Kit for the preparation of a vaccinating agent

The present invention relates to a kit for the preparation of a vaccinating agent, a use of the kit for preparing a vaccinating agent, a use of at least two starting materials for preparing a vaccinating agent and a process for providing a vaccinating agent.

The present invention relates in particular to the manufacture and provision of vaccinating agents, particularly in the veterinary medical field. Primarily, the present invention relates to vaccinating agents for immunising pigs against Porcine Circovirus, particularly type 2, also known as Porcine Circovirus Disease or PCVD, and/or against bacteria of the strain Mycoplasma hyopneumoniae, also known as Enzootic Pneumonia or EP.

It is known that the above-mentioned diseases can be prevented by immunisation with vaccines. Vaccinating agents are usually provided for injection and have to be correspondingly sterile. Moreover, each individual injection causes stress to the creature being treated and for this reason the number of vaccination processes should be kept to a minimum.

One known possibility for reducing the number of vaccination processes are so-called combined vaccinations by which immunisation against different diseases can be provided in just a few or even just one session. However, a combined vaccination is often not possible as a result of incompatibilities of different vaccines or components thereof with one another. Even if an at least short-time compatibility can be achieved, these combination vaccines have to be produced on site. In the veterinary medical field, in particular, the vaccines then have to be prepared and/or administered outdoors. A problem here is that the combination vaccine may become contaminated, for example with pathogens, particularly if a mixing vessel has to be punctured several times.

Object of the embodiments disclosed herein is to provide a kit for preparing a vaccinating agent, a use of this kit for preparing a vaccinating agent, a use of two starting materials for preparing a vaccinating agent and a process for providing a vaccinating agent by which a vaccinating agent can be produced, even from starting materials which are only briefly stable with one another, by the simplest possible method, which is not prone to errors and is at the same time hygienic.

The above problem is solved by a kit for preparing a vaccinating agent according to claim 1, by a use of such a kit for preparing a vaccinating agent according to claim 50, by a use of at least two starting materials for preparing a vaccinating agent according to claim 51 or by a process for providing a vaccinating agent according to claim 106. Advantageous embodiments are the subject of the sub-claims.

The present disclosure relates to a kit for preparing a vaccinating agent, particularly for preparing a vaccinating agent for use in immunising against the disease Porcine Circovirus Disease "PCVD" and/or Enzootic Pneumonia "EP" or against infections with Porcine Circovirus, particularly type 2, and/or Mycoplasma hyopneumoniae.

The kit according to the disclosure comprises a first starting material and a second starting material that is different from the first. A starting material for the purposes of the

present disclosure is preferably any source material, particularly a vaccine, a source material comprising a vaccine and/or a component or source material for a vaccinating agent, preferably an antigen or a composition containing an antigen.

Moreover, the kit comprises a first container that is only partly filled with the first starting material and a second container holding the second starting material.

A container for the purposes of the present disclosure is preferably a structure enclosing a volume, preferably configured to receive a liquid, particularly a vessel, a bottle, a bag or the like.

The kit further comprises an adapter device for establishing a fluid connection, wherein the fluid connection can be established between the first and second containers. It is also preferable that the adapter device should be configured to establish a fluid connection between the interiors of the first container and the second container.

Moreover in the proposed kit at least one of the containers is closed off by a factory-provided closure device. Preferably, both containers are closed off by a factory-provided closure device. Preferably, an airtight and/or sterile closure is provided. In particular this may be a seal, a rubber stopper or the like, wherein the closure device can preferably be penetrated and/or pierced, particularly reversibly. In this way the containers, i.e. at least one of the containers, can be sealed in sterile manner.

It is envisaged that the second container can be connected to the first container by means of the adapter device, when the closure device is pierced for the first and/or only time, such that the second starting material enters the first container, particularly is transported therein, and there forms the vaccinating agent with the first starting material. The closure device or closure devices are thus preferably embodied to be penetrated or pierced by means of the adapter device. The adapter device is preferably configured to be able to penetrate and/or pierce the closure device or closure devices. In this way a fluid connection can be provided between the first and second containers.

