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(54) Title: METHOD FOR THE MANUFACTURE OF A WOUND CARE PRODUCT, AND WOUND CARE PRODUCT

(57) Abstract: Method for the manufacture of a wound care product in which a fabric containing hydroactive constituents, in particular fibres, is processed, whereby the processing of the fabric comprises the application of an antimicrobial means onto the hydroactive constituents.



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Method for the manufacture of a wound care product, and wound care product

The invention relates to a method for the manufacture of a wound care product whereby a fabric containing hydroactive constituents, in particular fibres, is processed.

Bandages in the form of nonwoven material, foams, sponges and cloths are used for the care of wounds. These are normally a fabric. In the context of this description and the claims, a fabric is understood to be a three-dimensional product which, when laid out flat, has an elongation in the thickness direction of 20% or less of the elongation in the longitudinal or transverse direction.

According to WO 2017/137419, the outcomes of wound care can be improved if a wound care product is saturated with an antimicrobial means such as an aqueous solution containing PHMB. Wound care products thus saturated allow germs to be killed off when caring for the wound. In the context of this description and the claims, any means by which germs can be killed off is described as antimicrobial, and a germ is understood to be any microorganism that causes illness (pathogen).

According to another treatment concept, wound care products with hydroactive constituents are used. In the context of this description and the claims, constituents are described as hydroactive if they form a gel on contact with water. The water in the gel may form bonds by means of hydrogen bonding. If a wound care product has hydroactive constituents, a desired wound climate which prevents both excessive drying of the wound and maceration of the wound can be created, particularly in the treatment of acute and chronic wounds. In the manufacture of wound care products containing hydroactive constituents, fabrics in the form of woven or nonwoven material

or even sponges with hydroactive constituents can be manufactured and subsequently cut to the specified size and then packed in a sterile pack.

When wound care products containing hydroactive constituents and manufactured in the conventional method are used, however, it has been found in the treatment of acute wounds that in many cases the wound is only observed to heal slowly, while in the treatment of chronic wounds the outcomes in some cases are not very satisfactory.

In view of these problems in the state of the art, the object of the invention is to provide wound care products in the form of fabrics containing hydroactive constituents with which satisfactory outcomes in the treatment of acute and chronic wounds can be obtained.

According to the invention, this object is achieved by a further development of the known methods which is essentially characterised in that the processing of the fabric as part of the manufacture of a wound care product having hydroactive constituents comprises the application of an antimicrobial means on the hydroactive constituents, and by wound care products obtained using the corresponding methods.

The invention results from the surprising discovery that hydroactive constituents of a wound care product which are provided with an antimicrobial means release the antimicrobial constituents on contact with the wound fluid, before a gel is formed in which the fluid is bound. This result is unexpected because a stabilisation and hence deactivation of the antimicrobial means on contact with wound fluid or water as part of the gel formation of the hydroactive constituents of the wound care product seemed more likely. The release that is actually observed of the antimicrobial means applied to the hydroactive constituents of the fabric when wound care products manufactured according to the invention are used enables germs in the wound to be killed off and hence improves healing of the wound.

Surprisingly, it has been found that the desired release of the antimicrobial means applied to the hydroactive constituents is encouraged if this antimicrobial means is

applied to the fabric in a preferably aqueous solution. A solution containing the antimicrobial means can be sprayed preferably on respective sides, that is both sides of the fabric, whereby in the context of the invention it is particularly preferred if the solution is sprayed with at least one ultrasonic nozzle. In the context of this description and the claims, ultrasonic nozzles in which high-frequency oscillations are used to act on the nozzle tip and generate capillary waves in a fluid film are described as such spray nozzles. As soon as the amplitude of the capillary waves reaches a critical height, these waves become too great to support themselves. This causes tiny droplets to fall from the tip of the individual waves, which leads to atomisation. The main factors influencing the initially generated droplet size are the oscillation frequency, the surface tension and the viscosity of the fluid. In comparison to a pneumatic spray system, the ultrasonic spray system allows the droplet size, the distribution and the speed to be better adjusted.

If an aqueous solution of the antimicrobial means is sprayed onto the hydroactive constituents, droplet sizes can be set so that sufficiently low quantities of the water used as the solvent evaporate, meaning that an early swelling or early gel formation of the hydroactive constituent of the fabric can be suppressed. This simultaneously has the effect that although the antimicrobial means are bonded to the hydroactive constituents, the bonding forces remain so low that, contrary to expectation, on contact with wound fluid or water a release of the antimicrobial means occurs before a gel is formed under the influence of the wound exudate.

