

[54] **NON-STINGING WOUND DRESSING
CONTAINING TERTIARY BUTYL
ALCOHOL**

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[56]

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[57]

ABSTRACT

This invention is concerned with a solution of plastic material useful as a non-stinging wound dressing. The solvent system is a mixture of stinging and non-stinging solvents in which the non-stinging solvent is primarily tertiary butyl alcohol. The polarity of the solvent system is adjusted by altering the amount of stinging and non-stinging solvent to provide sufficient solvent capacity to dissolve the plastic material. This wound dressing is preferably applied to the wound as an aerosol spray dressing containing a germicide.

22 Claims, No Drawings

NON-STINGING WOUND DRESSING CONTAINING TERTIARY BUTYL ALCOHOL

The present invention is concerned with a clean, convenient, economical and effective wound dressing for small wounds, abrasions, burns, and varicose and decubitus ulcers. Conventional gauze bandages and plasters do not protect wounds from infection and water, and must be changed often. Conventional wound coverings often interfere with healing, inhibit normal bathing of the area around the wound, and are uneconomical in terms of staff time required for changing. Wound dressings of plastic material in solvents avoid many of the problems associated with conventional dressings in that they protect a wound against infection, permit visual inspection of wound healing, allow the patient to maintain normal bathing habits, and are simple to apply. Despite obvious advantages these products are not widely used because of the enormous stinging pain associated with their application to unanesthetized raw surfaces (*British Medical Journal*, 2 July 3 (1954) at page 18).

It is an object of this invention to prepare a non-stinging wound spray of plastics in a solvent system.

In its broadest context the present invention encompasses a non-stinging wound dressing comprising a plastic material dissolved in a solvent system, the solvent system containing 70% or more non-stinging solvent, the non-stinging solvent containing more than 50% tertiary butyl alcohol. The present invention includes the non-stinging wound dressings as set forth above further containing medicinally active agents and it also includes non-stinging aerosol spray wound dressings comprising propellant gases and a plastic material dissolved in a solvent system, the solvent system containing 70% or more non-stinging solvent, the non-stinging solvent containing 50% or more tertiary butyl alcohol. A solvent system consisting of tertiary butyl alcohol alone or tertiary butyl alcohol in combination with other non-stinging solvents stinging solvents, or mixtures of stinging and non-stinging solvents within the above specified limitations is suitable for practicing the present invention. The present invention encompasses also a method for dressing wounds, which comprises applying a film of any of the non-stinging wound dressings or non-stinging aerosol wound dressings herein described to a wound.

By applying solvents to open wounds produced by sandpaper on the lower arm of 10 subjects it has been discovered that saturated hydrocarbons and chloro-fluoro-substituted hydrocarbons are non-stinging solvents. The saturated straight or branched chain hydrocarbons containing 5-8 carbon atoms, saturated cyclic hydrocarbons containing 5-8 carbon atoms, and chloro-fluoro-substituted saturated hydrocarbons containing 1-2 carbon atoms are non-stinging solvents. Cyclopentane, cyclohexane, cycloheptane, cyclooctane, n-pentane, n-hexane, n-heptane, n-octane, fluorotrichloromethane, sym-tetrachlorodifluoroethane, trifluorotrichloroethane, difluorochloromethane, and sym-dichlorotetrafluoroethane are examples of non-stinging solvents.

Common polar solvents such as low molecular weight alcohols, ketones, and esters are determined to be stinging solvents by the above test. Primary and secondary alcohols containing 1-6 carbon atoms, ketones containing 3-7 carbon atoms, esters of acids containing 1-4 carbon atoms and alcohols having 1-6 carbon

atoms are stinging solvents useful for increasing polarity of the solvent system to facilitate dissolving the plastic material. Methanol, ethanol, n-propyl alcohol, isopropyl alcohol, n-butyl alcohol, isobutyl alcohol, secondary butyl alcohol, acetone, methyl ethyl ketone, ethyl acetate, methylamyl acetate, isopropyl acetate, ethyl lactate, chloroform, and trichloroethylene are suitable but not exclusive examples of a stinging polar solvent.

