

EUROPEAN QUALIFYING EXAMINATION

Paper A (MOCK)

This paper comprises:

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Gaiparee, 01.03.2012

Dear Mr Cavallo,

[0001] We would like you to draft and file today a European patent. Unfortunately, the timing of these instructions is not ideal: we are now leaving for an extensive team building exercise on a sail boat. We are not allowed to take any means of communication with us. We will hence not be available to answer any questions. We are, however, convinced that our invention is clearly described herein-below. In order to avoid unpleasant surprises at a later stage, we have already performed an extensive search for publications in our field. The only two documents we considered to be relevant are enclosed as D1 and D2. We have seen very interesting features in these documents, but we do not know whether we are allowed to introduce them into our patent application. Please consider doing so if you think that it is possible. In addition, we would like to stress that an opposition to one of our previous patent has taught us that, in the present field, it is very important to include from the start all the essential features of an invention in the independent claims.

[0002] Our invention relates to the field of skin patches for delivery of a skin care composition. Although skin care compositions can include both cosmetic and pharmaceutical compositions, we are not interested in the latter. The delivery of pharmaceutical compositions requires a very strict control of the delivery rate. This control can only be achieved on a case per case basis after an exhaustive fine tuning of all the elements of the patch. As a consequence, broad claims relating to patches for the delivery of pharmaceutical products are of almost no commercial value as key features will probably be missing. Hence, we do not wish you to spend time on such claims which are of no interest to our company.

[0003] Adhesive patches are commonly used to deliver cosmetic agents to human skin. However, conventional skin patches have several drawbacks.

[0004] Conventional patches have either a high flexibility or a high mechanical stability, but not both. Both properties are however required if the user is to easily apply and remove patches from body parts such as the armpits, fingers or the area around the eyes. A further problem associated with conventional patches lies in the fact that the patches do not allow air to circulate to the skin, which quickly leads to painful skin irritations.

[0005] In order to address these problems, our invention proposes a multi-layered patch shown schematically in the annexed figure 1. Patch 20 comprises a storage layer 22 containing an active ingredient, at least one top layer 23 covering the storage layer 22 and a support layer 21. Depending on the active ingredient, the multi-layered patch 20 can be used for various cosmetic (non-therapeutic) applications. For example, the multi-layered patch 20 can be used for cosmetic treatments such as anti-ageing (treating wrinkled skin) or deodorisation.

[0006] To obtain a flexible but mechanically stable patch, the storage layer 22 must be combined with a support layer 21. Any layer which can be loaded or soaked with a cosmetic active ingredient can be used as the storage layer 22. An example of a storage layer 22 is a layer of a polymeric matrix into which the active ingredient is absorbed or with which it is mixed. The support layer 21 can be formed from any non-woven or woven material which can be made from synthetic fibres (e.g. polymeric fibres) or natural fibres (e.g. cotton fibres). However, we found that for some multi-layered patches, for instance those of the type used in our example B

herein-below, it is indispensable to have a textile support layer (i.e. a flexible woven material, also known as fabric). When a support layer made of non-woven material is used for these patches, they inevitably fall apart during transport and storage and cannot be used at all. The same is also true for multi-layered patches lacking a support layer. As the active ingredient, any composition can be used, as long as it can be released from the storage layer and has a cosmetic effect on the skin.

[0007] To be useful and therefore commercially interesting, the multi-layered patch 20 of our invention has to release a sufficient amount of the active ingredient within the intended time of application. For some applications a release rate of from 5 to 10 mg of active ingredient per cm² per hour has been found to be advantageous. Theoretically, the release rate depends on both the nature of the storage layer 22 and on the nature of the support layer 21. Our long experience in this field has however taught us that for cosmetic applications it is only the nature of the support layer 21, through which the active ingredient stored in the storage layer 22 has to go through in order to reach the skin, which influences the release rate. This influence is to such an extent that the presence of a support layer 21 which allows and controls the release of the active ingredient is absolutely required to have an effective control of the release rate. Patches without support layer 21 are not commercially viable as it is impossible to control the release rate of any active ingredient.