Especially in the case of those fabrics which consist of hydroactive constituents to more than 50% by weight, in particular about 80% by weight, it has proved to be particularly expedient in the context of the invention if the antimicrobial means is applied in a quantity of 10^{-4} mg or more, in particular $4 \cdot 10^{-3}$ mg or more, per cm^2 of a respective side of the fabric. If the antimicrobial means is applied in a lower quantity, the desired antimicrobial effect is hardly observed.

Having regard to the stability of the aqueous solution used to apply the antimicrobial means, it has proved to be expedient if the antimicrobial means is applied in a quantity

of 1.0 mg or less, in particular 0.7 mg or less, per cm² of a respective side of the fabric. A greater quantity of the antimicrobially effective means can hardly be applied because the solubility of conventional antimicrobial means such as PHMB (polyhexanide) is limited in water and application of the antimicrobial means in a larger quantity would therefore be associated with a greater ingress of fluid into the hydroactive constituents of the fabric, which would in turn lead to premature gel formation.

As can already be determined from the above explanation, the antimicrobial means in the implementation of the method according to the invention preferably comprise PHMB. The PHMB in an aqueous solution can be present in a concentration in the range of 0.1 to 9% by weight, in particular in the range of 4 to 9% by weight, whereby preferably 0.1 to 8 mg, in particular 2 to 8 mg, of the solution is applied per cm² to a respective side of the fabric. If PHMB is present in a lower concentration, the application of sufficient quantities onto the hydroactive constituents can require too much fluid, which can lead to premature gel formation. If the concentration of PHMB in the solution exceeds 9% by weight, the solution begins to become unstable overall.

In many cases, the germs that impair the healing of chronically infected wounds exist as what are known as biofilms. The extracellular polymeric substances (EPS) that are excreted combine with water to form hydrogels, so that a mucous matrix in which nutrients and other substances are dissolved is created. Often inorganic particles or gas bubbles are also enclosed by the matrix. In this form the germs are protected from external influences such as attacks by the immune system or antibiotics or antimicrobial means. Having regard to the protection of the germs by the extracellular matrix, a wound care product that is to act against the biofilms must meet the following requirements:

1. Break up the extracellular matrix
2. Kill off the germs

Since conventional antimicrobial means manifest only deficient properties for breaking up the extracellular matrix, it has proved to be particularly expedient for the invention

if, in addition to the antimicrobial means, a chelator is also applied to the hydroactive constituents when wound care products containing hydroactive constituents are manufactured.

The chelator enables the extracellular matrix to be weakened, in particular through the bonding of cations, so that the germs living in the matrix can be killed off with the help of the antimicrobial means. In the context of the invention, the chelator is preferably applied in the preferably aqueous solution also containing the antimicrobial means, in particular sprayed onto the hydroactive constituents of the fabric, more preferably sprayed on with at least one ultrasonic nozzle.

The chelator is expediently applied in a quantity of $5 \cdot 10^{-4}$ mg or more, in particular 10^{-2} mg or more, per cm^2 of a respective side of the fabric. If the quantity of chelator is less, the desired matrix-weakening effect will hardly be achieved. It was also observed that a further improvement of the weakening effect on the matrix of the biofilm will hardly be achieved if the chelator is applied in a quantity of more than 1.2 mg per cm^2 of a respective side of the fabric. For this reason it has also proved to be expedient in the context of the invention if the chelator is applied in a quantity of 1.2 mg or less, in particular 0.8 mg or less, per cm^2 of a respective side of the fabric. In this regard also the stated limit values are in particular preferred in such fabrics in which more than 50% by weight of the fabric is formed by the hydroactive constituents, in particular if the hydroactive constituents form about 80% by weight of the fabric.

It has proved to be particularly expedient in the context of the invention if the chelator comprises EDTA (ethylenediaminetetraacetic acid), in particular a disodium salt of EDTA (ethylenediaminetetraacetic acid disodium salt dihydrate ($\text{C}_{10}\text{H}_{14}\text{N}_2\text{Na}_2\text{O}_8 \cdot 2\text{H}_2\text{O}$)). Alternatively, the following EDTA salt variants can also be used:

- Ethylenediaminetetraacetic acid calcium disodium salt ($\text{C}_{10}\text{H}_{12}\text{N}_2\text{O}_8\text{CaNa}_2$)
- Ethylenediaminetetraacetic acid trisodium salt hydrate ($\text{C}_{10}\text{H}_{13}\text{N}_2\text{Na}_3\text{O}_8 \cdot x\text{H}_2\text{O}$)
- Ethylenediaminetetraacetic acid tetrasodium salt dihydrate ($\text{C}_{10}\text{H}_{12}\text{N}_2\text{Na}_4\text{O}_8 \cdot 2\text{H}_2\text{O}$)