It has unexpectedly been found that of monohydroxy alcohols containing from 1 to 6 carbon atoms, tertiary butyl alcohol alone does not sting. It has also been found that non-stinging solvents do not cause vasodilation or haemolysis of red blood cells. Table 1 illustrates the relationship of stinging effects of solvents as determined by sandpaper wounds on the lower arm of human subjects and vasodilation as determined by microscopic examination. Table 2 illustrates the haemolysis effects of stinging solvents on red blood cells as determined by ultraviolet spectroscopy. Surprisingly up to 15% of tertiary butyl alcohol does not cause haemolysis.

Table 1

	Stinging Pain	Vasodilation
methyl alcohol	yes	pronounced
ethyl alcohol	yes	pronounced
n-propyl alcohol	yes	pronounced
isopropyl alcohol	yes	pronounced
n-butyl alcohol	yes	pronounced
isobutyl alcohol	yes	pronounced
sec-butyl alcohol	yes	pronounced
tert-butyl alcohol	no	none
acetone	yes	pronounced
ethyl acetate	yes	pronounced
ethylene chloride	yes	pronounced
ethyl lactate	yes	pronounced
chloroform	yes	pronounced
methyl amyl acetate	yes	pronounced
methyl ethyl ketone	yes	pronounced
methyl glycol	yes	pronounced
isopropyl acetate	yes	pronounced
propylene glycol	yes	pronounced
trichloroethylene	yes	pronounced
trichlorotrifluoroethane	no	none
difluorodichloromethane	no	none
fluorotrichloromethane	no	none
difluorochloromethane	no	none
dichlorodifluoromethane	no	none
sym-dichlorotetrafluoroethane	no	none

Table 2

Haemolysis in Per Cent	Solvent Per Cent by Volume					
	1%	3%	5%	7%	10%	15%
methyl alcohol	5	15	25	60	100	100
ethyl alcohol	5	10	15	50	60	100
n-propyl alcohol	0	5	15	30	60	100
isopropyl alcohol	0	5	15	30	60	100
tertiary butyl alcohol	0	0	0	0	0	0
ethyl acetate	0	15	55	80	100	100
acetone	5	20	50	60	100	100

From Tables 1 and 2 it is evident that of the low molecular weight alcohols tertiary butyl alcohol alone does not sting and it appears that stinging effects are related to vasodilation and haemolysis.

It has most surprisingly been found that mixtures of stinging solvents and non-stinging solvents provide non-stinging solvent systems. Thus solvent systems containing up to 30% stinging solvent and 70% or more non-stinging solvent wherein the non-stinging solvent contains 50% or more tertiary butyl alcohol do not

produce a painful stinging effect when applied to a wound.

Polymers and copolymers prepared from lower alkyl acrylates and methacrylates having 1 to 3 carbon atoms in the alkyl group such as methyl acrylate, ethyl acrylate, isopropyl acrylate, methyl methacrylate, ethyl methacrylate, propyl methacrylate, methoxyethyl acrylate, ethoxyethyl acrylate, methoxyethyl methacrylate, ethoxyethyl methacrylate, acrylamide, methacrylamide, n-alkyl substituted acrylamides and methacrylamides such as N-methyl, ethyl, propyl acrylamides and methacrylamides, N-vinyl pyrrolidone, hydroxy-(lower alkyl) acrylates and methacrylates form suitable but not exclusive plastic material useful in practicing this invention.

Plastic materials selected from the group comprising poly(lower alkyl)methacrylate, poly-2-alkoxyethyl methacrylate and copolymers thereof are preferred. For example, N-butyl methacrylate, isobutyl methacrylate, 2-ethoxyethyl methacrylate, 80/20 copolymer of isobutyl methacrylate/n-butyl methacrylate and methyl methacrylate are preferable plastic materials. Polyvinyl butyral, ethyl cellulose, polyvinyl ethyl ether, and polyisobutylene and copolymers thereof are representative of other desirable plastic materials.

