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(54) Title: TAMPON WHICH CONTAINS PH REGULATING, ANTIBACTERIAL, AND ANTIMYCOTIC ACTIVE FORMULATION AND THE PROCEDURE OF ITS PRODUCTION

(57) Abstract: The subject of the presented invention is a tampon which includes a pH regulating formulation with an antibacterial and antimycotic effect and which in the vagina has the ability to maintain its suitable moisture and has the ability to maintain and create its physiological pH value. At the same time it has an antibacterial and antimycotic effect. The tampon, in the sense of the invention, contains a basic material for tampon production on which we apply the formulation. This formulation is a solution of chitosan and/or chitosan material in diluted organic acid or its derivate, mostly lactic acid. The subject of the presented invention is also the procedure of making such a tampon and its use in preventing and/or medical treatment of vaginal inflammations.



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**Tampon which contains pH regulating, antibacterial, and antimycotic active
formulation and the procedure of its production**

Technical field, in which this invention is included

Presented invention refers to a tampon which contains a pH regulating, antibacterial, and antimycotic active formulation. This tampon has the ability to maintain an appropriate moisture and physiological pH value in the vagina and functions antibacterial and antimycotic at the same time. The tampon, in the sense of invention, contains the basic material for tampon production, onto which the formulation is applied. This is a solution of chitosan and/or chitosan material in a diluted organic acid substance or its derivative, mostly lactic acid. The presented invention also refers to the procedure of tampon production and its use in prevention and/or medical treatment of vaginal inflammation.

Technical problem and state of technology

We have noticed lately that the contemporary ways of living and some fashion trends, for example clothing, lead to a greater use of vaginal tampons. Today their use is not limited only to the time of menstruation. Women use them through the whole cycle as a protection from physiological and pathological vaginal leaks. Such use can cause problems to appear more frequently, for example a more frequent appearance and repetition of vaginal inflammation. Medical experiences show that vaginal leaks and inflammations are the most common reasons for visiting a gynaecologist. Vaginal inflammation is accompanied with a leak which women try to suppress with a more frequent washing, which only additionally reduces the vaginal sourness.

Under the influence of estrogens, glycogen is accumulated in the vaginal epithelia in women of reproductive age. Anaerobic metabolism of glycogen in epithelia cells and its decomposition according to the vaginal flora are the main reason for the low value of pH in the vagina, which lies between 3,6 and 4,5 in most women [Boskey ER, Telsch KM, Whaley KJ, Moench TR, Cone RA. Acid production by vaginal flora in vitro is consistent with the rate and extent of vaginal acidification. Infect Immun. 1999; 67: 5170-5]. This slightly sour condition in the vagina assures an effective barrier against the growth of pathogenic micro organisms, which can lead to a vaginal infection, given the fact that these micro organisms do not grow under the value of pH 5.

With vaginal inflammation the pH value increases causing the amount of lactobacilli to decrease. The consequence is the reduction of natural defence of the vagina allowing different bacteria to grow without hindrance [Tomas MS, Bru E, Nader-Macias ME. Comparison of the growth and hydrogen peroxide production by vaginal probiotic lactobacilli under different culture conditions. Am J Obstet Gynecol 2003;188: 35-44]. A similar change of the sour value in the vagina and the consequent infection of the vagina can appear with a frequent use of tampons.

It is also known that a vaginal infection and an infection of external genitals represent one of the risk factors for bladder infection, which is one of the main reasons for urine incontinence in elderly women.

To overcome the problem of the reduction of the sour value in the vagina and for the re-establishment of the required sour value and vaginal flora many formulations and techniques have been invented in the past. These efforts included the development of the formulations such as solutions, gels, suppositories, vaginalets and many others, which are inserted into the vagina in their prepared form. Yet, all these formulations show an imperfection from the view of practicality and acceptability. For example vaginalets, which among other substances, contain a combination of lactic acid and chitosan. By releasing the substance or with the dissolution of the substance directly on the mucous membrane, this combination can cause a large local concentration or sourness which is uncomfortable for the users.

We know from the available literature that chitosan contains antibacterial and antimycotic qualities. Chitosan is a natural anti-microbe instrument, which is used not only in alimental industry for prevention of growing bacteria and fungi in the food, but also in pharmaceutical industry, where it is included in different vaginal creams. It is known that chitosan reduces the activity of the *Candida albicans* fungus which is one of the possible causer of vaginal candidosis and the activity of the bacteria *Staphylococcus aureus* which is one of the possible inducers of the toxic shock syndrome. Its use is also safe in time of pregnancy, since the addition of chitosan for example in vaginal gel helps to maintain the suitable pH value in the vagina which could mean prevention of premature childbirth.