- Disodium ethylenediaminetetraacetate ($\text{Na}_2\text{H}_2\text{EDTA}$, sodium edetate, INS 386)
- Tetrasodium ethylenediaminetetraacetate (Na_4EDTA)
- Calcium disodium ethylenediaminetetraacetate (CaNa_2EDTA , E 385)

However, the disodium salt has proved to be particularly preferable in the context of the invention. With this salt of ethylenediaminetetraacetic acid, a pH value of less than 7 can be set in the aqueous solution with the desired solubility (high concentration). With other EDTA variants, higher pH values are normally observed alongside lower solubility. A colour change is also achieved if the final products are stored at temperatures above 40° C. The setting of a low pH value strengthens the desired antimicrobial effect. In addition, if EDTA is used, in particular the disodium salt thereof, an independent antimicrobial effectiveness of this chelator is also observed. EDTA can have the effect of killing off those germs against which PHMB has only a somewhat lesser effect. The main purpose of the addition of EDTA in the solution used for the manufacture of wound care products according to the invention is, however, the effect it has of weakening the matrix and stabilising the formulation and process. It has proved to be expedient, in relation both to the application of antimicrobial means and chelators on hydroactive constituents of the fabric and to the stabilisation of the aqueous solution manufactured using the method according to the invention for application of the stated substances, if in addition to the antimicrobial means, and where appropriate the chelator, a tenside such as EHG (ethylhexyl monoglycerine ether) and/or a polysorbate such as Tween 20 is also applied onto the hydroactive constituents. The tenside in the preferably aqueous solution can be applied, in particular sprayed on, more preferably sprayed on with the aid of at least one ultrasonic nozzle.

In the context of the invention, particularly if fabrics of which more than 50% by weight is comprised of hydroactive constituents are used, the tenside is applied preferably in a quantity of 10^{-4} mg or more, in particular $5 \cdot 10^{-4}$ mg or more, more preferably 10^{-3} mg or more, per cm^2 of a respective side of the fabric. If at least one tenside is applied in a lower quantity, the desired effect is no longer achieved. To avoid the inactivation of other substances of the solution, and having regard to biocompatibility, particularly

having regard to avoiding the formation of formaldehyde, it is more preferred in the context of the invention if the tenside is applied in a quantity of 0.6 mg or less, in particular 0.1 mg or less, per cm² of a respective side of the fabric.

In the implementation of the method according to the invention, the tenside in the aqueous solution can be present in a concentration in the range of 0.1 to 7.5% by weight, in particular 0.1 to 5% by weight, whereby preferably 0.1 to 8 mg, in particular 2 to 8 mg of the aqueous solution, is applied per cm² to a respective side of the fabric. If EHG is used as a tenside, the concentration of this tenside in the aqueous solution is preferably between 0.1 and 5% by weight. If Tween 20 is added to the aqueous solution as an additional or alternative tenside, the concentration of this tenside is preferably 0 to 2.5% by weight. The addition of a higher concentration of EHG can lead to the formation of formaldehyde. The addition of a higher concentration of Tween 20 can lead to an inactivation of the antimicrobial means, such as PHMB.

If the tensides are applied in a smaller quantity than indicated, this leads to a loss of regularity in the spraying process. A loss of the stabilisation effect of the solution is also observed. Both EHG and Tween 20 manifest an antimicrobial effect in addition to stabilising the solution. As soon as the concentration falls below the indicated lower limits, this leads to a loss of the antimicrobial effect. Furthermore, in the case of Tween 20 a destabilising effect on the extracellular matrix of the biofilm is also observed. This effect is no longer observed if the quantity of Tween 20 in the aqueous solution falls below 0.5% by weight.

A particularly preferred aqueous solution for the implementation of the method according to the invention preferably comprises the following constituents:

1. PHMB: 0.1 – 9% by weight, preferably 4 – 9% by weight
2. EDTA: 0.5 – 15% by weight, preferably 5 – 10.4% by weight
3. EHG: 0.1 – 5% by weight, preferably 2 – 5% by weight
4. Tween 20: 0 – 2.5% by weight, preferably 0.5 – 2.5% by weight
5. Water: rest and unavoidable contamination

In the implementation of the method according to the invention, it has surprisingly been found that the desired success in the treatment of chronic wounds with the formation of a biofilm is achieved particularly well if the proportion of the concentration of the antimicrobial means such as PHMB in the aqueous solution relative to the concentration of the chelator such as EDTA disodium salt in the aqueous solution is 0.6 or more. The relatively high proportion of the antimicrobial means such as PHMB leads, on contact of the hydroactive constituent of the fabric with water, to the release of a sufficient quantity of the antimicrobial means which is available after the matrix of the biofilm has been weakened by the chelator for killing off the germs.