Furthermore, medicinally active ingredients such as germicides, fungicides, antibiotics, steroids, local anesthetics or the like may be utilized by having the medicinally active ingredient suspended or entrapped in the polymer, or if desired, dissolved in the liquid phase of the system. Examples of such medicinally active ingredients include 2,4,4'-trichloro-2'-hydroxydiphenyl ether, benzocaine, xylocaine, aspirin, sodium omadine (a derivative of 1-hydroxypyridine-2-thione), hexachlorophene, bacitracin, cortisone, trimethyl benzyl ammonium chloride, cetyl pyridinium chloride, penicillin, Aureomycin (chlorotetracycline), chloromycetin (chloramphenicol), merthiolate, sulfanilamide, sulfathiazole, sulfaguanidine, sulfapyridine, salicylic acid, Griseofulvin, undecylenic acid, zinc undecylenate, tetracycline, Terracyclin (hydroxytetracycline), dienesol, ethynyl estradiol, diethyl stilbestrol, estradiol, methyltestosterone, progesterone, ascorbic acid. Thus this system of plastic material in a non-stinging solvent is an effective means for topically administering drugs.

The wound dressing of this invention of plastics in a solvent system is an effective method of treating wounds and may be applied by brushing, dabbing, by squeeze bottles or by aerosol spray. Aerosol spray is the preferred method of application, since it provides a thin, tough and transparent film. The invention can be used to form spray-on bandages not only for human wound but also is useful in the field of veterinary medicine for wounds on the skins of animals such as dogs, cats, sheep, cattle (e.g. to protect cows having mastitis on their teats), goats, pigs and horses and zoological animals such as lions, tigers, deer, zebra, etc. The film can be applied in a matter of seconds; there is no stinging upon application; healing of the wound can be observed; the patient may bathe normally, and the film is easily removed after several days. Thus, this invention embodies effective methods of dressing wounds.

Aerosols require that the solvent, plastic material and medicinal, if any, be placed in a pressurized container with propellant gases. Suitable propellant gases include those well known in the art. There can be used compressed gases such as carbon dioxide, nitrous oxide, nitrogen, liquified volatile hydrocarbons such as pro-

pane, n-butane, isobutane and 2-methylbutane, methylene chloride, vinyl chloride, fluorinated compounds including perhalogenated compounds and fluorinated hydrocarbons such as dichlorodifluoromethane, 1,1,2-trichloro-1,2,2-trifluoroethane, trichlorofluoromethane, 1,2-dichlorotetrafluoroethane, octafluorocyclobutane, chlorodifluoromethane, 1,1-difluoroethane, vinyl fluoride, vinylidene fluoride, 1-chloro-1,1-difluoroethane. The propellant should contain a substantial amount of volatile material boiling at not over 20° C., but there can also be present a significant amount of less volatile material boiling up to 50° C. Therefore non-stinging aerosol spray wound dressings of propellant gases and plastic material in a solvent system containing 70% or more non-stinging solvent, said non-stinging solvent containing 50% or more tertiary butyl alcohol, are in the scope of this invention. Non-stinging solvent may be used alone or in combination with stinging solvents selected from the group comprising alcohols containing 1-6 carbon atoms, ketones containing 1-4 carbon atoms, and esters of acids containing 1-4 carbon atoms and alcohols containing 1-6 carbon atoms or mixtures of the aforementioned polar solvents.

Preferred non-stinging wound dressings suitable for dabbing and brushing are prepared from 5-25% solutions of plastic material selected from the group comprising poly(lower alkyl)methacrylate, poly-2-alkoxyethyl methacrylate, and copolymers thereof in tertiary butyl alcohol (at least 50%) and trichlorotrifluoroethane. The addition of a germicide such as 2,4,4'-trichloro-2'-hydroxydiphenyl ether is desirable. The addition of up to 30% stinging solvent, usually 0.5 to 30%, improves the solubility characteristics of the plastic material without causing any stinging.

The preferred non-stinging wound dressings are converted to non-stinging aerosol wound sprays by combining the non-stinging wound dressing with suitable propellant gases in a pressurized aerosol container.

