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ABOGADOS

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Señora Jefe de la
DIVISION DE NUEVAS CREACIONES
Superintendencia de Industria y Comercio
E. S. D.

57 94
SUPERINDUSTRIA Y COMERCIO
Radicacion : 00042366 00000005 folios: 8
Fecha (AMB): 2005-06-31 17:09:21
Trámite : 002 PATENTES D 1 REGISTRO/ 444 REPUESTA
Dependencia: 2000 DIVISION DE NUEVAS CREACIONES

Trámite : 002
Evento : 001
Actuación: 444

Referencia : Expediente No. 00.042.366
Solicitante : **SCA HYGIENE PRODUCTS AB**
Asunto : Solicitud de patente para **"UNIDADES DE
EMPAQUE IMPERMEABLES A LA HUMEDAD PARA
ARTÍCULOS ABSORBENTES QUE CONTIENEN
ADITIVOS SENSIBLES A LA HUMEDAD"**

Fecha de solicitud : 7 de junio de 2000.

1. Yo, Emilio FERRERO, obrando como apoderado del solicitante en el asunto antes identificado, me refiero al oficio número 12619, notificado por fijación en lista del 21 de abril de 2005. Para atender la anterior providencia solicité un plazo de treinta días por medio de mi memorial número 00042366 00000005 radicado el 15 de julio de 2005.

2. Mediante el oficio número 12619 se puso en conocimiento del solicitante el informe que contiene las observaciones hechas por su Despacho sobre el examen de fondo de la presente solicitud de patente, las cuales resumo a continuación:

2.1. Su Despacho considera que la descripción no es clara, ya que el examinador argumenta que no se presenta una solución específica al problema expuesto en la presente solicitud.

2.2. Su Despacho considera que el capítulo reivindicatorio no es claro debido a que éste no caracteriza el producto por la forma o constitución del mismo, las partes que lo componen y cómo se obtuvo. Adicionalmente su Despacho considera que lo que se caracteriza no está debidamente soportado en la

descripción.

3. Atiendo a las observaciones de la manera siguiente:

3.1. Claridad. Con el objetivo de subsanar la falta de claridad de las reivindicaciones, presento junto con este escrito un nuevo capítulo reivindicatorio en el cual se han hecho las modificaciones necesarias para limitar y definir el alcance de la invención. Se han especificado los materiales utilizados en el empaque, la existencia de costuras impermeables y los números de capas del empaque y sus materiales preferidos.

Igualmente presento el recibo de pago de \$91,000.00 por concepto de modificaciones en solicitud pendiente así como el formato de modificaciones y correcciones.

Por otra parte, si bien la modificación realizada a las reivindicaciones subsana la posible falta de claridad de la solicitud, deseo resaltar algunos aspectos que dan mayor claridad a la invención y que demuestran que la descripción es clara tal como reposa en el expediente.

La descripción hace énfasis en la necesidad de proveer un empaque para productos absorbentes tales como pañales desechables, toallas higiénicas, protectores higiénicos, tampones y protectores para incontinencia. Dicho empaque proporciona una solución al problema de daño de los aditivos activos presentes en los artículos absorbentes causado por infiltraciones de humedad, de tal modo que el empaque garantiza la conservación de la calidad del producto. Por lo tanto la descripción sí proporciona una solución clara al problema expuesto en la misma y una persona versada en la materia con la información allí contenida podría producir el empaque objeto de la presente invención.

Por otro lado la invención consiste en un empaque que contiene al menos un material de película esencialmente impermeable con las características expuestas en las reivindicaciones. Si bien es cierto que los materiales allí listados existen en el mercado y que todos los empaques

impermeables existentes están constituidos por varias capas de diferentes materiales, la implementación y configuración de éstos en un nuevo producto tal y como se presenta en las reivindicaciones no ha sido realizada con anterioridad, como de hecho el solicitante sustenta en la descripción.

Considero que el nuevo pliego reivindicatorio caracteriza claramente el producto por la constitución del mismo y las partes que lo componen, y que lo que se caracteriza está debidamente soportado en la descripción.