[0008] The multi-layered patch 20 can use a hydrogel as the storage layer 22. It is well known that a hydrogel is a network of hydrophilic polymer chains in which water is the dispersion medium. Hydrogels are highly absorbent (they can contain over 90% water) natural or synthetic polymeric networks. Hydrogels also possess a degree of flexibility very similar to natural tissue, due to their high water content. This high degree of flexibility allows the amount of adhesive needed to maintain the patch securely on the skin to be reduced. The hydrogel can comprises water, gelatine and an alcohol. The preferred hydrogel for our invention comprises water, gelatine, an alcohol and silver particles. The content of the silver particles is preferably 10-30 % by weight of the hydrogel. In our most preferred embodiment, the content of the silver particles is 25 % by weight of the hydrogel. Silver has anti-bacterial properties and its presence in the hydrogel prevents the growth of bacteria, thereby ensuring that the patch can be stored and used for a long time.

[0009] Hydrogels have to be isolated from the environment, otherwise they leak and leave wet stains and the patches become unusable. To prevent the hydrogel leaking out, a top layer 23 entirely covering the storage layer 22 and preventing the passage of liquid has to be used. This top layer 23 is usually polymeric. When a perforated layer is used as top layer 23, these perforations must be small enough to prevent the passage of liquid. In our firm, we found that Gore-Tex ® membranes are highly suitable for this purpose.

[0010] In addition to the storage layer, the top layer and the support layer, the multi-layered patch of our invention can also contain one or more adhesive layers which are sticky at room temperature. Internal or external adhesive layers can be present anywhere in the multi-layered. For instance, internal adhesive layers placed between the storage layer and the support layer and/or between the storage layer and the top layer will enhance the structural integrity of the patch and thus help prevent separation of the various layers during use of the patch. An external adhesive layer placed on the external side of the support layer can be used so that the patch adheres to the skin. In such a case, the adhesive layer has to be such that it allows the active agent to reach the skin. In an example schematically illustrated in the attached figure 2, an adhesive layer A is placed between the top layer 23 and the storage layer 22, completely overlapping with the storage layer 22 and partly overlapping with the support layer 21. With such an arrangement, the adhesive layer can come into contact with the skin. An adhesive layer placed in such a way is both an internal and external layer.

[0011] The patch of our invention may contain a perfume to mask any unpleasant odours of the components of the patch or to make the patch more attractive to the consumer. The perfume composition may vary depending on the intended use (e.g. a fresh flowery perfume or a "clean and clinical" smell). The perfume composition is usually associated with the support layer 21. In some embodiments, the perfume can be present in a container and applied to the support layer during use or shortly before applying the patch to the skin.

[0012] It is important to note that a patch leading to a complete rupture of airflow to the skin is not acceptable as it will lead to adverse reactions. Therefore, the top layer has to have perforations which are large enough to allow air to pass through and

circulate to the skin. We found that Gore-Tex® membranes are highly suitable also for this purpose.