A preferred formulation of a non-stinging aerosol spray wound dressing is:

tertiary butyl alcohol	2.54%
2-ethoxyethylmethacrylate	3.09%
methyl methacrylate	0.01%
ethyl acetate	0.55%
amyl acetate	0.01%
1,1,2-trichloro-1,2,2-trifluoroethane	24.80%
trichlorofluoromethane	47.00%
difluorochloromethane	22.00%
polytetrafluoroethylene	0.001%
dichlorophene	400 ppm based on polymer content

EXAMPLE 1

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 15 parts polyvinyl butyral in 85 parts tertiary butyl alcohol.

EXAMPLE 2

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 15 parts ethyl cellulose in 85 parts tertiary butyl alcohol.

EXAMPLE 3

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dis-

solving 15 parts polyvinyl ethyl ether in 85 parts tertiary butyl alcohol.

EXAMPLE 4

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 15 parts polyisobutylene in 85 parts tertiary butyl alcohol.

EXAMPLE 5

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 15 parts of poly-n-butyl methacrylate in 45 parts of tertiary butyl alcohol and 40 parts of trichlorotrifluoroethane.

EXAMPLE 6

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 15 parts of poly-isobutyl methacrylate in 45 parts tertiary butyl alcohol and 40 parts trichlorotrifluoroethane.

EXAMPLE 7

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 14 parts of a 95/5 copolymer of 2-ethoxyethyl methacrylate/methyl methacrylate and 1 part dibutyl phthalate in 45 parts of tertiary butyl alcohol and 40 parts of trichlorotrifluoroethane.

EXAMPLE 8

A non-stinging wound dressing particularly suited for dabbing or brushing on a wound is prepared by dissolving 15 parts of a 80/20 copolymer of isobutyl methacrylate/n-butyl methacrylate in 60 parts of tertiary butyl alcohol and 25 parts acetone.

EXAMPLE 9

A non-stinging wound dressing particularly suited for brushing or dabbing on a wound is prepared by dissolving 15 parts polyvinyl butyral in 77 parts tertiary butyl alcohol and 8 parts ethyl alcohol.

EXAMPLE 10

A non-stinging wound dressing particularly suited for brushing or dabbing on a wound is prepared by dissolving 15 parts poly-2-ethoxyethoxy methacrylate in 60 parts tertiary butyl alcohol and 25 parts ethyl acetate.

EXAMPLE 11

An aerosol spray container is charged with 200 g. of a formulation which contains:

tertiary butyl alcohol	2.54%
2-ethoxyethylmethacrylate	3.09%
methyl methacrylate	0.01%
ethyl acetate	0.55%
amyl acetate	0.01%
1,1,2-trichloro-1,2,2-trifluoroethane	24.80%
trichlorofluoromethane	47.00%
difluorochloromethane	22.00%
polytetrafluoroethylene	0.001%
dichlorophene	400 ppm based on polymer content

This formulation provides about 250 2 cm. x 7 cm. bandage strips.

What is claimed is:

1. A non-stinging wound dressing comprising film forming plastic material dissolved in a solvent system, said solvent system containing 70% or more non-stinging solvent, said non-stinging solvent consisting of tertiary butyl alcohol and solvent selected from the group comprising straight and branched chain saturated hydrocarbons having 5-8 carbon atoms, saturated cyclic hydrocarbons having 5-8 carbon atoms and chloro-fluoro substituted saturated hydrocarbons containing 1-2 carbon atoms and mixtures thereof wherein the non-stinging solvent contains 50% or more tertiary butyl alcohol, said film forming plastic material selected from the group comprising, N-butyl methacrylate, isobutyl methacrylate, 2-ethoxyethyl methacrylate, methyl methacrylate, polyvinyl butyral, ethyl cellulose, polyvinyl ethyl ether, polyisobutylene polymers and 80/20 isobutyl methacrylate/N-butyl methacrylate and 95/5 2-ethoxyethyl methacrylate/methyl methacrylate copolymers, said film forming plastic material being skin adherent and washable upon drying.

2. As in claim 1, a non-stinging wound dressing comprising plastic material in a solvent system, said plastic material selected from the group comprising poly(lower alkyl)methacrylate, poly-2-alkoxyethyl methacrylate and copolymers thereof.

