

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 16/516,792 Confirmation No. 2546
Inventor(s) : Manuella Herb et al.
Filed : July 19, 2019
TC/A.U. : 1612
Examiner : Hong Yu

Title : FILM COMPOSITE FOR PACKAGING TRANSDERMAL
PATCHES, AND PACKAGE MADE OF SUCH A FILM
COMPOSITE
Docket No. : TRO-45953
Customer No. : 075626

DECLARATION UNDER 37 CFR 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, Manuella Herb hereby declare and state:

1. I am the <Senior Manager Product Development> for the Applicant of this application, namely, Huhtamaki Flexible Packaging Germany GmbH & Co. KG.
2. I have worked in the packaging industry for over 22 years and have significant experience in packaging and material designs for packaging.
3. I am one of the inventors of the film composite for packaging transdermal patches and package made of such a film of the above-identified patent application.
4. While Osborn may disclose that m-LLDPE exists, that is the extent of the teaching. The invention of this application relates to a specific arrangement of layers in a specific order that creates special properties that were not recognized or known before this application was filed.
5. As far as the disclosure in paragraphs [0076] and [0078] of Osborn, disclosed is

mLLDPE used in the examples, this can only refer directly to comparative example 2 presented in paragraph [0097] of Osborn, where the disclosed mLLDPE has no relation or interaction to any COC-layer.

6. As far as example 5, primarily referenced in the Office Action, this example refers to the identity of the base films of examples 5 and 2, this can only refer to the structure OPET/primer/LDPE/EAA/Al-foil which forms the base film of example 2 (which in turn corresponds to the base film of example 1, but without having been corona treated). Contrary to example 2, the layer structure on the inner, product-contacting side of the aluminum foil is EAA/LDPE/COC. Consequently, in example 5 the sealant layer mLLDPE of example 2 is replaced by a layer of COC.

7. The invention claimed in this application is directed to a specific arrangement of layers and the order of these layers that have been found to produce a superior result.

8. It is respectfully submitted that maintaining a rejection of the claims improperly ignores the arrangement of different layers made up of different chemical materials. Moreover, it disregards the order of appearance of the layers within the multilayer structure.

9. It has been found that the recited invention has unexpected effects in using certain metallocene polyethylene to tie the COC-layer to the EAA-layer and thereby to the aluminum foil.

10. It has been found and proven by laboratory testing that using metallocene C8 LLDPE as a layer connecting the COC-layer to the adhesive (EAA) layer surprisingly and tremendously promotes the delamination stability of the multilayer structure. Using regular LDPE allows to create a multilayer structure, but the COC-layer more or less easily delaminates or can be peeled off of the neighboring regular LDPE-layer. According to the results of laboratory tests conducted in March 2020, the bond between a regular LDPE layer and a COC layer connected to the regular LDPE layer within a laminate structure of paper/-adhesive/polyethylene terephthalate/adhesive/aluminum/ethylene acrylic acid copolymer/-LDPE/COC has a strength per length of 0.5 N per 15 mm. The tests were executed

according to industry standard DIN 55543-5.

11. In addition, metallocene C8 LLDPE, as is recited in the claims, increases the ties (lamination forces) between the polyethylene layer and the COC-layer to such an extent that, with the same laboratory equipment that allows for a rather easy delamination of the COC-layer from the neighboring regular LDPE-layer, the COC-layer cannot be delaminated from the metallocene C8 LLDPE layer without destroying the multilayer structure as such. This was shown by a comparative delamination test conducted by the same laboratory with the same equipment on a modified laminate. The modified laminate was the same as the laminate described above in 11. with the only exception that the layer of regular LDPE was replaced by a C8 metallocene LLDPE layer of the same weight per unit area as that of the regular LDPE layer. The bond strength per length between the C8 metallocene LLDPE layer and the COC layer was so large that any attempt to delaminate the C8 metallocene LLDPE layer and the COC layer resulted in a destruction of the laminate by tearing without achieving a delamination of the C8 metallocene LLDPE layer and the COC layer. The equipment used in the tests detected delamination forces per length between other layers of the laminate of up to 3.3 N per 15 mm. In other words, the adhesion between metallocene C8 LLDPE-layer and a COC-layer is significantly greater than the cohesion of the respective material within each layer. This effect was neither known, nor could it be expected.

12. While Osborn comprehensively lists the many different kinds of polyethylene that there are available for forming layers, Osborn and the remaining cited documents, are silent with regard to the type of metallocene-catalyzed LLDPE. C8 is one of the possibilities to metallocene-catalyze LLDPE, but not the only one. As far as Osborn discloses terms C2 to C10 in [0015], this disclosure relates to monomers, but not to locations for the metallocene-catalyzation to be effective within the carbon-molecule-string of a polyethylene polymer.

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Name: Manuella Herb

Title: Senior Manager Product Development
Huhtamaki Flexible Packaging Germany GmbH & Co.

KG.
Date: 21.07.2021

Huhtamaki Flexible Packaging
Germany GmbH & Co. KG
87671 Ronsberg