Por lo tanto, considero que la descripción que reposa en el expediente y el pliego reivindicatorio que aquí presento cumplen con el requisito de claridad de acuerdo con los artículos 28 y 30 de la Decisión 486.

Por las razones anteriormente expuestas, le solicito se sirva continuar con el trámite de la presente solicitud pues ésta se presenta de una forma clara y una persona versada en la materia podría realizar el producto objeto de esta invención con la información presentada en la descripción y reivindicaciones. Considero que con los argumentos expuestos anteriormente, así como con las modificaciones realizadas al pliego reivindicatorio se deben tener por superadas las objeciones que sobre claridad planteó ese Despacho en el oficio No. 12619. Sin embargo, en el evento que el Despacho considere que la presente invención todavía no es suficientemente clara, respetuosamente le solicito hacer uso de la facultad que le otorga el artículo 45 inciso 2. de la Decisión 486 de la Comisión de la Comunidad Andina a efecto de requerir nuevamente de nuestra parte cualquier complementación o aclaración que considere necesaria para efectos de proceder al examen de patentabilidad correspondiente.

Lo anterior, por cuanto el correspondiente examen de patentabilidad de la presente invención no solo fue oportunamente solicitado por mi representada sino que la tasa fijada por este mismo Despacho para llevarlo a cabo también se encuentra ya cancelada, de tal manera que la presente solicitud de patente de invención necesariamente debe ser

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objeto del mencionado examen en los términos del artículo 48 de la Decisión 486 de la Comisión de la Comunidad Andina.

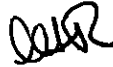
4. Puesto que se han atendido a cabalidad las observaciones hechas por su Despacho sobre la presente solicitud de patente, atentamente solicito se continúe con su tramitación.

Bogotá, 31 AGO. 2005
Señora Jefe,



EMILIO FERRERO

T.P.A. No. 31.929

 COLO 11256-801-037-8
MRE/MRE/
ID-001260/WPC11256



Industria y Comercio
SUPERINTENDENCIA

Espacio reservado para el adhesivo de radicación

FORMULARIO UNICO DE CORRECCIONES Y MODIFICACIONES

1

SOLICITUD DE:

☐ Corrección de Error Material

☒ Modificación a una solicitud

2

SOLICITANTE

Nombre: SCA HYGIENE PRODUCTS AB

Dirección: S-405 03
Goteborg
Suecia

Nacionalidad o Domicilio: Goteborg, Suecia
Lugar de Constitución: Suecia

Teléfono: 546 09 70 Fax: 249 40 70
E-mail: clientes@camyp.com

IDENTIFICACION

CC☐

NIT☐

CE☐

Otro☐

Número: _____

3

REPRESENTANTE
O APODERADO

Nombre: Emilio FERRERO

Dirección: Carrera 4ª No 72-35

Teléfono: 347 36 11 Fax: 217 92 11
E-mail: cavelier@cavelier.com

IDENTIFICACION

CC☒

NIT☐

CE☐

Otro☐

Número 438 019 TP 31 929

4

Número de expediente:

00 042.366

5

Descripción de la corrección o modificación solicitada:

Presento nuevo pliego reivindicatono con el fin de subsanar la falta de clandad del mismo y para definir de mejor forma al alcance de la protección solicitada Ninguna de las modificaciones realizadas amplía el alcance de la protección originalmente solicitada

6

Comprobante de pago No.

05-56.875

Fecha:

agosto 1 de 2005

7

Anexos

☒ Comprobante de pago de la tasa por valor de \$ 91,000 oo

☐ Poderes, si fuere el caso

☐ Documento que acredita la existencia y representación legal de las partes, cuando sean personas jurídicas

8

NOMBRE:

EMILIO FERRERO

FIRMA:



C.C. 438.019 de Usaquén T.P.A. 31 929

REIVINDICACIONES

1. Un empaque que contiene un artículo absorbente tal como una toalla sanitaria, un protector higiénico, un tampón, un protector de incontinencia, y un pañal, que contiene uno o más aditivos sensibles a la humedad, dicho empaque **caracterizado porque** comprende al menos un material de película esencialmente impermeable que tiene una WVTR (tasa de transmisión de vapor de agua) a lo sumo de $6 \text{ g/m}^2/\text{día}$ calendario según ASTM E 398-83, seleccionado del grupo que comprende polietileno, polipropileno, poliéster, poliamida, PETP, alcohol polivinílico, o papel aluminio, óxido de aluminio u óxido de sílice, en donde dicho empaque está completamente sellado con costuras o soldaduras impermeables, **y porque** dicho empaque comprende al menos dos capas de material de las cuales una es una capa interna de barrera a la humedad hecha del material de película esencialmente impermeable, y la otra es una capa externa hecha de PETP, polietileno o polipropileno.