In a first aspect, the present disclosure relates to a kit for preparing a vaccinating agent for use in immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP", the kit comprising a first starting material, a second starting material different from the first, a first container only partly filled with the first starting material and a second container comprising the second starting material, wherein at least one of the containers is closed off with a factory-provided closure device and the second container is connectable to the first container by means of an adapter device for providing a fluid connection between the first and second container by piercing the closure device for the first and/or only time, such that the second starting material enters the first container and there forms the vaccinating agent with the first starting material, wherein the first starting material and the second starting material are liquid, the first starting material comprises only a first of the components Mycoplasma vaccine and Circovirus vaccine, the second starting material comprises only the other of the components Mycoplasma vaccine and Circovirus vaccine, and the total volume of the first container exceeds the volume of the first starting material at least by the volume of the second material wherein the first container contains gas and the volume of the gas in the first container exceeds a volume of the second starting material by more than 2%.

With the kit according to the disclosure it is thus possible to prepare a vaccinating agent from two starting materials with only two containers and an adapter device, particularly for use in immunising against the diseases caused by infections with Porcine Circovirus and/or Mycoplasma hyopneumoniae, preferably for use in immunising against the diseases caused by infections with Porcine Circovirus and Mycoplasma hyopneumoniae. The kit also avoids the use of other incompatible starting materials, particularly by presenting the starting materials and containers in kit form.

In a second aspect, the present disclosure relates to use of a kit, particularly as defined above, for producing and/or preparing a vaccinating agent, preferably for, in particular, simultaneous immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP".

Advantageously, the vaccinating agent may be formed in the only partly filled first container, avoiding the need for additional containers and/or additional adapter devices. This makes the application as simple as possible. In addition, the use of materials is minimised as the number of components required is reduced to a minimum.

Also it is particularly advantageous that simply penetrating or piercing the closure device, for the first or only time, is enough to produce the vaccinating agent. In fact, this

It is also envisaged that a first starting material is used in a first container only partly filled with the first starting material and a second starting material that is different from the first is used in a second container holding the second starting material and an adapter device is used which is configured so as to establish a fluid connection between the first and second containers. At least one of the containers is closed off by a factory-provided closure device. A fluid connection between the first and second containers is produced by means of the adapter device when the closure device is penetrated for the first and/or only time, in order to transfer the second starting material through the adapter device and closure device into the first container and produce the vaccinating agent in the first container.

In a third aspect, the present disclosure relates to use of at least two starting materials for producing a vaccinating agent for, in particular simultaneous, immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP" in pigs, in which, in order to produce the vaccinating agent, the starting materials are placed in containers and used with an adapter device, particularly using a kit as defined above, using a first starting material in a first container only partly filled with the first starting material and a second starting material different from the first in a second container comprising the second starting material, and an adapter device designed to provide a fluidic connection between the first and second container, at least one of the containers being closed off with a factory-provided closure device and forming with the adapter device, when the closure device is pierced for the first and/or only time, a fluid connection between the first and second container, in order to transfer the second starting material through the adapter device and the closure device into the first container and produce the vaccinating agent in the first container, wherein the first starting material and the second starting material are liquid, the first starting material comprises only a first of the components Mycoplasma vaccine and Circovirus vaccine, the second starting material comprises only the other of the components Mycoplasma vaccine and Circovirus vaccine, and the total volume of the first container exceeds the volume of the first starting material at least by the volume of the second material wherein the first container contains gas and the volume of the gas in the first container exceeds a volume of the second starting material by more than 2%.

Another embodiment of the present disclosure that can also be implemented independently relates to a process for preparing a vaccinating agent from a first starting material and a second starting material different from the first, particularly for especially simultaneous immunisation against the disease Porcine Circovirus Disease "PCVD" and/or Enzootic Pneumonia "EP", preferably for particularly simultaneous immunisation against the diseases Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP". The vaccinating agent may be prepared using a kit as proposed.

Between a first container only partly filled with the first starting material and a second container holding the second starting material a fluid connection is established by an adapter device, such that the fluid connection between the first and second containers is established by means of the adapter device when at least one factory-provided closure device, which preferably closes off at least one of the containers, is penetrated or pierced for the first and/or only time by the adapter device. The second starting material is transferred or conveyed through the adapter device and the closure device into the first container. In the first container, the vaccinating agent is formed from the first starting material and the second starting material.