3. As in claim 1, a non-stinging wound dressing comprising a 5-25% solution of polyvinyl butyral in tertiary butyl alcohol.

4. As in claim 1, a non-stinging wound dressing comprising a 5-25% solution of ethyl cellulose in tertiary butyl alcohol.

5. As in claim 1, a non-stinging wound dressing comprising a 5-25% solution of polyvinyl ethyl ether in tertiary butyl alcohol.

6. As in claim 1, a non-stinging wound dressing comprising a 5-25% solution of polyisobutylene in tertiary butyl alcohol.

7. As in claim 1, a non-stinging wound dressing comprising 5-25% solution of plastic material selected from the group comprising poly(lower alkyl)methacrylate, poly-2-alkoxyethyl methacrylate and copolymers thereof in a tertiary butyl alcohol/trichlorotrifluoroethane solvent system.

8. As in claim 1, a non-stinging wound dressing comprising 45 parts tertiary butyl alcohol, 40 parts trichlorotrifluoroethane, and 15 parts polyisobutyl methacrylate.

9. As in claim 1, a non-stinging wound dressing comprising 45 parts tertiary butyl alcohol, 40 parts trichlorotrifluoroethane, and 15 parts poly-n-butyl methacrylate.

10. As in claim 1, a non-stinging wound dressing comprising 45 parts tertiary butyl alcohol, 40 parts trichlorotrifluoroethane, 14 parts 95/5 copolymer of 2-ethoxyethyl methacrylate/methyl methacrylate, and dibutyl phthalate.

11. As in claim 1, a non-stinging wound dressing comprising a 5-25% solution of plastic material selected from the group comprising poly(lower alkyl)methacrylate, poly-2-alkoxyethyl methacrylate and copolymers thereof in tertiary butyl alcohol containing 0.5-30 per cent stinging solvent.

12. As in claim 1, a non-stinging wound dressing comprising 60 parts tertiary butyl alcohol, 25 parts acetone, and 15 parts of 80/20 copolymer of isobutyl methacrylate/n-butyl methacrylate.

13. As in claim 1, a non-stinging wound dressing comprising 60 parts tertiary butyl alcohol, 25 parts ethyl acetate, and 15 parts poly-2-ethoxyethyl methacrylate.

14. As in claim 1, a non-stinging wound dressing further containing a medicinally active ingredient.

15. As in claim 1, a non-stinging wound dressing further containing a germicide.

16. As in claim 1, a non-stinging wound dressing comprising film forming plastic material dissolved in a solvent system, said solvent system containing stinging solvent and 70% or more non-stinging solvent, said non-stinging solvent consisting of tertiary butyl alcohol and a solvent selected from the group comprising straight and branched chain saturated hydrocarbons having 5-8 carbon atoms; saturated cyclic hydrocarbons having 5-8 carbon atoms and chlorofluoro substituted saturated hydrocarbons containing 1-2 carbon atoms and mixtures thereof wherein the non-stinging solvent contains 50% or more tertiary butyl alcohol, said stinging solvent selected from the group comprising primary and secondary alcohols containing 1-6 carbon atoms, ketones containing 1-4 carbon atoms, esters of acids containing 1-4 carbon atoms and alcohols containing 1-6 carbon atoms, said film forming plastic material selected from the group comprising, N-butyl methacrylate, isobutyl methacrylate, 2-ethoxyethyl methacrylate, methyl methacrylate, polyvinyl butyral, ethyl cellulose, polyvinyl ethyl ether, polyisobutylene polymers and 80/20 isobutyl methacrylate/N-butyl methacrylate and 95/5 2-ethoxyethyl methacrylate/methyl methacrylate copolymers, said film forming plastic material being skin adherent and washable upon drying.