The lactic acid is created with the help of lactic acid bacteria which are contained in the healthy vaginal flora. This acid is important for the natural protection from infections and inflammations. The sour environment in the vagina with the pH value from 3.85 to 4.00 stimulates the increase of lactic acid bacteria which can multiply and survive only in this pH environment. The increased number of lactic acid bacteria replaces other bacteria and protects the body from other harmful bacteria which cause unpleasant infections and inflammations. They keep a natural sour ecosystem in the vagina with the pH value from 3.85 to 4.00.

In the document US 6,710,220 B2 there is a description of a formulation which decreases the pH value and a description of tampons which contain a formulation for the purpose of decreasing the pH value in the vagina. The stated formulation contains a polymer of an organic acid (for example a polymer of the lactic acid), a solid organic acid and a soaking agent. This formulation is applied from the solution of acetone on a suitable tampon strip. The document deals mostly with the use of tampons during menstruation.

The document US 2005/0124799 A1 describes an invention which refers to products, such as absorption products for single use which contain cation polysaccharide, preferentially chitosan materials together with sour pH buffer agents. This document deals with the combination of chitosan with sour pH buffer agents for preventing unpleasant smells which occur with use of such products, mostly with the use of hygiene linings which are made up of many different components or many differently treated layers.

The patent report CN 1365833 describes the procedure of preparing an absorbing product on which chitosan, dissolved in a diluted acid, is drizzled,. The product is designed mainly for prevention of bedsores or unwanted changes on skin connected with bedsores.

Specification of the invention

The new invention is presented with the purpose of solving the mentioned problems given the fact that we cannot influence the mass or frequency of tampon use. The purpose was also to invent new and better tampons which would not show such negative effects in the use as mentioned earlier, such as increased risk of inflammation. Another reason for the invention was to invent tampons which would, with a frequent use, maintain the appropriate moisture in the vagina and keep and/or create its physiological pH value in the vagina. At the same time the tampons would have an antibacterial and antimycotic effect. In this way the subject of the

presented invention is a tampon which contains a pH regulating, antibacterial, and antimycotic active formulation and has certain progressive and new characteristics, such as: reducing and/or maintaining the pH value of the vagina on its physiological pH value, maintaining the needed moisture of the vagina and having antibacterial and antimycotic effects.

Despite of many separated applications of chitosan, chitosan materials, and organic acids, such as lactic acid on cellulose materials, to our knowledge until now there has not been a systematic research and realization of both components at the same time, that is chitosan and/or chitosan material and a suitable organic acid or its derivate, preferentially lactic acid and its derivatives, on the basic material which is suitable for tampon production in the sense of invention which would include and adjust:

- technical demands in applying the solution of chitosan and/or chitosan material in a suitable organic acid or its derivate, mostly lactic acid or its derivate, on the basic material suitable for the production of tampons in many ways, including the drizzling technique;
- demands for such a combination of substance or such a solution of chitosan and/or chitosan material in a suitable organic acid, mostly lactic acid or its derivate, which would, in the stage of applying on the basic material, enable a technically and ecologically unproblematic production of the tampon, where the production would be accomplished on the machine for producing tampons; and
- the demand to produce an end-product, the tampon, which would suit all prescribed technological standards and which would reduce and/or maintain the pH value of the vagina at its physiological pH value, maintain the needed moisture of the vagina and have antibacterial and antimycotic effects.

With the purpose of producing a new, improved, and modified tampon in the sense of an invention including all listed demands, we developed and optimized a formulation which is applied on the basic material for the production of tampons. This formulation is a solution of chitosan and/or chitosan material in an organic acid or its derivate and has the following characteristics:

- chitosan and/or chitosan material show antibacterial and antimycotic characteristics, but are preferentially presented in the formulation in a concentration higher than 0.5 mas.%;

- chitosan and/or chitosan material can dissolve completely in the formulation (the negative characteristic of chitosan is that it is alkaline and cannot dissolve in a water medium; it can dissolve only in a sour medium of certain acids);
- pH value of the solution fits the physiological pH value of the vagina, mainly in the area from 3.6 to 4.4; and
- has such a viscosity, which allows the applying of the solution on the basic material for the production of tampons mainly with the drizzling technique.