In view of the known compositions of aqueous solutions used for saturating conventional bandages, this too is surprising. With these known solutions a much greater proportion of chelator is required. The advantages arising in the method according to the invention from setting the proportions of the concentration of the antimicrobial means relative to the concentration of the chelator in the aqueous solution can be explained in that the chelator is surprisingly better released from the hydroactive constituent of the fabric on contact with water or wound exudate than the antimicrobial means.

In all embodiments of the invention, it is particularly preferred if the aqueous solution used to apply the antimicrobial means during the spraying process is held in a container which is kept at a constant temperature of between 35° and 70° C in order to increase solubility and in which the aqueous solution is continuously agitated.

A wound care product according to the invention having a fabric comprising hydroactive constituents is essentially characterised in that the hydroactive constituents are provided with an antimicrobial means. In preferred embodiments of wound care products according to the invention, the quantity of the antimicrobially effective means is between 10^{-4} mg and 1.0 mg, preferably between $4 \cdot 10^{-3}$ mg and 0.7 mg, per cm^2 of a respective side of the fabric. The antimicrobial means can comprise PHMB. In addition, a wound care product according to the invention can also be provided with a chelator in the area of its hydroactive constituents. The quantity of

chelator is preferably $5 \cdot 10^{-4}$ mg to 1.2 mg, in particular 10^{-2} to 0.8 mg, per cm^2 of a respective side of the fabric. In the context of the invention, the chelator of a wound care product according to the invention is preferably an EDTA disodium salt.

In addition or as an alternative to the chelator, the hydroactive constituent of the wound care product according to the invention can also be provided with a tenside such as EHG or a polysorbate, which can be applied in a quantity of 10^{-4} to 0.6 mg, in particular $5 \cdot 10^{-4}$ to 0.1 mg, per cm^2 of a respective side of the fabric. The fabric of a wound care product according to the invention is preferably comprised of the hydroactive constituent to 50% by weight or more, in particular about 80% by weight of the hydroactive constituent.

The hydroactive constituent of the wound care product according to the invention can be a cellulose ethyl sulphonate, in particular cellulose ethyl sulphonate fibres and/or carboxymethyl cellulose, in particular carboxymethyl cellulose fibres. The fabric can additionally also comprise cellulose fibres.

Fabrics according to the invention can also exist in the form of alginate fibre products or foams. If the fabric is formed of fibres, it has proved to be expedient if the fibres form a nonwoven material.

Claims

1. Method for the manufacture of a wound care product in which a fabric containing hydroactive constituents, in particular fibres, is processed, characterised in that the processing of the fabric comprises the application of an antimicrobial means onto the hydroactive constituents.
2. Method according to claim 1, characterised in that the antimicrobial means is applied in a preferably aqueous solution.
3. Method according to claim 2, characterised in that the solution containing the antimicrobial means is sprayed preferably onto both sides of the fabric, in particular with at least one ultrasonic nozzle.
4. Method according to claim 2 or 3, characterised in that 10^{-4} mg or more, in particular $4 \cdot 10^{-3}$ mg or more, of the antimicrobial means is applied per cm^2 of a respective side of the fabric.
5. Method according to one of claims 2 to 4, characterised in that 1.0 mg or less, in particular 0.7 mg or less, of the antimicrobially effective means is applied per cm^2 of a respective side of the fabric.
6. Method according to one of the previous claims, characterised in that the antimicrobial means has PHMB.
7. Method according to claim 6, characterised in that PHMB is present in an aqueous solution in a concentration in the range of 0.1 to 9% by weight, in particular in the range of 4 to 9% by weight, whereby preferably 0.1 to 8 mg, in particular 2 to 8 mg, of the solution is applied per cm^2 to a respective side of the fabric.