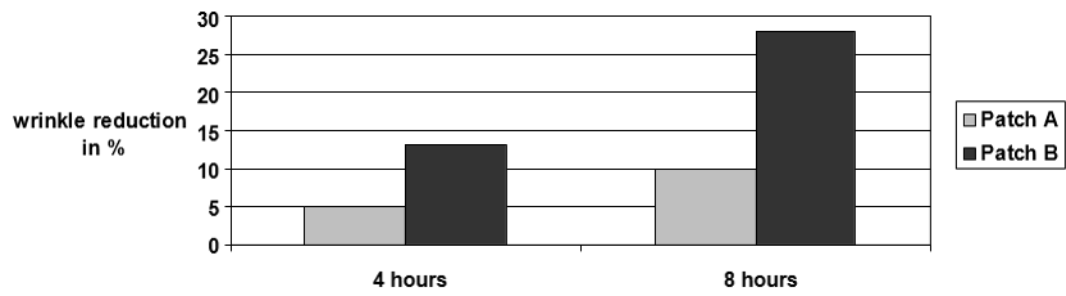
[0013] In the manufacturing process a further layer, a so-called protective layer, must be used. This necessary protective layer not only provides a foundation upon which the multiple layers of the multi-layered patch can be assembled, it also protects the patch during storage and is usually removed by the user shortly before the application of the patch to the skin. In the manufacturing process, the different layers are laid on top of one another on the protective layer, pressed together, using a pressure of 500 kPa or more for a classical polymeric storage layer, and heated in order to cure the different layers. For the sake of completeness, let us remind you that curing is a well-known process in polymer chemistry and process engineering and refers to the toughening or hardening of a polymer material by cross-linking of polymer chains. We have however found that when a hydrogel is used as the storage layer, the pressure, which must be more than 200 kPa, may not exceed 300 kPa as a higher pressure will damage the hydrogel. In view of this lower pressure, the patch must then be heated to a temperature between 80°C and 90 °C for at least 20 seconds in order to complete curing and achieve stability.

[0014] Examples

[0015] Patch A is prepared by arranging, on a protective layer, a support layer made of textile, a classical polymeric storage layer comprising an anti-wrinkle composition, an adhesive layer and a top layer made of a Gore-Tex® membrane. The protective layer was removed before application to the skin of volunteers.

[0016] Patch B was prepared and used as patch A, with the exception that the polymeric storage layer, which comprises the same anti-wrinkle composition, is a hydrogel layer with a content of silver particles of 25 % by weight of the hydrogel.

[0017] The following graph shows the percentage of wrinkle reduction when applying both patches on the skin of a panel of test users after 4 and 8 hours. As can be seen, using patch B clearly enhances wrinkle reduction.



With our best regards,

Charly Gouno

Theodore Margarete

P.S.: Please remember that, as usual, we are not willing to pay any additional claim fees or further filing fees.

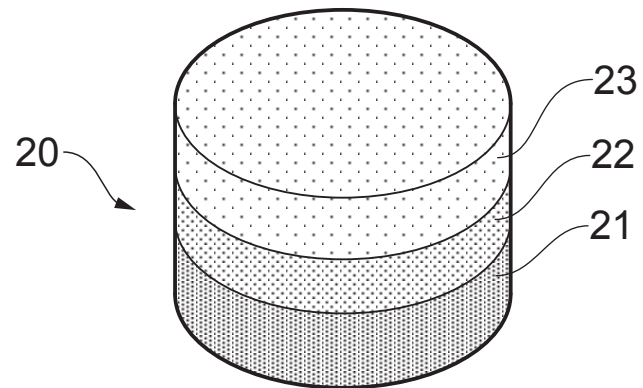


FIG. 1

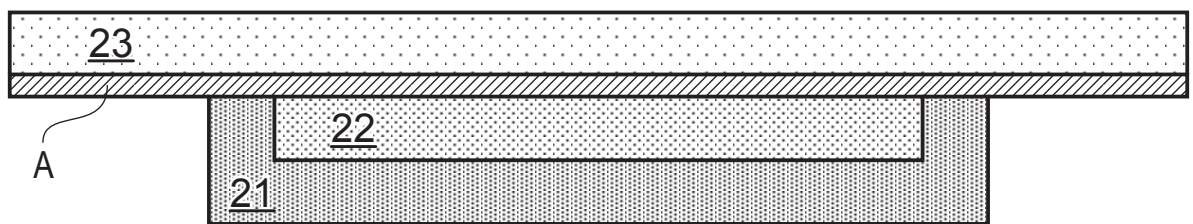


FIG. 2

Document D1

Cosmetic patch

[0001] The present invention relates to a cosmetic patch for skin treatment. In particular, the patches proposed by the present invention are suitable for reducing facial wrinkles by applying the patch to the skin.