The formulation at the same time enables:

- such an amount of formulation and its application on the material that the formulation can be absorbed in the basic material for the production of tampons;
- that the basic material for the production of tampons can be formed into the final product, the tampon, which suits all prescribed standards of this field; and
- that the accumulated amount of substance, especially chitosan and lactic acids, accomplishes the following characteristics when using the tampon: it has the ability to maintain a certain moisture of the vagina, it has the ability to reduce and/or maintain the pH value of the vagina on its physiological pH value and has an antibacterial and antimycotic effect.

In the sense of the invention the formulation is in the form of a solution, made from chitosan and/or chitosan material and suitable organic acid or its derivate. Accordingly, chitosan and/or chitosan material and the organic acid or its derivate can be in any kind of molar relation, which gives the formulation the earlier mentioned characteristics.

The suitable organic acid for the use in the formulation in the sense of the invention can be lactic acid, poly-lactic acid, citric acid or boric acid. For example the derivatives of lactic acid, such as any kind of sour lactate can be used as derivatives of organic acid. In the sense of the invention the diluted lactic acid is mainly used. The most suitable diluted lactic acid for the preparation of the formulation is the 3% to 20% dilution of lactic acid. According to the limitation of physiological pH value and final viscosity of the formulation, a 5% solution of the lactic acid is preferred in the sense of the invention.

Chitosan, suitable for the use in the formulation in the sense of the invention, does not dissolve in water. This is either the chitosan with a low or a high average molecule weight. Chitosan

materials or chitosan derivates, which are suitable for the use in the formulation, are, for example, sulphated chitosan (not completely) and carboxymethylated chitosan. The most favourable is the use of chitosan with a low average molecule weight.

It is known that the solutions of chitosan, with the concentration equal or higher than 0.5 mas.% of chitosan, have antibacterial and antimycotic characteristics. The still acceptable higher concentration of the chitosan solution is around 2 mas.% from the view of its viscosity and for application on the material with the drizzling technique.

In the realization of the invention the formulation is applied on the basic material for tampon production. For the formulation the 0.5–2.0 % solution of chitosan and/or chitosan material is preferred (calculated according to the concentration in the formulation). The solution of chitosan and/or chitosan materials is in dissolved organic acid or its derivate. For the preparation of the formulation a 3-20 % solution of the organic acid or its derivate is used.

In the sense of the invention the formulation in the form of 0.5-2.0 % solution of chitosan and/or chitosan material in the lactic acid is the most appropriate (calculated according to the concentration in the formulation). The formulation is prepared in the way that a 3-20 % solution of lactic acid, mostly used is 5 % of the lactic acid, is added to the water suspension of chitosan and/or chitosan material until the full melting while heating (at about 40°C).

The most favourable formulation which is applied on the basic material for tampons, in the sense of the invention, is a solution of chitosan in the lactic acid, which includes 0.8–1.2 mas.% of chitosan in a 0.8–1.2 % solution of the lactic acid or even more appropriate about 1 % of chitosan in about 1% solution of the lactic acid, calculated according to the final concentration of both components in the solution. Preferential is the solution which includes chitosan with a low average molecular weight.

In the sense of the invention the highest still appropriate viscosity of the formulation is the one, which allows the drizzling on the basic material. The viscosity of the solution can be from 1 to 1000 mPa.s at 25°C. Preferential is the viscosity of the formulation between 200 and 800 mPa.s.

The most suitable basic materials or their absorption components for the production of the tampons are cellulose materials, such as cotton, viscose, modal or liocel, but also cellulose materials treated with carboxymethyl cellulose (CMC), such as cotton treated with CMC or viscose treated with CMC. The most favourable is the use of a viscose material. The basic material for the production of tampons is mostly in the shape of a band. The solution in the sense of the invention is applied on this band.

Also suitable as the basic material for the production of tampons are other polymeric materials, which can be treated as fibre and which enable the suitable absorption and reversible/irreversible binding of the substance on the basic material, in the sense of the invention, on which the formulation is drizzled.