8. Method according to one of the above claims, characterised in that a chelator is applied to the hydroactive constituents.
9. Method according to claim 8, characterised in that the chelator is applied in the preferably aqueous solution, in particular is sprayed on.
10. Method according to one of claims 8 or 9, characterised in that $5 \cdot 10^{-4}$ mg or more, in particular 10^{-2} mg or more, of the chelator is applied per cm^2 of a respective side of the fabric.
11. Method according to one of claims 8 to 10, characterised in that 1.2 mg or less, in particular 0.8 mg or less, of the chelator is applied per cm^2 of a respective side of the fabric.
12. Method according to one of claims 8 to 11, characterised in that the chelator has EDTA, in particular EDTA disodium salt.
13. Method according to claim 12, characterised in that EDTA is present in the aqueous solution in a concentration in the range of 0.5 to 15% by weight, in particular in the range of 5 to 10.4% by weight, whereby preferably 0.1 to 8 mg, in particular 2 to 8 mg, of the solution is applied per cm^2 to a respective side of the fabric.
14. Method according to one of the above claims, characterised in that at least one tenside, such as EHG, and/or a polysorbate is applied to the hydroactive constituents.
15. Method according to claim 14, characterised in that the tenside is applied in the preferably aqueous solution, in particular is sprayed on.
16. Method according to one of claims 14 or 15, characterised in that 10^{-4} mg or more, in particular $5 \cdot 10^{-4}$ mg or more, more preferably 10^{-3} mg or more, of the tenside is applied per cm^2 of a respective side of the fabric.

17. Method according to one of claims 14 to 16, characterised in that 0.6 mg or less, in particular 0.1 mg or less, of the tenside is applied per cm² of a respective side of the fabric.
18. Method according to one of claims 14 to 17, characterised in that the tenside is present in the aqueous solution in a concentration in the range of 0.1 to 7% by weight, in particular 0.1 to 5% by weight, whereby preferably 0.1 to 8 mg, in particular 2 to 8 mg of the aqueous solution, is applied per cm² to a respective side of the fabric.
19. Method according to one of the previous claims, characterised in that the hydroactive constituents have carboxymethyl cellulose and/or cellulose ethyl sulphonate.
20. Method according to one of the previous claims, characterised in that the proportion of hydroactive constituents in the fabric is 50% or more by weight, in particular 75% or more by weight, more preferably about 80% by weight.
21. Wound care product manufactured using a method according to one of the previous claims, with a fabric having hydroactive constituents, in particular fibres, characterised in that at least some hydroactive constituents are provided with an antimicrobial means.
22. Aqueous solution for the implementation of a method according to one of claims 1 to 21, with 0.1 to 9% by weight of PHMB, 0.5 to 15% by weight of EDTA disodium salt, 0.1 to 5% by weight of EHG and 0 to 2.5% by weight of Tween 20.

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER INV. A61L15/28 A61F13/00 A61F13/02 A61K31/198 A61K31/785 ADD. 		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61F A61L C09J		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) EPO-Internal, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2010/015208 A1 (KERSHAW DAVID [GB] ET AL) 21 January 2010 (2010-01-21) paragraphs [0009] - [0012], [0018], [0023] examples 1-3 claims 1-4, 6, 8 <div style="text-align: center;">-----</div>	1-5, 20, 21
X	US 2009/306157 A1 (ROHRER CHRISTIAN [AT] ET AL) 10 December 2009 (2009-12-10) paragraphs [0020], [0021], [0024], [0026], [0032], [0034] - [0038] examples 1-2 claims 20, 23, 24, 31, 32 <div style="text-align: center;">-----</div> <div style="text-align: center;">-/-</div>	1, 2, 6, 7, 20, 21
<div style="display: flex; justify-content: space-between;"> <div> ☒ Further documents are listed in the continuation of Box C. </div> <div> ☒ See patent family annex. </div> </div>		
<div style="display: flex;"> <div style="flex: 1;"> <p>* Special categories of cited documents :</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> </div> <div style="flex: 1;"> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance;; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance;; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> </div> </div>		
Date of the actual completion of the international search <div style="text-align: center;">5 May 2022</div>		Date of mailing of the international search report <div style="text-align: center;">13/05/2022</div>
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer <div style="text-align: center;">Schmitt-Humbert, C</div>

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International application No

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C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>US 2014/107555 A1 (PATEL HARISH [US]) 17 April 2014 (2014-04-17) figures 2-3 paragraphs [0074] - [0082], [0090], [0107], [0109], [0111], [0114] examples 1-16</p> <p>-----</p>	1-3, 6-21
X	<p>EP 3 088 010 A1 (DICOSMO FRANK [CA]) 2 November 2016 (2016-11-02) paragraphs [0118], [0119], [0132] claims 1, 9, 14, 15</p> <p>-----</p>	1, 6-13, 19, 21
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INTERNATIONAL SEARCH REPORT

Information on patent family members

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