In a fourth aspect, the present disclosure relates to a process for preparing a vaccinating agent from a first starting material and with a second starting material different from the first, for, in particular simultaneous, immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP", particularly with a kit as defined above, wherein between a first container only partly filled with the first starting material and a second container comprising the second starting material a fluid connection is formed by an adapter device, such that, by means of the adapter device, when at least one factory-provided closure device of at least one of the containers is pierced for the first and/or only time a fluid connection is formed between the first and second container, and the second starting material is conveyed through the adapter device and the closure device into the first container, and in the first container the vaccinating agent is formed from the first and second starting material, wherein the first starting material and the second starting material are liquid, the first starting material comprises only a first of the components Mycoplasma vaccine and Circovirus vaccine, the second starting material comprises only the other of the components Mycoplasma vaccine and Circovirus vaccine, and the total volume of the first container exceeds the volume of the first starting material at least by the volume of the second material wherein the first container contains gas and the volume of the gas in the first container exceeds a volume of the second starting material by more than 2%.

Preferably, the first and/or second starting material is or comprises a vaccine, an antigen and/or an antigen-containing composition. Moreover, the first starting material may differ from the second starting material. The first starting material may thus be or comprise a first vaccine, a first antigen and/or a composition containing a first antigen and the second starting material may be or comprise a second vaccine, different from the first, a second antigen different from the first and/or an antigen-containing composition, the antigen of which differs from that of the first antigen-containing composition. Preferably, the first vaccine and the second vaccine, or the first antigen and the second antigen, or the compositions containing the various antigens are for particularly simultaneous immunisation against various diseases or pathogens such as for example against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP", or for immunisation against Porcine Circovirus, preferably Porcine Circovirus type 2 and against Mycoplasmas, preferably against Mycoplasma hyopneumoniae. This makes it possible to produce a combination vaccine. The starting materials may contain other substances apart from vaccines, particularly water, adjuvants and/or excipients.

Patent Claims:

1. Kit for preparing a vaccinating agent for use in immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP", the kit comprising a first starting material, a second starting material different from the first, a first container only partly filled with the first starting material and a second container comprising the second starting material,

wherein at least one of the containers is closed off with a factory provided closure device and the second container is connectable to the first container by means of an adapter device for providing a fluid connection between the first and second container by piercing the closure device for the first and/or only time, such that the second starting material enters the first container and there forms the vaccinating agent with the first starting material,
wherein the first starting material and the second starting material are liquid, the first starting material comprises only a first of the components Mycoplasma vaccine and Circovirus vaccine, the second starting material comprises only the other of the components Mycoplasma vaccine and Circovirus vaccine, and the total volume of the first container exceeds the volume of the first starting material at least by the volume of the second material wherein the first container contains gas and the volume of the gas in the first container exceeds a volume of the second starting material by more than 2%.

2. Kit according to claim 1, characterised in that the first starting material comprises the vaccine in amounts of more than 30 % by weight, preferably more than 40 % by weight, particularly more than 50 % by weight; and/or less than 90 % by weight, preferably less than 80 % by weight, particularly less than 70 % by weight.

3. Kit according to claim 1 or 2, characterised in that the second starting material comprises the vaccine in amounts of more than 30 % by weight, preferably more than 40 % by weight, particularly more than 50 % by weight; and/or less than 90 % by weight, preferably less than 80 % by weight, particularly less than 70 % by weight.

4. Kit according to one of the preceding claims, characterised in that the first starting material, the second starting material and/or the vaccinating agent is a suspension, preferably with vaccines and/or insoluble proteins, preferably in amounts of more than 30 % by weight, preferably more than 40 % by weight, particularly more than 50 % by weight; and/or less than 90 % by weight, preferably less than 80 % by weight, particularly less than 70 % by weight.

14. Kit according to claim 13, characterised in that at least one of the starting materials and/or the vaccinating agent comprises the adjuvant in amounts of more than 0.1 % by weight and/or less than 20 % by weight, preferably more than 1 % by weight and/or less than 10 % by weight, particularly more than 2 % by weight and/or less than 5 % by weight.