The subject of this invention is a tampon which has an absorption component made from the basic material for tampon production. This is preferably a cellulose material, particularly cellulose material on which the formulation in the sense of the invention is applied. In this case the formulation is a 0.5-2.0 % solution of chitosan and/or chitosan material (calculated according to the final concentration in the formulation) in organic acid or its derivate, which is preferably lactic acid. For the preparation of the formulation a 3-20 % solution of organic acid and/or its derivate is used.

According to the preferable realization the tampon contains the basic material which includes the formulation. This formulation contains a 0.8-1.2 mas.% of chitosan in a 0.8-1.2 % solution of lactic acid, calculated according to the final concentration in the formulation. Even more preferable is the tampon with the basic material, which includes a formulation containing about 1 mas.% of chitosan in about 1% solution of lactic acid, calculated according to the final concentration in the solution.

According to the most favourable realization the formulation is applied on the basic material with the drizzling technique. Due to its characteristics the formulation allows an evenly homogeneous and constant drizzling on the basic material. It is adsorbed into the material so that the surface does not have an unwanted adhesive layer, which deposited on those revolving parts of the machine for producing tampons, which come in contact with the tampon band. The drizzling technique is appropriate not only from the ecological view, but also from the technical and economic view, because there are no waste solutions with such a technique, as there are

with the technique of plunging the material into a bath. In this case the bath loses its effect after some time and it has to be replaced therefore producing a waste solution. The drizzling technique in comparison to the plunging technique applies only the needed amount of the solution on the tampon material. The amount of the solution needed to make a tampon with the required pH regulating, antibacterial and antimycotic characteristics is previously defined and selected. With the drizzling technique there are no waste solutions. Even more, the used water solution or formulation in the sense of the invention contains no additional substances harmful to the environment, which would be problematic not only from the technical but also from the ecological point of view.

We invented a new procedure of making a new tampon with all its pH regulating, antibacterial and antimycotic characteristics. The production of this new tampon does not need any additional investments for the already existing machines for tampon production as a side effect of new requirements of the drizzling technique. There is no need for additional equipment for drying on the tampon production machines or additional safety and ecological demands, because of using for example a special melting material in the formulation, etc.

The stated formulation allows a continuing production of the tampon in the sense of the invention. The formulation is applied on the basic material primarily with the drizzling technique. The basic material is preferably a viscid tampon band. The formulation is applied on the material shortly before the tampon is put in the machine for tampon production. After that the material with the formulation is added into the machine and the tampon is produced as a final product.

In further production of the tampons the formulation in the sense of the invention can be applied on the material with the drizzling technique in the stage of producing the tampon band, which is carried out separately from the production of the tampon as the final product. This viscid tampon band accumulated with the formulation is later used for the production of tampons on the appropriate machine.

Typical but not limited examples of tampons in the sense of the invention are also those tampons, which have an absorptive component or a layer made from the basic material for tampon production, which is a viscid tampon band with the length of 20-25 cm, the width of 4-6 cm and the mass of viscid fibres from 2 to 4 g. Before this band is put into the machine for

tampon production it is drizzled with 0.2-0.5 g of formulation, which contains 0.8-1.2 mas.% of chitosan in a 0.8-1.2 % solution of the lactic acid, all calculated according to the final concentration in the formulation.

Even more appropriate is the accumulation of the formulation on the tampon band with the quantity of 0.08–0.2 g of the formulation on 1 g of viscid fibres.

The use of the formulation in the sense of the invention on the basis of chitosan and/or chitosan materials and organic acids and their derivatives, most of all lactic acid, is favourable also from the economic point of view, since these materials are relatively cheap so that their usage in the production of tampons has no greater effect on the price of the final product. According to this fact, the new tampons are very accessible to users if we look at this product from the financial point of view.

Concluding from results of analysis and tests made so far, which are listed in this document, we can confirm that the use of the new tampons, in the sense of the invention, which contain the basic material treated with the formulation mean an effective prevention from building as well as repetition of all kind of fungal and bacterial inflammations in the vagina. Due to all their characteristics, the new tampons are suitable for frequent use not only during menstruation, but also during other times. Because of the antibacterial and antimycotic activity of the substances in the tampons, these tampons are very useful for preventive and/or curative treatments in gynaecology (for example as a preventive medicine protecting the users from inflammations, white vaginal discharge, etc).

According to the testing made so far we also think that the use of tampons or the prevention of vagina infections could consecutively lower the risk of bladder infection, which is one of the main reasons for urine incontinence in elderly women. With the use of tampons of a bigger dimension we could also compress the cutting line a little more, so that the tampons would influence the incontinence in two ways, precautionary and in the curative sense. The following accomplished examples are meant only to illustrate the newly presented invention and do not limit its extent in any way.