[0002] Wrinkles occur on the face as a result of several factors, including the gradual loss of skin elasticity, or the loss of fat tissue in certain areas of the face as one ages. Cosmetic makeup or anti-ageing creams are often used to reduce facial wrinkles. Although wrinkles can be reduced at an early stage of skin ageing, the contact time or amount of anti-wrinkle composition is frequently not sufficient to reduce deep facial wrinkles.

[0003] Increasing the amount of active ingredient delivered to the skin usually enhances the intended effect. The present invention therefore proposes using a cosmetic patch for treating wrinkles instead of a creams to increase the contact time, thereby increasing the amount of active ingredient delivered.

[0004] As schematically shown in the figure, the patch 30 of the present invention is composed of layers, wherein the anti-wrinkle composition is stored in a polymeric matrix layer constituting a depot layer 31. The depot layer 31 is attached to a fabric layer 33 by the use of an adhesive layer 32. The adhesive layer can have side flaps to fix the patch to the skin. The fabric layer 33, which can be made of many different textiles ranging from cotton to high-tech textile such as Gore-Tex®, is the layer which comes into contact with the skin upon use of the patch. In some patches, this fabric layer has been made adhesive. The only requirement for said fabric layer 33 is that it must allow the anti-wrinkle composition to reach the skin. The layers should hence be such that the anti-wrinkle composition can pass through them and reach the skin. Usually, a protection layer is present before the use of the patch in order to protect the fabric layer during packaging, transport and storage of the patch. In addition, further layers can be present, such as a decorative backing layer, made for instance of the same materials as the fabric layer, which protects the depot layer from the environment. Such a backing layer can also be used to fix the patch to the skin in a

manner well known in the art. For instance, a further adhesive layer is placed between the backing layer and the depot layer, partly overlapping with the depot layer and completely overlapping with the backing layer, so that the adhesive layer can come into contact with the skin and fix the patch to the skin.

[0005] The anti-wrinkle composition migrates to the surface of the fabric layer 33 over time and is gradually absorbed by the skin. The amount of anti-wrinkle composition delivered may be increased by wearing the patch overnight.

[0006] In a preferred embodiment, the cosmetic patch in combination with a container containing a perfume forms a kit, a commercially very interesting product. Drops of the perfume composition can be applied onto the fabric carrier before applying the patch to the skin in order to mask any unpleasant odour of the depot layer or simply to provide a pleasant smell.

Claim:

A cosmetic patch (30) comprising a depot layer (31), an adhesive layer (32) and a fabric carrier (33).

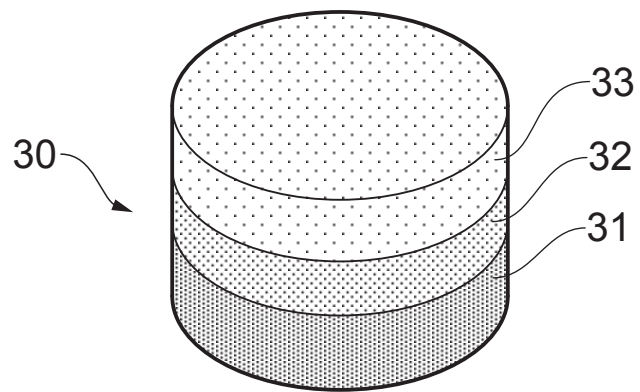


FIG.

Document 2 (D2)

Underarm Hygiene Product

[0001] The invention relates to an underarm hygiene product in the form of a deodorant patch. The term "patch" is used in general for a product to be applied to the skin which comprises several layers including an adhesive layer and a carrier layer.

[0002] Deodorants are known for underarm hygiene purposes. Common deodorant application forms are roll-ons, aerosols and sticks. All of these dispensing containers provide sufficient quantities of deodorant for multiple uses over several days or weeks. Deodorant patches are known, but are liable to tear when in use.

[0003] The deodorant patch of the present invention makes use of a reinforcing non-woven fibre layer in order to provide the deodorant patch with the required tear strength.

