

[54] SKIN PROTECTIVE GEL CONTAINING
POLYVINYL METHYLETER OR
MONOISOPROPYL ESTER OF POLYVINYL
METHYLETER MALEIC ACID /
[75] Inventor: Wilhelm G. Denner, Chicago, Ill.
[73] Assignee: Hallister Incorporated, Chicago, Ill.
[22] Filed: Sept. 4, 1973
[21] Appl. No.: 394,061

3,134,720	5/1964	Green et al.	424/362 X
3,269,903	8/1966	Von Fieandt et al.	424/81
3,485,915	12/1969	Gerstein et al.	424/81
3,632,547	1/1972	Kajioka.	424/80 X
3,710,779	1/1973	Bunnell et al.	424/80 X
3,749,773	7/1973	Ninger et al.	424/78 X

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Stellman & McCord

[52] U.S. Cl. 424/78; 252/316; 424/80;
424/81; 424/362
[51] Int. Cl. A61k 9/00
[58] Field of Search 424/78, 80, 81, 362;
252/316

[56] References Cited
UNITED STATES PATENTS
2,542,897 2/1951 Brown et al. 424/362 X

[57] ABSTRACT
The present invention provides a protective skin coat-
ing material in the form of a gel primarily intended for
use in combination with ostomy appliances and the
like. The gelatinous material is made up of a film-
forming protective colloidal material in combination
with a solvent and a gelling agent.

6 Claims, No Drawings

SKIN PROTECTIVE GEL CONTAINING POLYVINYL METHYLETHER OR MONOISOPROPYL ESTER OF POLYVINYL METHYLETHER MALEIC ACID

BACKGROUND OF THE INVENTION

Surgical correction of intestinal disorders is becoming a common practice. Where the colon is damaged or infected, a portion or even all of the large intestine may be removed (colostomy), and the new terminus of the intestinal tract is led out through an opening made in the abdominal wall to form a stoma. Where the disturbance is in the small intestine or extends into the small intestine, the same technique may be employed and the operation in this instance is called an ileostomy. In the case of a colostomy, the waste material discharged from the stoma is generally noncorrosive and appliances, often referred to as ostomy appliances, are employed to collect and retain the discharged waste material for subsequent disposal. In the case of an ileostomy, the material discharged may still be incompletely digested and the discharge may include a significant amount of gastric juices which are still active and will attack the skin of the patient if allowed to come in contact therewith. Again, ostomy appliances are worn by the patient to collect the waste discharged from the ileostomy stoma, but care must be taken to effect a proper seal around the stoma not only to prevent soiling of the clothes of the wearer and the escape of unpleasant odors, problems common to both colostomy and ileostomy patients, but also to prevent the still active gastric juices from coming in contact with and damaging the skin.

causes skin irritation even though there has been no contact with discharged waste material. Repeated applications of an adhesive device serves further to irritate the skin.

Attempts have been made in the past to remedy the situation described above by providing a skin coating material in the form of a liquid which may be applied to the skin by a sponge or other means. Because the liquid was extremely fluid, it was difficult to maintain the liquid in place until it had dried, and often the patient was required to lie on his back while applying the liquid and permitting the same to dry to form a protective coating. This provided a far from satisfactory solution.

BRIEF SUMMARY OF THE INVENTION

In accordance with the present invention, there is provided a skin coating or skin protective material in the form of a gel. The gel is sufficiently stiff as to be able to support itself in position without running, even when applied to the skin surface surrounding the stoma while the patient is standing. The gel dries to a thin protective coating against which the adhesive or other sealing means of the ostomy appliance may be pressed, and the stress of subsequently removing the appliance is directed primarily against the coating material rather than directly against the skin.

DETAILED DESCRIPTION OF THE INVENTION

As previously indicated, the gel of the present invention comprises film formers in a solvent mixed with preservatives and a gelling agent. The preferred ingredients and their proportions are set forth below, and where available the trade name and manufacturer, as presently known, is also stated.

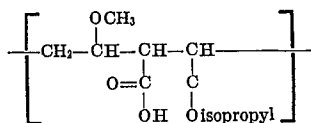
Chemical Name	Trade Name	Manufacturer
Isopropanol(70%)	Isopropyl alcohol	Shell or Exxon
Methyl para-hydroxybenzoate	Methyl parasept	Tenneco Heyden Div.
Butyl para-hydroxybenzoate	Butyl parasept	do.
Polyvinyl pyrrolidone having a molecular wt. of 40,000	Polyvinyl pyrrolidone K-30	GAF
Polyvinyl methylether having an acid value of (1) and being soluble in water and low boiling alcohols	Lutonal M-40	BASF Wyandotte
Modified polyacrylic acid having a molecular wt. of 3,000,000	Carbopol 934	B.F. Goodrich
Polyoxyethylene cocoamine having 15 oxy groups	Ethomeen C/25	Armour Chem.
Monoisopropyl ester of polyvinyl methylether/maleic acid	Gantrez ES 335	GAF
2,4 Hexadienoic acid	Sorbic acid	Pfizer Chem Co.
Hydroxypropyl cellulose having a molecular wt. of 300,000	Klucel GF	Hercules Inc.