*Accomplished examples***Preparation of chitosan solution in the lactic acid and the production of tampons which contain this solution****Example 1**

We dissolved 5 g of chitosan (chitosan with a low average molecule weight, trademark Aldrich) in 500 ml of water and progressively added 5% of lactic acid (80 ml). We heated the solution at 40°C so that we accomplished the pH value from 3.6 to 3.8. The final concentration of chitosan in the solution was 0.86%, the final real concentration of lactic acid was 0.8 mas.%. The viscosity of the solution came up to 653 mPa.s at 25°C.

We applied the prepared solution on the basic material for the production of tampons. This material is in the shape of earlier manufactured viscid tampon bands with the width of 5 cm in the amount which suits 0.3-0.5 g of the solution on 2.5 g of viscid fibres (2.5 g of viscid fibres suit the mass of viscid fibres needed for production of one tampon). According to the procedure generally known in this specialised field we made tampons out of treated tampon band on a machine prepared for tampons production.

The analysis of the tampons with the solution of chitosan in the lactic acid presented in example 1*1. Mechanical characteristics*

According to the standard methods in this special field, we determined corresponding parameters for two kinds of tampons. First of all, tampons, whose basic viscid material was drizzled with the solution of chitosan in lactic acid and is presented in example 1. The second group are all referenced tampons made from basic viscid material.

Table 1: Mechanical characteristics / technological parameters of tampons, which contain the solution of chitosan in lactic acid, presented in example 1 and referenced tampons.

Tampon parameters	Tampons, which contain the solution of chitosan in the lactic acid, presented in example 1	Referenced tampons
Length	50.5 mm	50.5 mm

Diameter	12.7 mm	12.7 mm
Weight	2.70 g	2.50 g
Stability	50.6 N	50.2 N
Absorption ability	11.3 ml	10.5ml

Technological parameters of tampons, prepared as presented in example 1, are all within the limitations of product standards defined by the special field.

2. Determination of chemical characteristics: pH value of tampons and the content of nitrogen in the tampons

We analysed the pH value of the tampons so that we measured the pH value of the distilling water (50 ml) in which we previously plunged the tampons. The results of the measures are presented in table 2.

Table 2: pH value of the distilling water after previously plunged tampons into the water.

Temperature pH of distilling water	Referenced tampons	Tampons, which contain the solution of chitosan in lactic acid, presented in example 1
25 °C; 6,0	6,1	4,7
38 °C; 6,6	6,9	5,0

Results show that tampons produced as described in example 1, effectively lower the pH value of the distilling water, which points to a potential decrease of the pH value or the maintenance of the pH value on the physiological pH value in the vagina.

With the Kjeldahl method (SIST EN 25663) we defined the content of total nitrogen in tampons whose basic material was drizzled with the solution of chitosan in the lactic acid as presented in example 1. With this method we can observe qualitative binding of chitosan on the

tampons. The results of the nitrogen content in the tampons produced as presented in example 1 and in referenced tampons are presented in table 3.

Table 3: Concentration of total nitrogen (%)

Nitrogen content (%)		
Referenced viscid tampons	Tampons, which contain the solution of chitosan in the lactic acid, presented in example 1	Increase of the content
0,015	0,03	100
0,013	0,024	85
0,014	0,038	171
0,012	0,026	117

Given results prove that chitosan is present on the modified tampons.

3. Spectro-photometric determination of chitosan content in tampons, produced according to example 1

The spectro-photometric method is based upon the principle of binding between the sulfonic pigment and chitosan. With this method we measured the content of chitosan in tampons produced as described in example 1. The content was 3.3 mmol/kg. The measured content of chitosan in a referenced tampon was 0 mmol/kg.

4. Antibacterial and antimycotic characteristics of tampons, produced according to example 1

The results of the tests on antibacterial and antimycotic characteristics (according to ASTM E2149-01) of tampons, which contain a chitosan solution in lactic acid according to example 1, have shown that the viscid tampons, which contain the solution described in example 1, reduce the amount of bacteria *Staphylococcus aureus* for 97 %, *Streptococcus agal* for 100 %, MRSA for 91 % and fungus *Candida* for 68 %.

