FORM 1

COMMONWEALTH OF AUSTRALIA

PATENTS ACT 1952 604952

APPLICATION FOR A STANDARD PATENT

I\We,

HUTCHINSON S.A.

of 2, RUE BALZAC 75008
PARIS
FRANCE

hereby apply for the grant of a standard patent for an invention entitled:

PROPHYLACTIC DEVICE MADE OF ELASTOMERIC MATERIAL, SUCH AS A CONTRACEPTIVE SHEATH OR THE LIKE, AND PROCESS FOR ITS MANUFACTURE

which is described in the accompanying complete specification

Details of basic application(s):

Number of basic application	Name of Convention country in which basic application was filed	Date of basic application
87 11753	FR	20 AUG 87

My/our address for service is care of GRIFFITH HACK & CO., Patent Attorneys, 601 St. Kilda Road, Melbourne 3004, Victoria, Australia.

DATED this 08th day of August 1988

HUTCHINSON S.A.

GRIFFITH HACK & CO

TO: The Commissioner of Patents.

APPLICATION ACCEPTED AND AMENDMENTS ALLOWED 26.9.90

Australia Patent Declaration Form

Forms 7 and 8

AUSTRALIA

Patents Act 1952

DECLARATION IN SUPPORT OF A CONVENTION OR NON-CONVENTION APPLICATION FOR A PATENT OR PATENT OF ADDITION

Name(s) of Applicant(s)

In support of the application made by HUTCHINSON S.A.

Title

for a patent for an invention entitled PROPHYLACTIC DEVICE MADE OF ELASTOMERIC MATERIAL, SUCH AS A CONTRACEPTIVE SHEATH OR THE LIKE, AND PROCESS FOR ITS MANUFACTURE

Name(s) and address(es) of person(s) making declaration

I/We, Danick Rousseau
c/o Hutchinson S.A.
2 rue Balzac, 75008 PARIS, France

do solemnly and sincerely declare as follows:-

1. I am/we are the applicant(s) for the patent, or am/are authorised by the abovementioned applicant to make this declaration on its behalf.

2. The basic application(s) as defined by Section 141 of the Act was/were made in the following country or countries on the following date(s) by the following applicant(s) namely:-

Country, filing date and name of Applicant(s) for the or each basic application

in FRANCE on AUGUST 20, 1987 19
by HUTCHINSON
in on 19
by

3. The said basic application(s) was/were the first application(s) made in a Convention country in respect of the invention the subject of the application.

Name(s) and address(es) of the or each actual inventor

4. The actual inventor(s) of the said invention is/are BUSNEL René Guy, Chemin de la Butte du Diable, 91570 BIEVRES France and ARGY Gilles, 15 Ter rue Nationale, 78940 LA QUEUE LES YVELINES FRANCE

See reverse side of this form for guidance in completing this part

5. The facts upon which the applicant(s) is/are entitled to make this application are as follows:-
The Applicant would be entitled to have assigned to it a patent granted to any of the actual inventors in respect of the said invention.

DECLARED at Paris this 28 day of July 1988 19

HUTCHINSON
2 Rue Balzac - 75008 Paris

Danick ROUSSEAU
Directeur Général

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PROPHYLACTIC DEVICE AND PROCESS FOR ITS MANUFACTURE

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(71) Applicant(s)
HUTCHINSON S.A.

(72) Inventor(s)
RENE GUY BUSNEL; GILLES ARGY

(74) Attorney or Agent
GRIFFITH HACK & CO, GPO Box 1285K, MELBOURNE VIC 3001

(56) Prior Art Documents
US 4332243

(57) Claim

1. A prophylactic device composed of elastomeric material comprising at least two layers of elastomeric material arranged to at least partially abut one another and at least one substance which is biologically active against micro-organisms being located between the two said layers, wherein said biologically active substance is enclosed in microcapsules having walls which rupture either under the action of rubbing or shearing forces which are applied to the microcapsules in use or under the action of micro tears which may result in the prophylactic device becoming permeable.

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Form 10

COMPLETE SPECIFICATION

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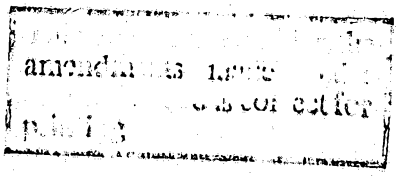

Priority:

Related Art:

TO BE COMPLETED BY APPLICANT

Name of Applicant:
HUTCHINSON S.A.

Address of Applicant: 2, RUE BALZAC 75008
PARIS
FRANCE

Actual Inventor:

Address for Service: GRIFFITH HACK & CO.,
601 St. Kilda Road,
Melbourne, Victoria 3004,
Australia.