As a consequence of the foregoing, ostomy appliances have been provided with an adhesive face adapted to adhere to the skin surrounding the stoma, and in some cases have used a gum karaya seal such as the seal shown and described in U.S. Pat. No. 3,302,647. In all cases, a bag or other container is provided in conjunction with the sealing means in order to collect the discharged waste.

In the case of the ostomy appliance, which includes a ring-like member having an adhesive face on one side and a bag to receive the discharged material on the other, the application and removal of the device often

Of the ingredients set forth above, the isopropanol is, of course, the solvent, Gantrez ES 335 I is a film former, as are polyvinyl pyrrolidone K-30 and the Lutonal M-40. The Carbopol 934 and the Klucel GF are the gelling agents, while the parasepts are the preservatives and the Ethomeen C/25 is neutralizing agent for the Carbopol 934.

Carbopol 934 is a water-soluble polyacrylic acid crosslinked with about 1% of polyallyl sucrose having an average of about 5.8 allyl groups for each sucrose molecule; U.S. Patent No. 3,133,865. Gantrez ES 335 I has the following repeating unit



Which is a clear viscous liquid with an acid number of 255-285, a specific gravity of 0.957 and a density (pounds/gallon) of 7.98.

An example of the preparation and the method of mixing the same is as follows:

Ingredients	Example 1 Grams	Percent
Isopropanol (70%)	97.50	64
Lutonal M-40	48.00	31
Methyl parasept	0.214	0.14
Butyl parasept	0.092	0.06
Polyvinyl pyrrolidone K-30	1.50	0.98
Carbopol 934	3.00	1.96
Ethomeen C/25	3.00	1.96

In forming the gel, the methyl and butyl parasepts are dissolved in isopropanol and the polyvinyl pyrrolidone K-30 is added under agitation. When completely dissolved, the Carbopol 934 is added slowly while subjecting the mixture to high speed agitation. The agitation should be continued until it is certain that no lumps remain. The mixture is then neutralized with Ethomeen C/25. This will form a thick gel. A second solution is made comprising 25% Lutonal M-40 and 75% isopropyl alcohol. This Lutanol/isopropyl alcohol mixture is then added to the thick gel under rapid agitation, which agitation is continued until a homogenous mixture has been formed. The resulting material will still be in gel form and can be packaged as desired for use.

The proportion of ingredients set forth above may be varied and still result in a gel usable for the purposes intended. The upper and lower limits of the ingredients are set forth below.

Ingredient	Upper Limit	Lower Limit
Isopropanol	80%	50%
Methyl and butyl parasepts	5%	1%
Lutonal M-40	50%	5%
Polyvinyl pyrrolidone K-30	5%	1%
Carbopol 934	5%	1%
Ethomeen C/25	upper limit and lower limit equal to percentage of Carbopol 934.	

The isopropanol should, of course, be cosmetic grade.

Ingredients	Example 2 Grams	Percent
Isopropyl alcohol	75	70.61
Sorbic Acid	0.214	0.20
Polyvinyl pyrrolidone K-30	1.0	0.94
Distilled Water	5.0	4.71
Klucel GF	5.0	4.71
Gantrez ES 335 I	10.0	9.41
Isopropanol	10.0	9.41

In mixing the ingredients for the example set forth just above, the Klucel GF is added to the 75 grams of isopropyl alcohol under high agitation. Continuing the agitation, the distilled water is added which will initially result in a granular appearing mixture, which will subsequently disappear during the mixing process.

The 10 grams of isopropanol is used to dissolve the sorbic acid and then the polyvinyl pyrrolidone is added thereto. The Gantrez ES 335 I is then mixed into the isopropanol/sorbic acid/polyvinyl pyrrolidone mixture and thoroughly mixed therein. The resulting mixture is then combined with the mixture first formed, and the two are thoroughly blended together. The result will be a gel of the desired viscosity and characteristics.

The upper and lower limits of the ingredients in Example 2 are set forth below.

Ingredient	Upper Limit	Lower Limit
Isopropyl alcohol	90%	25%
Sorbic acid	0.4%	0
Polyvinyl pyrrolidone K-30	2%	0
Distilled water	20%	5%
Klucel GF	10%	2%
Gantrez ES 335 I	45%	5%

plus what additional isopropanol CG is required to dissolve the polyvinyl pyrrolidone to form the second mixture described above.

