CONVENTION

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REQUEST FOR A STANDARD PATENT AND NOTICE OF ENTITLEMENT

The Applicant identified below requests the grant of a patent to the nominated person identified below for an invention described in the accompanying standard complete patent specification.

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Invention Title:

HYDROCOLLOID WOUND GEL

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Details of the basic application(s):-

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Applicant states the following:

The nominated person is the assignee of the actual inventor(s).

The nominated person is authorised to make this application by the applicant of the basic application.

The basic application was the first made in a convention country in respect of the invention.

The nominated person is not an opponent or eligible person described in Section 33-36 of the Act.

17 November, 1995

BRISTOL-MYERS SQUIBB COMPANY
by PHILLIPS ORMONDE & FITZPATRICK
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Our Ref 325334

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(56) Prior Art Documents
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(57) Claim

1. A hydrocolloid wound gel composition which comprises:

   (a) from 0.05% to 1.0% by weight of a pectin;

   (b) from 2.0% to 4.5% by weight of sodium carboxymethylcellulose;

   (c) from 15.0% to 20.0% by weight of propylene glycol; and

   (d) water in a sufficient amount to make up the difference between the amount of ingredients (a) - (c) and 100 % by weight.

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Invention Title:

HYDROCOLLOID WOUND GEL

Our Ref : 325334
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The following statement is a full description of this invention, including the best method of performing it known to applicant(s):

HYDROCOLLOID WOUND GEL

This invention relates to a hydrocolloid wound gel. More particularly, this invention relates to a hydrocolloid wound gel useful for cleansing and debriding wounds and having some moisture absorption capacity.

The invention also relates to a method of treating a wound comprising applying the wound gel to a wound. It is particularly useful for the filling of cavity wounds.

It is well known that the cleansing and debriding of wounds and the removal of wound exudates is important to the process of healing of wounds. Commonly used wound dressings utilize gauze, foams, sponges, cotton wads or other fibrous materials. Gauze and other fibrous materials absorb fluids by capillary action. However, gauze and other fibrous materials have the disadvantage in that when new tissue is formed, in the process of healing, it engulfs the fibers of these materials and it is torn when the material is removed causing wound injury on removal.

Various other materials have been used, such as gels, hydrogels, granules and pastes to remove exudates from wounds. Scherisorb Gel marketed by

Smith & Nephew containing propylene glycol and a starch-acrylamide t-graft co-polymer has been used as an interactive wound treatment.

The present invention provides a hydrocolloid wound gel composition which cleanses and debrides wounds and has some exudate absorption capacity. The wound gel promotes healing of wounds. The hydrocolloid wound gel contains from about 0.05% to 1.0% by weight of pectin, from about 2.0% to 4.5% sodium carboxymethylcellulose, from about 15.0% to 20.0% by weight of propylene glycol and the remainder water to make 100% by weight.

The invention is also directed to a method of wound healing which comprises placing the hydrocolloid wound gel into the wound to cleanse, debride the wound and absorb exudate to promote wound healing.

The hydrocolloid wound gel keeps the wound bed moist and produces a wound environment suitable for healing. The gel cleanses the wound, debrides necrotic matter from the wound, absorbs exudate without dessiccating or dehydrating the wound bed and promotes wound healing. Freshly generated tissue does not grow into the gel causing injury on removal. The hydrocolloid wound gel of this invention is particularly useful for chronic cavity type wounds and for wounds containing sloughy or necrotic material

The hydrocolloid wound gel composition of the present invention contains from about 0.05% to 1.0% by weight of pectin, from about 2.0% to 4.5% by weight of sodium carboxymethylcellulose, from about

15.0% to 20.0% by weight of propylene glycol and the remainder water to make 100%.

The most preferred hydrocolloid wound gel contains 0.1% pectin, 3.4% sodium carboxymethylcellulose, 15% propylene glycol and 81.5% water.

The pectin is present in the gel composition in an amount of 0.05% to 1.0% by weight and preferably 0.1%. The preferred pectin is a high ester pectin derived from citrus peel consisting chiefly of the partial methyl esters of polygalacturonic acid (approximately 65% of the carboxyl groups are esterfied). Representative of the pectin useful in the gel composition is that marketed under the name GENU pectin type VIS-L by Copenhagen Pectin.

The gel composition contains sodium carboxymethylcellulose in the amount of 2.0% to 4.5% by weight and preferably 3.4%. The preferred sodium carboxymethylcellulose is a high viscosity sodium carboxymethylcellulose (typically in the range 2000-4500 CPS as measured by Brookefield LV Viscometry of a 1% solution, oven dry basis, 25°C (spindle 4/30 rpm).

Propylene glycol is present in the amount of 15.0% to 20.0% by weight and preferably 15%.

The water used in the present invention is preferably purified and pyrogen free water and is present in an amount sufficient to bring the composition up to 100% weight and in the preferred composition constitutes 81.5% by weight.

Various optional ingredients can also be included in the final composition such as preservatives, e.g., methylhydroxybenzoate and propylhydroxybenzoate. In addition, the hydrocolloid

wound gel composition can, if desired, contain small amounts (effective amount), i.e., less than 5%, of pharmacologically active ingredients. For example, an antibiotic or antimicrobial agent such as metronidazole, silver sulfadiazine, neomycin or penicillin, an antiseptic agent such as povidone iodine, an anti-inflammatory agent such as hydrocortisone or triamcinoloone acetonide, or a skin protective agent such as zinc oxide can be included in the composition.