17. A non-stinging aerosol spray wound dressing comprising propellant gases together with film forming plastic material dissolved in a solvent system, said solvent system containing 70% or more non-stinging solvent, said non-stinging solvent consisting of tertiary butyl alcohol and solvent selected from the group comprising straight and branched chain saturated hydrocarbons having 5-8 carbon atoms, saturated cyclic hydrocarbons having 5-8 carbon atoms and chlorofluoro substituted saturated hydrocarbons containing 1-2 carbon atoms and mixtures thereof wherein the non-stinging solvent contains 50% or more tertiary butyl alcohol, said film forming plastic material selected from the group comprising, N-butyl methacrylate, isobutyl methacrylate, 2-ethoxyethyl methacrylate, methyl methacrylate, polyvinyl butyral, ethyl cellulose, polyvinyl ethyl ether, polyisobutylene polymers and 80/20 isobutyl methacrylate/N-butyl methacrylate and 95/5 2-ethoxyethyl methacrylate/methyl methacrylate copolymers, said film forming plastic material being skin adherent and washable upon drying.

18. As in claim 17, a non-stinging aerosol spray wound dressing comprising:

tertiary butyl alcohol	2.54%
2-ethoxyethylmethacrylate	3.09%
methyl methacrylate	0.01%
ethyl acetate	0.55%
amyl acetate	0.01%
1,1,2-trichloro-1,2,2-trifluoroethane	24.80%
trichlorofluoromethane	47.00%

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difluorochloromethane	22.00%
polytetrafluoroethylene	0.001%
dichlorophene	400 ppm based on polymer content

19. As in claim 17, a non-stinging aerosol spray wound dressing further containing a germicide.

20. As in claim 17, a non-stinging aerosol spray wound dressing comprising propellant gases together with film forming plastic material dissolved in a solvent system, said solvent system containing stinging solvent and 70% or more non-stinging solvent, said non-stinging solvent consisting of tertiary butyl alcohol and a solvent selected from the group comprising straight and branched chain saturated hydrocarbons having 5-8 carbon atoms, saturated cyclic hydrocarbons having 5-8 carbon atoms and chlorofluoro substituted saturated hydrocarbons containing 1-2 carbon atoms and mixtures thereof wherein the non-stinging solvent contains 50% or more tertiary butyl alcohol, said stinging solvent selected from the group comprising primary and secondary alcohols containing 1-6 carbon atoms, ketones containing 1-4 carbon atoms, esters of acids containing 1-4 carbon atoms and alcohols containing 1-6 carbon atoms, said film forming plastic material selected from the group comprising, N-butyl methacrylate, isobutyl methacrylate, 2-ethoxyethyl methacrylate, methyl methacrylate, polyvinyl butyral, ethyl cellulose, polyvinyl ethyl ether, polyisobutylene polymers and 80/20 isobutyl methacrylate/N-butyl methacrylate and 95/5 2-ethoxyethyl methacrylate/methyl methacrylate copolymers, said film forming plastic material being skin adherent and washable upon drying.

21. As in claim 17, a non-stinging aerosol spray wound dressing further containing a germicide, fungicide, antibiotic, steroid or local anesthetic.

22. A method for dressing wounds comprising applying to the wound a thin film of a non-stinging wound dressing comprising film forming plastic material dissolved in a solvent system, said solvent system containing stinging solvent and 70% of more non-stinging solvent, said non-stinging solvent consisting of tertiary butyl alcohol and a solvent selected from the group comprising straight and branched chain saturated hydrocarbons having 5-8 carbon atoms; saturated cyclic hydrocarbons having 5-8 carbon atoms and chlorofluoro substituted saturated hydrocarbons containing 1-2 carbon atoms and mixtures thereof wherein the non-stinging solvent contains 50% or more tertiary butyl alcohol, said stinging solvent selected from the group comprising primary and secondary alcohols containing 1-6 carbon atoms, ketones containing 1-4 carbon atoms, esters of acids containing 1-4 carbon atoms and alcohols containing 1-6 carbon atoms, said film forming plastic material selected from the group comprising N-butyl methacrylate, isobutyl methacrylate, 2-ethoxyethyl methacrylate, methyl methacrylate, polyvinyl butyral, ethyl cellulose, polyvinyl ethyl ether, polyisobutylene polymers and 80/20 isobutyl methacrylate/N-butyl methacrylate and 95/5 2-ethoxyethyl methacrylate/methyl methacrylate copolymers, said film forming plastic material being skin adherent and washable upon drying.

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