

PATENT SPECIFICATION

NO DRAWINGS

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COMPLETE SPECIFICATION

Improvements in Contraceptive Devices

We, CHEMOLIMPEX MAGYAR VEGYIARU KULKERESKEDELMI VALLALAT, a Hungarian Body Corporate of 7—9 Deak Ferenc u, Budapest 5, Hungary, do hereby declare the invention for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention relates to improvements in contraceptive devices and more particularly it concerns water soluble polyvinyl alcohol films or moulded articles which may be employed as contraceptive devices.

The use of synthetic compounds and plastics has gained ground in the fields of hygiene and medicine in recent times. The use of inert plastics for surgical and prosthetic purposes is well known. Water soluble plastics such as, for example, polyethylene-oxide are used as vehicles in ointments and suppositories.

Local chemical contraceptives have a double aim: to constitute a mechanical barrier against direct insemination and to destroy the spermatozoa within a short time. However, the vehicles of the chemical contraceptives on the market: pessaries, jellies and foams, do not afford the required mechanical protection even if their spermicidal activity reaches the necessary level.

Known chemical contraceptives are closely associated with the coital act, and therefore present problems that cause non-acceptance or irregularity of use. Their acceptability is diminished also by the fact that they cause, in many cases, local complaints such as irritation, soreness and messiness, and present difficulties in application. Besides, they are neither safe nor effective enough.

In recent years large scale trials have been carried out with oral contraceptive pills and intra-uterine plastics devices for family planning and population control. The disadvantage of both methods is the fact that

they are so-called clinical methods requiring medical examination, control or intervention. In view of their side effects and contra-indications, neither method is suitable for all women.

According to the invention there is provided a water-soluble contraceptive device consisting essentially of a film or moulded article of water-soluble polyvinyl alcohol in admixture with and/or coated with a water-soluble spermicide.

By contraception and antivenereal device" is meant, in the case of a film, a discrete piece of a size suitable, without subdivision, for introduction into the vagina.

The water soluble polyvinyl alcohol may be employed in various forms.

We have found that for the purposes of this invention films of 0.05—0.08 mm thickness were optimal. Such film ensures quick dissolution on the site of application because of its large surface area compared to its mass. One polyvinyl alcohol film which can be used as starting material for preparing the device according to our invention is a flexible, elastic, almost transparent film, containing about 7% by weight of water. The film keeps its physico-chemical properties for years. When dissolved in a tenfold amount of water it dissolves within one minute forming a slightly sticky viscous solution having surface active properties, and a pH value of 6. Being a macro-molecular compound it is not absorbed through the mucous membranes. Physiologically it is inert causing neither local irritation nor allergy. It is not carcinogenic.

For a contraceptive device the water soluble polyvinyl alcohol film is used preferably in the form of films having a surface area of 10—40 cm² (on one face) and less than 0.1 mm in thickness, the preferred weight is in the range 0.10—0.30 g. This material, however, can be used in other forms too, for instance

[Price 5s. 0d. (25p)]

Price 25p

in the form of a cap or, part-spherical calotte of 3—4 cm diameter and about 2 cm height. The spermicides may be dissolved or impregnated in the polyvinyl alcohol medium in the course of production. Another way of preparing the device according to our invention consists in coating and impregnating the film or moulded article with the spermicide. For this purpose the film or moulded article is contacted with a solution of the spermicide which is prepared in a suitable concentration and form so as to deposit the desired quantity of the active ingredient on the surface of the film or moulded article. In covering the film or moulded article with said solution any known method may be used which ensures uniform application and distribution on the surface. Thus the solution may be applied by brushes or sponges or by spraying or dipping processes etc. or preferably by calendering.

As active ingredient any known spermicide may be used which is soluble in water and in the body fluids, such as for example nonylphenoxypolyethoxyethanol, triisopropylphenoxypolyethoxyethanol, hexylresorcinol, phenylmercuric acetate. It has been found preferable to use quaternary ammonium compounds for example cetyl pyridinium bromide. It is known that cetyl pyridinium bromide is a highly active bactericide and spermicide even at a dilution of 0.02%, destroying within a few minutes the spermatozoa as well as the pathogens of venereal diseases. Besides it causes no local irritation on the mucous membranes.

The device according to the present invention is used by inserting the film or moulded article as high up into the vagina as possible either immediately before the sexual act or within two hours beforehand. As it does not leak out after having been dissolved it is possible to walk about with the device inserted. Moulded articles of a cap shape can be used also by the male partner in the manner of a condom.

In order that the invention may be better understood, the following Examples are given by way of illustration only.

EXAMPLE 1

From a polyvinyl alcohol film roll (commercially obtainable in a weight of 1 kg), 90 cm broad and 0.08 mm thick, 40×90 cm pieces are cut off. These sheets of film are fixed by their edges on a glass plate. A measured quantity of a solution of cetylpyridinium bromide (10% by weight in aqueous alcohol) is applied to the surface by a procedure ensuring uniform distribution of the solution, e.g. by means of a special brush, sponge or by a spray method.

