrs.</td>
<td>Over 24 hrs.</td>
<td>100</td>
<td>270</td>
</tr>
</tbody>
</table>

**EXAMPLE IX**

Further endurance and tack test were conducted using the base formula set out in Example I and the procedure therein. The silica was varied from 0.2 to 4.0%. The total of the fumed silica and the glycerin blend was maintained at 50% by weight, the amount of the glycerin blend being correspondingly reduced as the amount of fumed silica was increased. The endurance times were measured on the basis of hours per gram of test sample, and the test samples were prepared with a diameter of 0.25 cm. The results obtained are summarized below in Table B.
<table>
<thead>
<tr>
<th>% Fumed Silica</th>
<th>Endurance Time (hrs/gm)</th>
<th>Tack (gms/0.25 cm. dia)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Simul. Urine</td>
<td>Simul. Int. Fluid</td>
</tr>
<tr>
<td>5</td>
<td>0.2</td>
<td>98.7</td>
</tr>
<tr>
<td></td>
<td>0.5</td>
<td>61.0</td>
</tr>
<tr>
<td></td>
<td>1.0</td>
<td>93</td>
</tr>
<tr>
<td></td>
<td>2.0</td>
<td>148.7</td>
</tr>
<tr>
<td></td>
<td>3.0</td>
<td>128.8</td>
</tr>
<tr>
<td>10</td>
<td>4.0</td>
<td>132</td>
</tr>
</tbody>
</table>

EXAMPLE X

In any formulation, where the molded ring or sheet has insufficient dry tack, a coating of a suitable pressure-sensitive adhesive can be applied to the side of the ring or sheet which will be pressed against the skin of the wearer. For example, a vinyl acrylic medical pressure-sensitive adhesive can be used, such as adhesive H49, supplied by U.S. Adhesives, Chicago, Illinois, U.S.A. Alternatively, an adhesive may be incorporated in the mix before molding, for example, as a glycerin emulsion of the adhesive.

"Lab-o-Sil" and "Aerosil" are acknowledged in this specification as being registered trade marks.
In relation to mixes of karaya gum and glycerin, approximately equal parts by weight of the gum and the alcohol give good results. However, a moldable mix can be prepared using more or less of the glycerin or other poly-
The claims defining the invention are as follows:

1. A protective sealing composition in gelled and molded form, said composition including a mixture of a gellable, water-absorbing, particulate hydrocolloid gum and a non-toxic liquid polyhydroxy alcohol, wherein said composition has dispersed therein from 0.1 to 4.0% weight of colloidal silica.

2. The composition as claimed in Claim 1, in which said silica is fumed silica.

3. The composition as claimed in Claim 1 or Claim 2, in which said silica is present in an amount from 0.1 to 1.5% by weight.

4. The composition as claimed in any one of the preceding claims, in which said hydrocolloid gum is karaya gum powder.

5. The composition as claimed in any one of the preceding claims, in which said alcohol is glycerin, or a mixture of glycerin and propylene glycol.

6. The composition as claimed in any one of the preceding claims, in which said composition also contains from 2 to 15% by weight of sodium carboxymethylcellulose.

7. The compositions as claimed in Claim 1 in which said composition includes a mixture of karaya gum powder and glycerin having dispersed therein from 0.1 to 1.5% by weight of fumed silica together with from 3 to 8% by weight of sodium carboxymethylcellulose.

8. A protective sealing composition, substantially as described herein with reference to any one of the Examples.

D A T E D this 26th day of October, 1982.

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By its Patent Attorneys:
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