As previously indicated, the gel formed in accordance with the formulation set forth may be applied without regard to the posture of the patient. The gel will dry to a thin coating surrounding the stoma and will not only improve the adhesion of the appliance, but also serves to protect the skin of the user from irritation.

I claim:

1. A gelatinous mixture for application to human skin, comprising:

25 to 90% by weight of isopropanol,

0.1 to 5% by weight of a preservative selected from the group consisting of sorbic acid, butyl parahydroxybenzoate and methyl parahydroxybenzoate,

0 to 50% by weight of polyvinyl pyrrolidone,

5 to 50% by weight of a film forming agent selected from the group consisting of monoisopropyl ester of polyvinyl methylether and polyvinyl methylether, and

1.5 to 5% by weight of a gelling agent selected from the group consisting of hydroxypropyl cellulose and water-soluble polyacrylic acid crosslinked with 1% of polyallyl sucrose having an average of about 5.8 allyl groups for each sucrose molecule.

2. A gelatinous mixture for application to human skin, comprising:

25 to 90% by weight of isopropanol,

0.1 to 5% by weight of a preservative selected from the group consisting of sorbic acid, butyl parahydroxybenzoate and methyl parahydroxybenzoate,

0 to 5% by weight of polyvinyl pyrrolidone,

5 to 50% by weight of a film forming agent selected from the group consisting of monoisopropyl ester of polyvinyl methylether and polyvinyl methylether,

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- 1.96 to 3% by weight of water-soluble polyacrylic acid crosslinked with 1% of polyallyl sucrose having an average of about 5.8 allyl groups for each sucrose molecule.
- 2 to 3% by weight of polyoxyethylene cocoamine having 15 oxy groups.
3. A gelatinous mixture for application to human skin, comprising:
 - 63 to 80% by weight of isopropanol,
 - 0.1 to 5% by weight of a preservative selected from the group consisting of butyl para-hydroxybenzoate and methyl para-hydroxybenzoate
 - 1.0 to 5% by weight of polyvinyl pyrrolidone,
 - 31 to 50% by weight of polyvinyl methylether,
 - 2 to 3% by weight of water-soluble polyacrylic acid crosslinked with 1% of polyallyl sucrose having an average of about 5.8 allyl groups for each sucrose molecule, and
 - 2.0 to 3% by weight of polyoxyethylene having 15 oxy groups cocoamine.
4. A gelatinous mixture for application to human skin, comprising:
 - 25 to 90% by weight of isopropanol,
 - 0.1 to 0.4% by weight of sorbic acid,
 - 0 to 2% by weight of polyvinyl pyrrolidone,
 - 5 to 20% by weight of water,

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- 5 to 45% by weight of monoisopropyl ester of polyvinyl methylether, and
- 2 to 10% by weight of hydroxypropyl cellulose.
5. A gelatinous mixture for application to human skin, comprising:
 - 63% by weight of isopropanol,
 - less than 5% by weight of methyl para-hydroxybenzoate and butyl para-hydroxybenzoate
 - 1.0% by weight of polyvinyl pyrrolidone,
 - 31% by weight of polyvinyl methylether,
 - 2% by weight of water-soluble polyacrylic acid crosslinked with 1% of polyallyl sucrose having an average of about 5.8 allyl groups for each sucrose molecule, and
 - 2% by weight of polyoxyethylene cocoamine having 15 oxy groups.
6. A gelatinous mixture for application to human skin, comprising:
 - 80% by weight of isopropylalcohol,
 - less than 0.4% by weight of sorbic acid,
 - 1% by weight of polyvinyl pyrrolidone,
 - 5% by weight of distilled water,
 - 5% by weight of hydroxypropyl cellulose, and
 - 9% by weight of monoisopropyl ester of polyvinyl methylether.

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UNITED STATES PATENT OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 3,876,771
DATED : April 8, 1975
INVENTOR(S) : Wilhelm G. Denner

It is certified that error appears in the above-identified patent and that said Letters Patent are hereby corrected as shown below:

In the title, change "METHYLETHER MALEIC ACID" to
--METHYLETHER/MALEIC ACID--.

The name of the assignee is HOLLISTER INCORPORATED.

Column 2, near the bottom of the table, the trade name
"Gantrez ES 335" should read --Gantrez ES 335 I--.

Column 3, in the penultimate line of Example 2,
"6771" should be deleted.

Signed and Sealed this

twenty-eight Day of October 1975

[SEAL]

Attest:

RUTH C. MASON
Attesting Officer

C. MARSHALL DANN
Commissioner of Patents and Trademarks