15. Kit according to one of the preceding claims, characterised in that a preferably polymeric adjuvant, particularly carbomer, is formed in the vaccinating agent.

16. Kit according to one of the preceding claims, characterised in that the Mycoplasma vaccine and/or the Circovirus vaccine contains formaldehyde in a concentration of less than 2.5 mg/m^3, preferably less than 1.5 mg/m^3, particularly 0.74 mg/m^3 or less.

17. Kit according to one of the preceding claims, characterised in that the first starting material contains water in a concentration of at least 20 % by weight, preferably at least 30 % by weight, particularly at least 40 % by weight; and/or at most 80 % by weight, preferably at most 70 % by weight, particularly at most 60 % by weight.

18. Kit according to one of the preceding claims, characterised in that the first starting material contains one or more excipients, particularly preservatives, antioxidants and/or emulsifier, each preferably in a concentration of at least 0.1 % by weight, preferably at least 0.2 % by weight, particularly at least 0.3 % by weight; and/or at most 10 % by weight, preferably at most 5 % by weight, particularly at most 3 % by weight.

19. Kit according to one of the preceding claims, characterised in that the first container is filled with the first starting material in an amount of less than 70 %, preferably less than 50 % , particularly less than 45 %.

20. Kit according to one of the preceding claims, characterised in that the first container contains gas, namely protective gas.

21. Kit according to claim 20, characterised in that the volume of the gas corresponds at least to the volume of the second starting material in the second container.

22. Kit according to claim 20 or 21, characterised in that the volume of the gas in the first container exceeds the volume of the second starting material by more than 5 %, particularly more than 8 % and/or less than 80 %, preferably less than 50 %, particularly less than 40 % or 30 %.

23. Kit according to one of claims 20 to 22, characterised in that the adapter device is configured so that during the transfer of the second starting material into the first container the gas or protective gas passes, particularly is transported, from the first container into the second container.

47. Kit according to one of the preceding claims, characterised in that the longitudinal extent and/or the diameter of the first container is designed for use in a particularly multiple-use injection device, particularly an injection gun, pressure injector and/or self-filling syringe.

48. Kit according to one of the preceding claims, characterised in that the first container has a diameter of more than 1 cm, preferably more than 2 cm, particularly more than 3 cm; and/or less than 10 cm, preferably less than 8 cm, particularly less than 6 cm.

49. Kit according to one of the preceding claims, characterised in that the first container has a longitudinal extent that is more than 3 cm, preferably more than 5 cm, particularly more than 6 cm and/or less than 30 cm, preferably less than 25 cm, particularly less than 20 cm.

50. Use of a kit according to one of the preceding claims for producing and/or preparing a vaccinating agent, preferably for, in particular, simultaneous immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP".

51. Use of at least two starting materials for producing a vaccinating agent for, in particular simultaneous, immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP" in pigs, in which, in order to produce the vaccinating agent, the starting materials are placed in containers and used with an adapter device, particularly using a kit according to one of claims 1 to 49,

using a first starting material in a first container only partly filled with the first starting material and a second starting material different from the first in a second container comprising the second starting material, and an adapter device designed to provide a fluidic connection between the first and second container,

at least one of the containers being closed off with a factory provided closure device and forming with the adapter device, when the closure device is pierced for the first and/or only time, a fluid connection between the first and second container, in order to transfer the second starting material through the adapter device and the closure device into the first container and produce the vaccinating agent in the first container,
wherein the first starting material and the second starting material are liquid, the first starting material comprises only a first of the components Mycoplasma vaccine and Circovirus vaccine, the second starting material comprises only the other of the components Mycoplasma vaccine and Circovirus vaccine, and the total volume of the first container exceeds the volume of the first starting material at least by the volume of the second material wherein the first container contains gas and the volume of the gas in the first container exceeds a volume of the second starting material by more than 2%.

52. Use according to one of claim 51, characterised in that the adapter device is used to penetrate the closure device.

53. Use according to claim 51 or 52, characterised in that the adapter device is used to penetrate the closure devices of both containers, preferably for the first and/or only time.