2. El empaque según la reivindicación 1, caracterizado porque la WVTR del empaque es a lo sumo $4 \text{ g/m}^2/\text{día}$ calendario según ASTM E 398-83.

3. El empaque según cualquiera de las reivindicaciones anteriores, donde la WVTR del empaque es a lo sumo $2 \text{ g/m}^2/\text{día}$ calendario según ASTM E 398-83.

100-103

4. El empaque según cualquiera de las reivindicaciones anteriores, donde la WVTR del empaque es a lo sumo $1 \text{ g/m}^2/\text{día}$ natural ASTM E 398-83.

5. El empaque según una cualquiera de las reivindicaciones anteriores, caracterizado porque el empaque comprende además una capa de sello hecha de polietileno, polipropileno, EVA, EEA o cera, y colocada hacia dentro de la capa de barrera a la humedad.

6. El empaque según cualquiera de las reivindicaciones anteriores, caracterizado porque la capa de barrera a la humedad es de aluminio.

7. El empaque según cualquiera de las reivindicaciones anteriores, caracterizado porque el empaque incluye un indicador de humedad, tal como gel de sílice.

8. El empaque según cualquiera de las reivindicaciones anteriores, caracterizado porque incluye un absorbente de humedad.

COLO 11256-801-037-8

MRE-1261

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Radicacion: 00012366 00000005 Folios: 8
Fecha (AMD): 2005-08-31 17:09:21
Tramite: 002 PATENTES/ 1 REGISTRO/ 444 REPUESTA
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 05 - 56,875
FECHA : AGOSTO 1 DE 2005

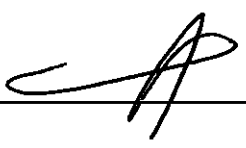
***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PGO	Vr. PAGO
CAVELIER ABOGADOS	CONSIGNACION	BANCO POPULAR	050-00110-6	36494400	01/08/2005	48,265,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-03	CAMBIO DE MODALIDAD Y MODIFICA	
12		MARCAS Y LEMAS COMERCIALES	91,000.00
		TOTAL :	\$ 91,000.00

SON: NOVENTA Y UNO MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

Colo 11256-801-037-8

105
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**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES**

2020

Bogotá, D.C., 22 de diciembre de 2005

Doctor
EMILIO FERRERO
Apoderado

Oficio-Nº. 13957

ASUNTO	Radicación	00-42366
	Trámite	002
	Evento	001
	Actuación	430
	Folios	017

Como resultado del examen de fondo, realizado con fundamento en el artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le comunica:

1. Documentos estudiados

- Para el presente estudio se tuvo en cuenta el capítulo descriptivo que se encuentra en los folios 58 a 76, los dibujos que se encuentran en los folios 84 a 86, el nuevo capítulo reivindicatorio que se encuentra en los folios 102 y 103 que comprende ocho (8) reivindicaciones, el concepto técnico No. 531 que obra en los folios 91 a 94 y el memorial de respuesta del señor solicitante que obra en los folios 95 a 100.

El nuevo capítulo reivindicatorio fue anexado como respuesta al requerimiento de fondo arriba citado y fue aceptado porque no implica la ampliación de la materia presentada originalmente.

- Se considerará la prioridad reivindicada sobre la solicitud de Suecia No. 9902207-1 del 11 de junio de 1999. ✓

2. Objeto de la invención

- La invención propuesta se relaciona con unidades de empaque impermeables a la humedad para artículos absorbentes que incluyen una o varias sustancias o aditivos sensibles a la humedad, activos. La unidad de envasado se compone de material de película que tiene baja permeabilidad de vapores y gases y uniones estancadas.