Complete Specification for the invention entitled:
PROPHYLACTIC DEVICE MADE OF ELASTOMERIC MATERIAL, SUCH AS A CONTRACEPTIVE SHEATH OR THE LIKE, AND PROCESS FOR ITS MANUFACTURE

The following statement is a full description of this invention including the best method of performing it known to me:-

The invention relates to a prophylactic device made of elastomeric material and to the process for its manufacture.

It relates in particular, although without in any way implying a limitation, to contraceptive sheaths suitable for use as an obstacle to contamination of their users by germs or viruses during sexual intercourse, and also to products having an analogous protective effect during certain types of medical examination, such as finger stalls, or else during certain types of surgical or dental intervention for which the doctors or dentists use protective gloves.

Both in cases of examination or intervention and in cases of protection against agents of sexually transmitted diseases, the rupture or sometimes even just cracking of the membrane (generally rubber) which forms the contraceptive sheath, finger stall or gloves can result in contamination of the person wearing the device, so its use is not without risk. This risk, which is measured by the value of the AQL factor (Acceptable Quality Level) is currently of the order of 0.4% for contraceptive sheaths, i.e. a value considered unsatisfactory by the medical profession as a whole. In an attempt to reduce the margin of risk, it has already been proposed to associate a product active against the AIDS virus with contraceptive sheaths, the said product being applied as a coating on the rubber forming the contraceptive sheath. Although this kind of device is theoretically satisfactory, it can have disadvantages, for example due to possible interactions between the active product and the polymer of the sheath which are capable of causing a modification of the elastic properties and ageing properties of this sheath or, conversely, a loss of activity of the molecules of the active product by adsorption and complex formation on

rubber and other polymers. Moreover, the presence of an active product applied in the form of a film to one or both sides of the rubber sheath, from which it is transferred to the skin and/or mucosa of the sexual partners, may lead, after repeated use, to phenomena of attack or irritation of the mucosa, allergy, hypersensitivity, etc.

Devices consisting of an association of two separate sheaths with a pharmacologically active liquid in between have already been known for some time (cf. especially US patent 2 586 674): apart from the fact that the active principles brought into direct contact with the latex or its derivatives act on the latter, often very rapidly destroying the mechanical properties and hence the impermeability of the latex, it should also be noted that the liquid contained between the two sheaths tends to collect in one place when rubbing occurs, thereby leaving unprotected a whole area of the organ which is supposed to be protected.

It is consequently a general object of the invention to provide a prophylactic device made of elastomeric material which mitigates the above-mentioned disadvantages.

According to the present invention there is provided a prophylactic device composed of elastomeric material comprising at least two layers of elastomeric material arranged to at least partially abut one another and at least one substance which is biologically active against micro-organisms being located between the two said layers, wherein said biologically active substance is enclosed in microcapsules having walls which rupture either under the action of rubbing or shearing forces which are applied to the microcapsules in use or under the action of micro tears which may result in the prophylactic device becoming permeable.

AUSTRALIAN PATENT OFFICE

Microcapsules obtained by the coacervation process or by other conventional methods are known in the art of inclusion of pharmaceutical products and, for example, in carbonless copy paper or analogous flexible substrates.

A device with this structure only releases the active product in contact with the skin and/or mucosa of its user and/or the sexual partners when one of the constituent layers of elastomer ruptures, so, on the one hand, there is no need to fear the adverse effects of habituation and, on the other hand, any phenomena of interaction between the rubber, or any other elastomeric material forming the layers, and the active product are avoided. The chosen active product can therefore be one molecule or a mixture of several chemically compatible molecules having the desired pharmacological effect, for example an antiviral effect acting on the AIDS virus, herpes virus, etc., or a spermicidal, fungicidal, trichomonacidal, bactericidal or all-embracing effect.

The process according to the invention for the manufacture of a prophylactic device as defined above therefore comprises giving a first layer of elastomeric material the desired shape of the prophylactic device using the appropriate customary manufacturing techniques, carrying out a first prevulcanization treatment on the said first layer, applying to one side of the said layer a film formed of microcapsules containing one or more active products, then depositing on the said film a second layer of elastomer having the shape of the desired device, and vulcanizing the whole before removing it from the form.

In a preferred embodiment, the microcapsules are deposited on the first layer of elastomer by means of a fluidized bed or the like, in which is placed the

said first layer, arranged on its form and in the prevulcanized state, i.e. in a condition such that the microcapsules adhere to the said layer by the tack effect as soon as they come into contact therewith.