From tests and analysis carried out up to now we can gather that the tampon with the addition of the formulation, in the sense of the invention, with the usage in the vagina and with the release of substances in the tampon, has the following progressive and new characteristics: it maintains the physiological pH value of the vagina, it maintains the moisture of the vagina and has antimycotic and antibacterial effects.

PATENT CLAIMS

1. Tampon with a pH regulating, antibacterial, and antimycotic effect **characterized by** having an absorptive component made from the basic material for tampon production, which is treated with the formulation, the formulation is a solution of chitosan and/or chitosan material in a organic acid or its derivate and has the following characteristics:
 - chitosan and/or chitosan material have antibacterial and antimycotic characteristics;
 - chitosan and/or chitosan material are totally soluble in the formulation;
 - the pH value of the solution suits the physiological pH value of the vagina; and
 - the formulation has a viscosity which allows that the formulation is to be applied on the basic material with the drizzling technique.
2. The tampon with the pH regulating, antibacterial, and antimycotic effect according to claim number 1 **characterized by** having an absorptive component made from the basic material for tampon production, which is treated with the formulation, the formulation is a solution of chitosan and/or chitosan material in an organic acid or its derivate and has the following characteristics:
 - chitosan and/or chitosan material have anti-bacteril and antimycotic characteristics and are present in the formulation with the concentration higher than 0.5 mas.%;
 - chitosan and/or chitosan material are totally soluble in the formulation;
 - the pH value of the solution is in the region from 3.6 to 4.4; and
 - the formulation has the viscosity in the area from 1 to 1000 mPa.s.
3. The tampon with the pH regulating, antibacterial, and antimycotic effect according to the claims 1 and/or 2 **characterized by** having a cellulose material as the base material, chosen from the group with cotton, viscose, modal or liocel or any kind of cellulose material treated with carboxymethyl cellulose.
4. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 3 **characterized by** the basic material for tampon production, which is a viscose material.

5. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 4 **characterized by** the fact than chitosan and/or chitosan material, used for the preparation of the formulation and later applied on the basic material, are chosen from the group which includes in water nonsolvent chitosan, such as chitosan with low or average high molecule mass, sulphonated chitosan (partly) and carboxymethylated chitosan.
6. The tampon with the pH regulating, antibacterial, and antimycotic effect according to the claim 5 **characterized by** use of chitosan with a low average molecule mass.
7. The tampon with the pH regulating, antibacterial, and antimycotic effect according to the claim 6 **characterized by** the fact that the formulation is brought on the basic material for tampon production, the formulation includes chitosan with a low average molecule mass in concentration of 0.5-2.0 mas.%.
8. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 7 **characterized by** the organic acid used in the preparation of the formulation, which is brought on the basic material for tampon production, the organic acid is chosen from the group which includes lactic acid, poly-lactic acid, citric acid and boric acid.
9. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 8 **characterized by** the fact that the used organic acid is a lactic acid.
10. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 9 **characterized by** the usage of 3-20 % solution of lactic acid to prepare the formulation which is later applied on the basic material for tampon production.
11. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 10 **characterized by** the usage of 5 % solution of lactic acid to prepare the formulation which is later applied on the basic material for tampon production.

12. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 5 **characterized by** the fact that the derivate of organic acid is the derivate of lactic acid.
13. The tampon with the pH regulating, antibacterial, and antimycotic effect according to the claim 12 **characterized by** the fact that the derivate of organic acid is any kind of acid lactate.
14. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 13 **characterized by** the formulation which is applied on the basic material for tampon production and includes 0.5-2.0 mas.% of chitosan and/or chitosan material in a solution of organic acid or its derivate, calculated according to the concentration in the formulation. 3-20 % solution of organic acid or its derivate is used in the formulation and has the viscosity from 200 to 800 mPa.s at 25°C.
15. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 14 **characterized by** the fact that chitosan with a low average molecule mass and a solution of the lactic acid are used for the preparation of the formulation.
16. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 1 to 11 and/or 14 to 15 **characterized by** the fact that the formulation, applied on the basic material for the production of tampons, includes 0.8-1.2 mas.% of chitosan in a 0.8-1.2 % solution of lactic acid, calculated according to the concentration in the formulation.
17. The tampon with the pH regulating, antibacterial, and antimycotic effect according to the claim 16 **characterized by** the fact that the formulation applied on the basic material for tampon production includes about 1 % of chitosan with a low average molecule mass in about 1 % solution of lactic acid, calculated according to the concentration in the formulation.
18. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any of the previous claims **characterized by** the fact that the formulation applied on the basic

material for tampon production has the quantity of 0.08-0.2 g of the formulation on 1 g fibres viscose basic material.