En la **reivindicación independiente 1** se define un empaque que contiene un artículo absorbente tal como una toalla sanitaria, un protector higiénico, un tampón, un protector de incontinencia, y un pañal, que contiene uno o más aditivos sensibles a la humedad, dicho empaque **caracterizado** porque comprende al menos un material de película esencialmente impermeable que tiene una WVTR (tasa de transmisión de vapor de agua) a lo sumo de 6 g/m²/día calendario según ASTM E 398-83, seleccionado del grupo que comprende polietileno, polipropileno, poliéster, poliamida, PETP, alcohol polivinílico, o

papel aluminio, óxido de aluminio u óxido de sílice, en donde dicho empaque está completamente sellado con costuras o soldaduras impermeables, y porque dicho empaque comprende al menos dos capas de material de las cuales una es una capa interna de barrera a la humedad hecha del material de película esencialmente impermeable, y la otra es una capa externa hecha de PETP, polietileno o polipropileno.

- Se afirma que es necesario empacar artículos absorbentes que contienen aditivos sensibles a la humedad de una manera que garantizará que dichos aditivos no se dañen o destruyan y que también garantizará que se conserve la calidad del producto.
- El objeto de la invención definido se catalogó como **A61L 15/16**, según la Clasificación Internacional de Patentes (IPC).

3. Determinación del estado de la técnica

El artículo 16 de la Decisión 486 de la Comisión establece: "El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.

Sólo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el artículo 40."

- Se consultaron las bases de datos con que cuenta y tiene acceso la entidad y se consideró el **11 de junio de 1999** como fecha para investigar el estado de la técnica.
- De acuerdo con lo establecido en el artículo 16 se determinó el estado de la técnica y se encontraron los siguientes antecedentes:

No.	Documento No.	Título	Fecha de Publicación
1	US4014433	"PACKAGE FOR MOISTURE SENSITIVE SUTURES AND METHOD FOR MAKING SAME"	29 de marzo de 1977
2	US5763028	"DOUBLY - PACKAGED EASILY OXIDIZABLE ARTICLE"	9 de junio de 1998

4. Evaluación de los requisitos de patentabilidad

El artículo 14 de la Decisión 486 de la Comisión de la Comunidad Andina establece: "Los Países Miembros otorgarán patentes para las invenciones, sean de producto o de procedimiento, en todos los campos de la tecnología, siempre que sean nuevas, tengan nivel inventivo y sean susceptibles de aplicación industrial."

En cumplimiento con este artículo, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

Evaluación del Nivel Inventivo

El art. 18 de la Decisión 486 de la Comisión de la Comunidad Andina establece: "Se considerará que una invención tiene nivel inventivo, si para una persona del oficio normalmente versada en la materia técnica correspondiente, esa invención no hubiese resultado obvia ni se hubiese derivado de manera evidente del estado de la técnica."

Respecto al estado de la técnica:

- En el documento **US4014433** (llamado D1 de aquí en adelante) se divulga un empaque laminado que comprende dos paneles de un material impermeable a la humedad tal como una hoja de aluminio recubierta con una resina sellable al calor tal como polipropileno, y periféricamente sellada al calor por los bordes marginales con un sello continuo y sustancialmente libre de burbujas para encerrar una sutura quirúrgica sensible a la humedad dentro del empaque. El empaque es altamente resistente a la penetración de vapor de agua y las suturas sensibles a la humedad así empacadas son bien protegidas contra la degradación por la humedad atmosférica que se difunde dentro del empaque a través de la capa de sello al calor durante el almacenamiento.
- En el documento **US5763028** (llamado D2 de aquí en adelante) se divulga un artículo fácilmente oxidable doblemente empacado que debe ser protegido durante el almacenamiento. El empaque en forma de bolsa es elaborado de una capa plástica con características de cierre al calor, una capa de un óxido inorgánico y una capa plástica laminada en orden desde el interior al exterior.