In another embodiment, a production form on which a first layer of elastomer has been deposited, the said layer having undergone a prevulcanization treatment, is immersed in a latex which contains, in addition to the elastomer in dispersion, the microcapsules enclosing the active product or products, this stage being followed by the deposition of a further layer of elastomer on the intermediate layer containing the microcapsules, and then by a vulcanization treatment of the whole.

The process for the manufacture of a prophylactic device as described above, i.e. a device with two layers of elastomer between which there is a film or sheet of microcapsules containing one or more active products - deposited according to the first or second embodiment - can of course be repeated for the manufacture of devices with a larger number of layers, such devices not only having an increased impermeability and increased mechanical strength but also being capable of having a greater quantity of active product(s) associated therewith.

This type of process, which mechanically joins the first and second envelopes together through the presence of "bridges" of elastomer between the two constituent layers of each of the envelopes, favors the overall mechanical behavior of the device, the act of placing the said device over the penis or over the finger or hand of the practitioner carrying out an examination or a surgical intervention developing sufficient forces to cause the shells of the microcapsules to break, rupture or burst and thus cause the active product to be

released into the space created between the adjacent layers of elastomer.

In an advantageous embodiment of the subject of the invention, the microcapsules containing the active principles have a mean diameter of the order of 5 to 50 μ, the layers of elastomeric material having a thickness of 10 to 50 μ in the case of contraceptive sheaths or a greater thickness, which can be as much as 300 to 500 μ, in the case of finger stalls or gloves.

These dimensions were chosen so that dynamics of small amplitude (consisting of two to three movements of the male wearing the contraceptive sheath and, in the case of the gloves, a pressure of 300 to 500 g, which is identical to that exerted in a wiping action, for example) on the one hand cause the microcapsules to burst and the pharmacological agent to be distributed, and on the other hand, by virtue of the simultaneous tearing of the thin inner layer of latex, cause the organ wearing the device (sexual organ, finger or the like) to be covered.

Further characteristics and advantages of the invention will become apparent from the following description, which is given by way of example and refers to the attached drawing; in this drawing:

- Figure 1 is a schematic view, on a large scale and in section, illustrating the structure and a first embodiment of a manufacturing process according to the invention;

- Figure 2 is a view analogous to Figure 1 for a second embodiment; and

- Figure 3 is a very schematic view of part of the prophylactic device according to the invention.

As shown in this last Figure, the prophylactic device 10, such as a contraceptive sheath, a finger stall, surgical gloves or the like, comprises essentially

two layers of elastomer 11 and 12, for example based on natural rubber, between which one or more active products 13, in the form of microcapsules, microgranules or the like, are trapped. In this respect, the representation in Figure 3 is very schematic and must not be considered as giving an indication of the scale of the constituent parts of the device. The microcapsules containing the active product or products actually have a mean diameter of the order of 5 to 50 μ, while the layers of elastomeric material have a thickness of 10 to 30 μ in the case of contraceptive sheaths or a greater thickness, which can be as much as 300 μ, in the case of finger stalls or gloves.

The microcapsules or microspheres form a matrix system whose shell is made of a known material such as, for example: cellulose acetophthalate, polyvinyl alcohol, pectin, gum arabic, methyl cellulose, gelatin, epoxy resin or the like, containing one or more products having specific and complementary desired properties, especially antiviral, trichomonacidal, fungicidal, germicidal or spermatocidal properties, the said products being taken, without implying a limitation, from the group comprising the following in particular: moroxydine hydrochloride, vidarabine, aciclovir, 5-iododeoxycytidine and idoxuridine (DCI); quaternary ammonium compounds, such as alkyldimethylbenzylammonium chloride or benzalkonium chloride, hexylresorcinol of acid pH with added benzyldodecinium bromide or of neutral pH with sodium laurylsulfate, nonoxynol, paradiisobutylphenoxypolyethoxyethanol, benzethonium chloride (DCI) and phenylmercury nitrate with added methyl parahydroxybenzoate; miconazole nitrate, econazole nitrate, nystatin, nifuratel and natamycin; acetarsol, chlorquinaldol (5,7-dichloro-8-hydroxyquinaldine), tenonitrozole (DCI) and ternonidazole (DCI); iodinated polyvinylpyrrolidones,

chlorhexidine (DCI), digluconate, neomycin sulfate (DCI) and polymyxin B sulfate (DCI); and sodium hypochlorite, potassium permanganate, silver nitrate and mercury derivatives; the active molecules being complemented, if necessary, by the addition of an excipient and/or a preservative.