After drying for 24 hours at room temperature the impregnation with cetylpyridinium bromide is complete and the other

side of the film is then impregnated in the same manner. Heating should not be used to accelerate drying because above 80°C the water solubility of the film diminishes.

The impregnated film is cut into 4×4 cm pieces. Each piece contains 0.015 g of cetylpyridinium bromide. The films thus prepared can be packed in a simple way without using water-tight or air-tight containers. The films retain their activity for a long time. According to our experiences no alteration in activity was found after more than a year of storage.

Laboratory and clinical trials have been carried out with the above prepared device. Solubility: in a tenfold quantity of water, or physiological sodium chloride solution, or in the vaginal fluid it is readily dissolved within one minute forming a sticky solution.

In order to test the toxicity of the product, the aqueous solution of the film prepared above was administered orally to animals. No pathological alterations were observed in the internal organs of rabbits and rats fed with the solution of the film for 20 days. 50 times the human local dose was calculated to the body-weight.

According to the International Planned Parenthood Federation Medical Testing Committee who tested our product the film reaches the desired level of spermicidal activity.

Clinical trials have been carried out on 300 volunteer couples for testing the effectiveness of the film. The failure rate of 5 unwanted pregnancies per 1200 couple months of use indicates its high effectiveness compared with that of the existing traditional methods. In the case of couples using the film correctly no unwanted pregnancy occurred. Some of the patients were subjected to vaginal investigations. No local irritation was observed. Microscopic examinations of the vaginal fluid showed improved cleanness of the vaginal. Discharges caused by trichomonas cleared up.

EXAMPLE 2

From the polyvinyl alcohol film roll of Example 1, pieces of 2 m length and full breadth are cut off and put on tables covered with plate-glass. One surface of the film is coated with a 20% solution of cetyl pyridinium bromide by a roll calender method. Drying is accelerated by an air-blast apparatus. The film is interleaved with aluminium foil and cut into pieces of 4×4 cm together with the aluminium foil by a cutting machine. This procedure makes the packing of the products easier.

EXAMPLE 3

To a 20% solution of cetyl pyridinium bromide in aqueous alcohol 10% by weight of polyvinyl alcohol granules is added. This enables a type of printing machine to be employed for the impregnation of the polyvinyl alcohol film roll mentioned in Example 1 with the solution of cetyl pyridinium bro-

65 midc and polyvinyl alcohol. In this case the
film roll can be used in a continuous process
without having first been cut into smaller
70 pieces. It is then subdivided into pieces of a
size suitable for use as contraceptive de-
vices.

EXAMPLE 4

75 To a solution of polyvinyl alcohol granules,
10 10% by weight of cetyl pyridinium bromide
is added. This solution is formed by known
methods into film or part-spherical calottes.
The film is cut into pieces of a size suitable
for use as contraceptive devices.

WHAT WE CLAIM IS:—

- 15 1. A water-soluble contraceptive device con-
sisting essentially of a film (as hereinbefore
defined) or moulded article of water-soluble
polyvinyl alcohol in admixture with and/or
85 coated with a water-soluble spermicide.
20 2. A contraceptive device according to claim
1 in which said spermicide is a quaternary
ammonium compound.

3. A contraceptive device according to
claim 2 in which said quaternary ammonium
compound is cetyl pyridinium bromide.

25 4. A contraceptive device according to any
one of the preceding claims in the form of a
film having a surface area of 10—40 cm²
(on one face) a thickness of 0.05—0.08 mm
and weighing 0.10—0.30 g.

30 5. A contraceptive device according to any
one of claims 1—3 in the form of a cap or
part-spherical calotte.

35 6. A contraceptive device according to
claim 5 having a diameter of 3—4 cm and
a height of about 2 cm.

7. A contraceptive device according to
claim 1, substantially as herein described with
reference to any one of the examples.

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5 mid and polyvinyl alcohol. In this case the film roll can be used in a continuous process without having first been cut into smaller pieces. It is then subdivided into pieces of a size suitable for use as contraceptive devices.

EXAMPLE 4

10 To a solution of polyvinyl alcohol granules, 10% by weight of cetyl pyridinium bromide is added. This solution is formed by known methods into film or part-spherical calottes. The film is cut into pieces of a size suitable for use as contraceptive devices.

WHAT WE CLAIM IS:—

- 15 1. A water-soluble contraceptive device consisting essentially of a film (as hereinbefore defined) or moulded article of water-soluble polyvinyl alcohol in admixture with and/or coated with a water-soluble spermicide.
- 20 2. A contraceptive device according to claim 1 in which said spermicide is a quaternary ammonium compound.

3. A contraceptive device according to claim 2 in which said quaternary ammonium compound is cetyl pyridinium bromide. 25
4. A contraceptive device according to any one of the preceding claims in the form of a film having a surface area of 10—40 cm² (on one face) a thickness of 0.05—0.08 mm and weighing 0.10—0.30 g. 30
5. A contraceptive device according to any one of claims 1—3 in the form of a cap or part-spherical calotte.
6. A contraceptive device according to claim 5 having a diameter of 3—4 cm and a height of about 2 cm. 35
7. A contraceptive device according to claim 1, substantially as herein described with reference to any one of the examples.

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