En D2 se enseña que el empaque flexible puede estar comprendido de:

- a) Una capa base plástica interna que tiene propiedades de cierre al calor;
- b) Una capa de resina de dicha capa base que tiene una propiedad de barrera a los gases, que puede ser de alcohol polivinílico, copolímero de etilen vinil alcohol, cloruro de polivinilideno, poliamida o poliéster;
- c) Una capa inorgánica que tiene propiedades de barrera al vapor sobre dicha capa de resina; y
- d) Una capa plástica exterior sobre dicha capa c).

La capa inorgánica que tiene propiedades de barrera al vapor puede ser una capa de óxido de sílice o una capa de óxido de aluminio.

En D2 se explica que el empaque está herméticamente sellado y que presenta una permeabilidad al oxígeno de no más que 4.0 ml/m^2 medido sobre 24 horas a 1 atmósfera.

Respecto a la solicitud en estudio:

- El técnico de nivel medio versado en la materia puede ser un ingeniero químico que labore en la industria de películas poliméricas que atienda a planes de mejoramiento continuo normalmente formulados por las empresas.
- En la reivindicación independiente 1 se define un producto tal como empaque que se caracteriza por su estructura, naturaleza química de los elementos y por un parámetro. Particularmente se menciona que el empaque comprende al menos un material de película esencialmente impermeable, en donde dicho empaque está completamente sellado con costuras o soldaduras impermeables. No obstante, en D1 se revela un empaque que también comprende una película de material impermeable (D1; resumen) y que está completamente sellado con soldaduras impermeables como se puede observar en la figura 1 de la anterioridad.

Paralelamente, en D2 se revela un empaque que también comprende al menos un material de película con propiedades de barrera a los gases.

En la reivindicación citada también se menciona que dicho empaque comprende al menos dos capas de material de las cuales una es la mencionada capa interna de barrera a la humedad hecha del material de película impermeable, y la otra es una capa externa. Sin embargo, en D1 se revela que el empaque también tiene por lo menos dos capas, incluso se muestran tres capas en la figura 3 cuyos numerales son 21, 22 y 23. La única diferencia es que la capa impermeable en la invención de la solicitud se encuentra interna mientras que en D2 se encuentra externa. A pesar de ello, dicha diferencia puede consistir en una modificación de la invención de D1 que no va más allá del espíritu de la invención o incluso, un técnico de nivel medio versado en la materia que tenga acceso a la información de dicho documento podría realizar modificaciones mediante ensayos de rutina y determinar la mejor disposición de las capas.

Asimismo, en D2 se presenta otro empaque con más de dos capas impermeables que únicamente se diferencia con la propuesta estudiada en la disposición particular de cada una de las capas.

En cuanto a los materiales de las capas en la reivindicación citada se menciona que el material de película impermeable con el cual se elabora una de las películas puede ser seleccionado del grupo que comprende polietileno, polipropileno, poliéster, poliamida, PETP, alcohol polivinílico, o papel aluminio, óxido de aluminio u óxido de sílice. No obstante, en D1 se menciona que la película impermeable puede ser una hoja de aluminio y más aún, en D2 se menciona que las películas pueden ser óxido de aluminio, óxido de sílice.

De la otra capa se menciona que está hecha de PETP, polietileno o polipropileno. Asimismo, en D1 también se enseña que puede estar elaborada de polipropileno o en D2 se menciona que puede estar elaborada de alcohol polivinílico, poliamida, poliéster y otros.

Respecto al parámetro incluido en la reivindicación se menciona que el material de película esencialmente impermeable tiene una WVTR a lo sumo de 6 g/m²/día calendario.

Aún cuando D1 no revela explícitamente ningún dato sobre este parámetro, se puede afirmar que al D1 divulgar un empaque con estructura y materiales del empaque equivalentes entonces con seguridad la película tendría un WVTR equivalente si se sometiera a análisis de laboratorio.

D2 divulga datos de permeabilidad de oxígeno muy bajos. Aun cuando estos no se puedan comparar con la WVTR por ser parámetros diferentes, sí se puede deducir la tendencia a desarrollar empaques con muy baja transferencia de gases para evitar daños de productos sensibles a ellos.

De hecho, si un técnico de nivel medio versado en la materia tuviera acceso a D1 o D2 de seguro se vería impulsado a desarrollar un empaque que presentara la menor transferencia de gases posible mediante elaborar dicho empaque con películas poliméricas equivalentes a los de la propuesta respecto a la naturaleza química y propiedades de barrera.