To manufacture a device according to the invention, provision is made for depositing a first layer of elastomer 12 on a form made of ceramic, glass or an analogous material, defining the glove, finger stall or contraceptive sheath to be manufactured; the said layer can be obtained by immersion in a latex with capillary fixation under the action of coagulants, or advantageously by means of an electrophoresis process. The said first layer coated on the form is then subjected to a prevulcanization treatment in a hot air tunnel, the temperature of the tunnel and the passage time being set so that the elastomer is not totally vulcanized and thus retains adhesive properties, these being utilized when, on leaving the said tunnel, the form coated with its prevulcanized layer of elastomer is immersed in a fluidized bed of microcapsules 14 containing the active principle or principles. These microcapsules deposit on contact with the outside 15 of the layer 12 and remain fixed by adhesion to the said layer. The whole is then coated with the layer 11, advantageously by immersion in a bath of latex, the elastomer of the said layer coating the microcapsules 14 and the spaces left free between the said microcapsules so as to form bridges like those referred to by 16 in Figure 1, which simultaneously ensure that the layers 11 and 12 are mechanically joined together and that the microcapsules 14 are trapped.

The whole prepared in this way is then vulcanized by a second passage through a hot air tunnel, the temperature of which is in all cases lower than that which

is capable of damaging the active product or products and/or the shell of the microcapsules or microspheres thus embedded between the two layers of elastomer.

Solvents for one or more active products, whose vaporization points are above the normal vulcanization temperature of elastomers, can advantageously be used, such as silicone oil, ethylene glycol or any other chemically and pharmacologically compatible solvent. In the case of water-soluble substances, it may be very advantageous to polymerize the elastomer in an oven under pressure, since this will prevent the gelatin microcapsules from bursting under the effect of the vapor pressure.

In a second embodiment, illustrated in Figure 2, the first layer 12 is manufactured in the manner indicated above as far as the prevulcanization stage. This stage is then followed by immersion, not in a fluidized bed of microcapsules but in a latex in which the microcapsules 15' have been homogeneously dispersed, so as to form, on the layer 12, an intermediate layer 17 containing the microcapsules 15' in a matrix of elastomer 18, which mechanically joins the layer 12 to the layer 11' - analogous to the layer 11 - the said layer 11' being applied to the matrix 18 and the microcapsules 15' by immersion in a latex in a manner analogous to that described above. Vulcanization of the whole prepared in this way gives the desired prophylactive device.

Although the description referring to Figures 1 and 2 relates to a device with two layers of elastomer enclosing one or more active products in the form of microcapsules, it is self-evident that the operations indicated can be repeated to form a multilayer device, such a device having increased mechanical strength and being capable of releasing a greater quantity of active product(s) if needed.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A prophylactic device composed of elastomeric material comprising at least two layers of elastomeric material arranged to at least partially abut one another and at least one substance which is biologically active against micro-organisms being located between the two said layers, wherein said biologically active substance is enclosed in microcapsules having walls which rupture either under the action of rubbing or shearing forces which are applied to the microcapsules in use or under the action of micro tears which may result in the prophylactic device becoming permeable.

2. The prophylactic device according to claim 1 in the form of a contraceptive sheath, a finger stall, or a glove.

3. A prophylactic device according to either claim 1 or 2 wherein the micro-organism is a germ, virus, fungi or other pathogen.

4. A prophylactic device according to any preceding claim wherein the biologically active substance has antiviral, trichomonacidal, fungicidal, germicidal or spermatocidal properties.

5. A prophylactic device according to any preceding claim in which rupture of the walls of the microcapsules are facilitated in use the device is located in use over the organ to be protected.

6. A prophylactic device according to any one of claims 2 to 5 wherein the microcapsules containing the biologically active substance have a mean diameter of the order of 5 to 50 micron, and the layers of elastomeric

AUSTRALIAN PATENT OFFICE

material have either a thickness of from 10 to 50 micron in the case of contraceptive sheaths or a greater thickness, which can be as much as 300 micron to 500 micron, in the case of finger stalls or gloves.

7. The prophylactic device according to any preceding claim wherein the microcapsules contain one or more biologically active substances having specific and/or complementary desired properties.