19. Method of tampon production with the pH regulating, antibacterial, and antimycotic effect **characterized by** the fact that we apply the formulation on the basic material for tampon production before this material is put in the machine for tampon production, the formulation is a solution of chitosan and/or chitosan material in organic acid or its derivate and has the following characteristics:

- chitosan and/or chitosan material have antibacterial, and antimycotic characteristics;
- chitosan and/or chitosan material are totally soluble in the formulation;
- the pH value of the solution suits the physiological pH value of the vagina; and
- the formulation has such a viscosity which allows that the formulation is applied on the basic material with the drizzling technique;

this course is followed by the entrance of the material treated with the formulation into the machine for tampon production and the production of the tampon itself.

20. The method of tampon production with the pH regulating, antibacterial, and antimycotic effect according to the claim 19 **characterized by** the fact that we apply the formulation on the basic material for tampon production before it is put into the machine for tampon production, the formulation is a solution of chitosan and/or chitosan material in an organic acid or its derivate and has the following characteristic:

- chitosan and/or chitosan material have antibacterial and antimycotic characteristics and are present in the formulation with the concentration higher than 0.5 mas.%;
- chitosan and/or chitosan material are totally soluble in the formulation;
- the pH value of the solution is in the range from 3.6 to 4.4; and
- the formulation has the viscosity in the area from 1 to 1000 mPa.s;

this course is followed by the entrance of the material treated with the formulation into the machine for tampon production and the production of the tampon itself.

21. The method of tampon production with the pH regulating, antibacterial, and antimycotic effect according to the claims 19 and/or 20 **characterized by** the fact that the formulation is applied on the basic material for tampon production with the drizzling technique.

22. According to any claim 19 to 21 the procedure for the tampon production with the pH regulating, antibacterial, and antimycotic effect is arranged according to any claim 1 to 18.
23. The method of tampon production with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 19 to 21 **characterized by** the fact that it is continual. We apply the formulation on the basic material with the drizzling technique directly before this material is put into the machine for tampon production, the formulation applied on the basic material contains 0.5-2.0 mas.% of hotisan and/or chitosan material in a solution of an organic acid or its derivate, calculated according to the concentration in the formulation, for the preparation of the formulation a 3-20 % solution of organic acid or its derivate is used and has the viscosity from 200 to 800 mPa.s at 25°C, this course is followed by the entrance of the material treated with the formulation into the machine for tampon production and the production of the tampon itself.
24. The method of tampon production with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 19 to 22 **characterized by** the fact that we apply the formulation on the basic material in the course of making the tampon band, which is carried out separately from the production of tampons, this course is followed by a separate production of tampons on the machine for tampon production with the material treated with the formulation.
25. The method of tampon production with the pH regulating, antibacterial, and antimycotic effect according to any of the claims 19 to 24 **characterized by** the fact that we apply the formulation on the basic material for tampon production with the use of the drizzling technique, the formulation contains, calculated according to the concentration in the formulation, 0.08-0.2 mas.% of chitosan in a 0.8-1.2% solution of lactic acid, in the quantity of 0.08-0.2 g of the formulation on 1 g of fibres of viscose basic material, this course is followed by the production of tampons in the machine for tampon production with the material treated with the formulation.

26. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any claim 1 to 18 **characterized by** the ability to maintain the appropriate moisture in the vagina and can maintain and create its physiological pH value.
27. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any claim 1 to 18 and/or 26 **characterized by** its use in the vagina for prevention and/or curative medical treatments of fungal and bacterial inflammations in the vagina and/or urine incontinence in women.
28. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any claim 1 to 18 and/or 26 and/or 27 **characterized by** its use in the vagina for reduction of micro organisms which cause vaginal inflammations like Staphylococcus aureus, Streptococcus Agal, MRSA and Candida.
29. The tampon with the pH regulating, antibacterial, and antimycotic effect according to any claim 1 to 18 **characterized by** the use of the tampon with the pH regulating, antibacterial, and antimycotic effect helps to prevent and/or treat vaginal fungal and bacterial inflammations and/or urine incontinence with women.