The hydrocolloid wound gel of this invention is prepared by mixing pectin in water with heating (for example at a temperature from about 50° to 60°C) to form a solution. Propylene glycol is added while mixing and sodium carboxymethylcellulose gradually added with constant mixing to form the gel.

The composition may be packaged in conventional containers, for example, squeeze tube containers or jars and sterilized by wet heat.

Throughout the description and claims of this specification, the word "comprise" and variations of the word, such as "comprising" and "comprises", is not intended to exclude other additives or components or integers.

The following examples are intended to illustrate the invention described herein without unduly restricting it.

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Example 1

A gel composition was prepared having the following composition:

	% by Weight	Weight
Pectin	0.1%	0.2 g
Sodium Carboxymethyl-cellulose	3.4%	6.8 g
Propylene glycol	15.0%	30.0 g
Purified Water	81.5%	163.0 g

Pectin (0.2 g) was added to purified water (163.0 g) in a beaker heated to 50-60°C with constant stirring until the pectin was dissolved. Propylene glycol (30.0 g) was added and sodium carboxymethylcellulose (6.8 g) was gradually added with constant mixing. A hydrocolloid gel (200 g) was produced.

The gel was packaged in epoxy lined aluminum tubes sealed and terminally sterilized by wet heat at 121°C for 30 minutes. The gel when applied to a wound or body surface has good cohesive properties and remains *in situ*.

Examples 2 -3

Following the procedure described in Example 1, and using the following compositions:

	Example 2 % by Weight	Example 3 % by Weight
Pectin	0.7%	0.9%
Sodium Carboxymethyl-cellulose	4.0%	2.5%
Propylene glycol	20.0%	17.0%
Purified Water	75.3%	79.6%

gel compositions are prepared which are useful for treating wounds.

The hydrocolloid wound gel of the present invention cleanses and debrides wounds and absorbs large quantities of wound exudate. The gel enhances wound healing. The main application of the gel is directed to chronic necrotic or sloughy wounds, with large cavities, where debridement absorption and filling are indicated. The wound gel is also useful in treatment of ulcers, burns, pressure sores, etc.

The hydrocolloid wound gel is applied to the wound generally from a tube to cleanse and debride wounds, absorb wound exudate and to enhance healing. Usually the wound cavity is partially filled with the gel and the wound sealed with an occlusive dressing. As exudate is generated, it is absorbed by the gel/dressing combination which swells to fill the entire wound cavity. Usually, the hydrocolloid wound gel will not be required to be replaced for several days.

Thus it is apparent from the foregoing description that the objects of this invention have been attained. A novel hydrocolloid wound gel has been invented which has some exudate absorbing capacity, debridement activity and promotes wound healing. In addition, a novel method of treating wounds has been invented.

While this invention has been described and exemplified in terms of its preferred embodiment, those skilled in the art will appreciate that modifications can be made without departing from the spirit and scope of this invention.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A hydrocolloid wound gel composition which comprises:

(a) from 0.05% to 1.0% by weight of a pectin;

(b) from 2.0% to 4.5% by weight of sodium carboxymethylcellulose;

(c) from 15.0% to 20.0% by weight of propylene glycol; and

(d) water in a sufficient amount to make up the difference between the amount of ingredients (a) - (c) and 100 % by weight.

2. The hydrocolloid wound gel of claim 1 wherein said wound gel composition comprises:

(a) 3.4% by weight of sodium carboxymethylcellulose;

(b) 0.1% by weight of pectin;

(c) 15.0% by weight of propylene glycol; and

(d) 81.5% by weight of purified water.

3. The hydrocolloid wound gel of claim 1 wherein said wound gel composition contains an effective amount of a pharmacologically active ingredient.

4. A method of treating a wound, which comprises applying a hydrocolloid wound gel composition to said wound, wherein said hydrocolloid wound gel composition comprises:

(a) from 0.05% to 1.0% by weight of pectin;

(b) from 2.0% to 4.5% by weight of sodium carboxymethylcellulose;

(c) from 15.0% to 20.0% by weight of propylene glycol; and

(d) water in an amount to make up the difference between the amount of ingredients (a) - (c) and 100% by weight.

5. The method of treating a wound of claim 4 wherein the hydrocolloid wound gel composition comprises:

(a) 0.1% by weight of pectin;

(b) 3.4% by weight of sodium carboxymethylcellulose;

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(c) 15% by weight of propylene glycol; and

(d) 81.5% by weight of deionized water.

6. The method of treating a wound of claim 4 wherein the hydrocolloid wound gel composition contains an effective amount of a pharmaceutically active ingredient.

7. Use of the gel composition of claim 1, 2 or 3 for the manufacture of a medicament for the treatment of wounds.

8. A hydrocolloid wound gel composition substantially as hereinbefore described with reference to any one of the examples.

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HYDROCOLLOID WOUND GEL

Abstract

A hydrocolloid wound gel composition useful for cleansing an debriding wounds and having some capacity for absorbing wound exudate and a method of treating wounds comprising applying the hydrocolloid wound gel to a wound.

The composition includes sodium carboxymethylcellulose, pectin, propylene glycol and water.