54. Use according to one of claims 51 to 53, characterised in that the adapter device is used first to penetrate the closure device of the second container and then the closure device of the first container, preferably for the first and/or only time.

81. Use according to one of claims 51 to 80, characterised in that the first container is filled with the first starting material by an amount of less than 70 %, preferably less than 50%, particularly less than 45 %.

82. Use according to one of claims 51 to 81, characterised in that the first container contains gas, namely protective gas.

83. Use according to claim 82, characterised in that the volume of the gas corresponds at least to the volume of the second starting material in the second container.

84. Use according to claim 82 or 83, characterised in that the volume of the gas in the first container exceeds the volume of the second starting material by more than 5 %, particularly more than 8 % and/or less than 80 %, preferably less than 50 %, particularly less than 40 % or 30 %.

85. Use according to one of claims 82 to 84, characterised in that the adapter device is configured so that during the transfer of the second starting material into the first container the gas or protective gas passes, particularly is transported, from the first container into the second container.

86. Use according to one of claims 51 to 85, characterised in that the adapter device is configured for preferably fluidically connecting the inner spaces formed by the containers.

87. Use according to one of claims 51 to 86, characterised in that the adapter device comprises a fluid channel for providing a fluidic connection between the inner spaces formed by the containers.

88. Use according to claim 87, characterised in that the adapter device comprises a venting or exhaust device.

89. Use according to one of claims 51 to 88, characterised in that the adapter device comprises a channel for venting or exhaust.

90. Use according to claim 87 and claim 88 or 89, characterised in that the venting or exhaust device, particularly the channel for venting or exhaust, is provided in addition to the fluid channel of the adapter device, particularly parallel thereto.

91. Use according to claim 87 and one of claims 88 to 90, characterised in that one opening of the channel for venting or exhaust is set back, in respect of the outlet opening of the fluid channel on the side facing the first container, in the direction of the main extent of the adapter device.

105. Use according to one of claims 51 to 104, characterised in that the vaccinating agent is intended for preventing disease in pigs caused by infection with porcine Circovirus type 2 and/or Mycoplasma hyopneumoniae.

106. Process for preparing a vaccinating agent from a first starting material and with a second starting material different from the first, for, in particular simultaneous, immunisation against the disease Porcine Circovirus Disease "PCVD" and Enzootic Pneumonia "EP", particularly with a kit according to one of claims 1 to 54,

wherein between a first container only partly filled with the first starting material and a second container comprising the second starting material a fluid connection is formed by an adapter device, such that, by means of the adapter device, when at least one factory-provided closure device of at least one of the containers is pierced for the first and/or only time a fluid connection is formed between the first and second container, and

the second starting material is conveyed through the adapter device and the closure device into the first container, and

in the first container the vaccinating agent is formed from the first and second starting material,

wherein the first starting material and the second starting material are liquid, the first starting material comprises only a first of the components Mycoplasma vaccine and Circovirus vaccine, the second starting material comprises only the other of the components Mycoplasma vaccine and Circovirus vaccine, and the total volume of the first container exceeds the volume of the first starting material at least by the volume of the second material wherein the first container contains gas and the volume of the gas in the first container exceeds a volume of the second starting material by more than 2%.

107. Process according to claim 106, characterised in that closure devices of both containers are penetrated with the adapter device, preferably for the first and/or only time.

108. Process according to claim 106 or 107, characterised in that first the closure device of the second container and then the closure device of the first container is penetrated by the adapter device, preferably for the first and/or only time, or *vice versa*.

109. Process according to one of claims 106 to 108, characterised in that a fluid connection is provided between the containers such that the second starting material passes from the second container into the first container under the effect of gravity.

110. Process according to one of claims 106 to 109, characterised in that the first container is moved during and/or after the transfer of the second starting material into the first container, so as to achieve or speed up a homogeneous reaction, particularly dissolving or mixing.

111. Process according to one of claims 106 to 110, characterised in that the first container is placed in or on an injection device.

112. Process according to one of claims 106 to 111, characterised in that the first container is placed in or on a preferably multiple-use injection device, particularly an injection gun, pressure injector and/or self-filling syringe.