[0004] As schematically shown in the figure, the deodorant patch of the present invention comprises a release layer 51 which protects an adhesive layer 52 prior to the intended use. A polymeric matrix layer 53 encloses a perfume composition. The properties of the adhesive layer 52 must be such that the perfume enclosed in the polymeric matrix layer 53 will be able to migrate to the skin and thereby will mask any odour arising from perspiration of the user wearing the deodorant patch. In our research, we found that a layer made of cotton soaked with a skin-friendly glue makes an ideal adhesive layer 52. The matrix layer 53 is reinforced by a non-woven fibre layer 54 which provides the deodorant patch with the required tear strength. A further polymeric layer 55 is used as the outermost layer. The matrix layer 53 or the polymeric layer 55 can comprise silver particles. Preferably, the content of the silver particles is 5%-30 % by weight of the layer. As well known in the art, the content the silver particles must be at least 5% by weight of the layer to demonstrate any effect. Moreover, when the content of silver particles is more than 40% by weight of the layer the layer becomes unstable. Silver's association with anti-bacterial properties has long been established. Wound dressings containing silver have been an important aspect of healthcare for more than a century; soldiers in World War I relied heavily upon such dressings.

[0005] A further problem associated with patches is the separation of the layers during use due to movement of the user wearing the deodorant patch, e.g. during sport. By adding internal adhesive layers to the patch structure, the tendency of the layers to separate is reduced. However, the mere addition of internal adhesive layers does not prevent this completely.

[0006] The patch of the present invention must therefore be pressed at a pressure of at least 500 kPa during manufacture. This treatment strongly enhances the adhesive strength of the adhesive layers and therefore avoids any separation of the layers. The use of internal melt adhesive, which are absorbed when the structure is strongly pressed or treated at elevated temperature ($>200\text{ }^{\circ}\text{C}$), can be of advantage. The methods of manufacture are quite simple as they consist of laying the layers on top of each other, pressing them together to form a structure and, if necessary, curing said structure, preferably by application of high temperatures.

Claims:

1. A patch comprising a polymeric matrix layer (53) enclosing a perfume composition for deodorising the human body characterized in that the matrix layer (53) is reinforced by a non-woven fibre layer (54).
2. A manufacturing process for a patch according to claim 1, wherein the layers are laid on top of each other, pressed together at a pressure of at least 500 kPa thereby forming a structure and wherein said structure is optionally cured.
3. The manufacturing process of claim 2, wherein curing is achieved by the use of high temperature.

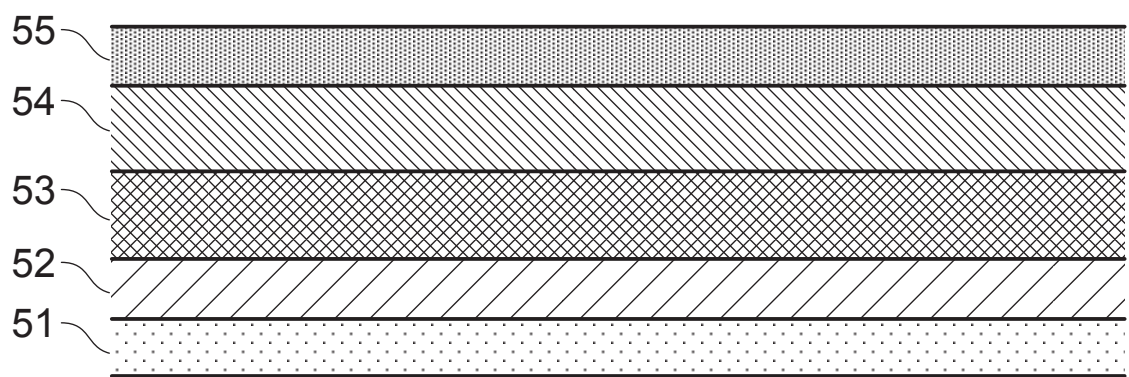


FIG.