8. A prophylactic device according to any preceding claim in which the biologically active substance is spermatozoa.

9. The prophylactic device of any preceding claim in which the biologically active substance is moroxydine hydrochloride, vidarabine, aciclovir, 5-iododeoxycytidine, idoxuridine (DCI), quaternary ammonium compounds, hexylresorcinol of acid pH with added benzyldodecinium bromide or of neutral pH with sodium laurylsulfate, nonoxynol, paradiisobutylphenoxypolyethoxy-ethanol, benzethonium chloride (DCI), phenyl-mercury nitrate with added methyl parahydroxybenzoate, miconazole nitrate, econazole nitrate, nystatin, nifuratel, natamycin, acetarsol, chlorquinaldol (5,7-dichloro-8-hydroxyquinaldine), tenonitrozole (DCI), ternonidazole (DCI), iodinated polyvinylpyrrolidones, chlorhexidine (DCI), digluconate, neomycin sulfate (DCI), polymyxin B sulfate (DCI), sodium hypochlorite, potassium permangate, silver nitrate or mercury derivatives, the active molecules of the biologically active substance being complemented, if necessary, by the addition of an excipient and/or a preservative.

10. A prophylactic device according to claim 9 wherein the quaternary ammonium compound is

AUSTRALIAN PATENT OFFICE

alkyldimethylbenzylammoniumchloride or benzalkonium chloride.

11. A prophylactic device according to any one of claims 1 to 10 in which the microcapsules are arranged in a matrix system of either a homogeneous or heterogeneous structure.

12. A prophylactic device according to any one of claims 1 to 11 wherein the biologically active substance enclosed in the microcapsules is suspended in a non-aqueous solvent with high vaporisation point.

13. A prophylactic device according to any one of claims 1 to 11 wherein the biologically active substance enclosed in the microcapsules is suspended in an aqueous solution so that the final stage of vulcanization is carried out by oven drying under pressure.

14. The prophylactic device according to claim 12 wherein the non-aqueous solvent is ethylene glycol and/or silicon oil.

15. A process for the manufacture of a prophylactic device according to any preceding claim comprising forming a first layer of an elastomeric material into a desired shape of the prophylactic device, carrying out a first prevulcanization treatment of the first elastomeric layer, applying to one side of the first layer a film formed of microcapsules containing one or more of the biologically active substances, depositing on the film a second layer of elastomeric material having the shape of the prophylactic device and vulcanizing the combined layers.

16. A process according to claim 15 in which the device is shaped on an appropriately shaped form and is

AUSTRALIAN PATENT OFFICE

removed from the form after vulcanizing the combined layers.

17. The process according to claim 16 wherein the microcapsules are deposited on the first layer of elastomeric material by means of a fluidized bed in which is placed the first layer which is placed on the form in a prevulcanized state such that the microcapsule adhere to the layer of said elastomeric material due to the tack effect of the layer as soon as the microcapsules come into contact with the layer.

18. The process according to claim 16 wherein the first layer of elastomer when placed on the form undergoes a prevulcanization treatment and is immersed in a latex comprising, in addition to the elastomeric dispersion, the microcapsules enclosing the biologically active substance, followed by the deposition of a further layer of elastomer on an intermediate layer containing the microcapsules and vulcanizing the combined layers to form the device.

19. A process according to any one of claims 15 to 18 which is repeated a plurality of times to produce a device having more than two layers of elastomeric material, so that the device has increased mechanical strength and has a larger quantity of microcapsules containing the biologically active substance.

20. A prophylactic device substantially as hereinbefore described with reference to the accompanying drawings.

21. A process for the manufacture of a prophylactic

AUSTRALIAN PATENT OFFICE

device substantially as hereinbefore described with reference to the accompanying drawings.

Dated this 3rd day of September, 1990
HUTCHINSON S.A.
By its Patent Attorneys:
GRIFFITH HACK & CO.
Fellows Institute of Patent
Attorneys of Australia.

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FIG. 1

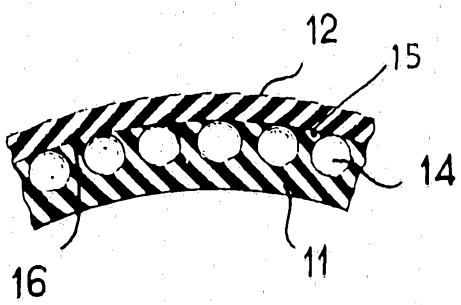

FIG. 2

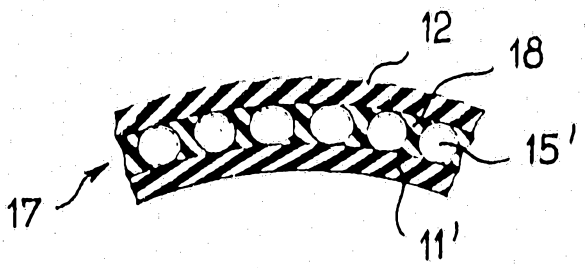

FIG. 3