- Finalmente, es claro que el uso dado al empaque de la solicitud en estudio es diferente al uso revelado en los documentos D1 y D2. No obstante, el uso no puede ser considerado como un indicio de nivel inventivo y por tanto, el análisis no tiene en cuenta dicha diferencia. De hecho, el análisis se centra en el empaque en sí mismo con su estructura, elementos y composición.

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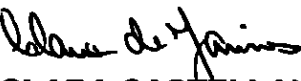
- De acuerdo con lo anterior, si un técnico de nivel medio versado en la materia tuviera acceso a D1 o D2, se vería motivado a elaborar empaques de más de dos capas de naturaleza química equivalente, las cuales formarían un empaque impermeable con bordes sellados. Además, se vería impulsado a realizar un empaque que impidiera el acceso de vapor de agua o gases (como el oxígeno) al interior para procurar conservar aislado el elemento que se incluya en dicho empaque.
- Por lo anteriormente expuesto, la invención definida por las reivindicaciones 1 a 8 de la solicitud, podría verse afectada en su nivel inventivo ya que se deriva de manera evidente del estado de la técnica y puede ser obvia para un técnico de nivel medio versado en la materia. Por tanto, no cumpliría con las disposiciones del artículo 18 de la Decisión 486 de la Comisión de la Comunidad Andina.
- Los requisitos de patentabilidad de la presente solicitud se encontrarían afectados así:

No.	Documento	Reivindicaciones Afectadas	Requisito que afecta
1.	US4014433	1 – 8	Nivel Inventivo
2.	US5763028	1 – 8	Nivel Inventivo

Se anexan los apartes principales de las anterioridades en el documento adjunto.

En cumplimiento del artículo 45 de la Decisión 486 de la Comisión de la Comunidad Andina, se le indica que debe dar respuesta dentro del término de sesenta días contados a partir de la fecha de notificación de la presente comunicación. En caso de no dar respuesta al presente requerimiento, o si a pesar de la respuesta subsistieran los impedimentos para la concesión, se denegará la patente.

Notifíquese el presente oficio conforme a lo dispuesto en el numeral 5.2, literal e), del capítulo quinto del título primero de la circular única No. 10 de 2001.



CLARA CASTELLANOS DE JAIMES
Jefe de División de Nuevas Creaciones (E)

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United States Patent

Cerwin

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[11] 4,014,433

[45] Mar. 29, 1977

[54] PACKAGE FOR MOISTURE SENSITIVE SUTURES AND METHOD FOR MAKING SAME

[75] Inventor: Robert J. Cerwin, Pittstown, N.J.

[73] Assignee: Ethicon, Inc., Somerville, N.J.

[22] Filed: May 27, 1975

[21] Appl. No.: 581,057

[52] U.S. Cl. 206/63.3; 53/29; 156/309; 206/434

[51] Int. Cl.² A61L 17/02

[58] Field of Search 53/39, 42, 329, 341; 156/309; 206/63.3, 84, 438, 527, 484, 811, 819; 229/3.5 R, 3.5 MF, 48 T

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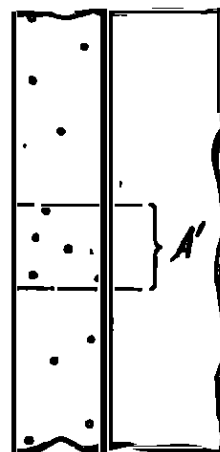
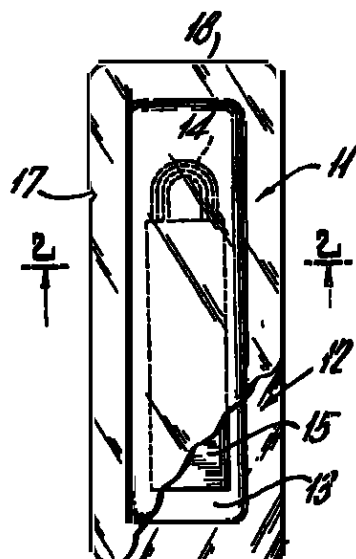
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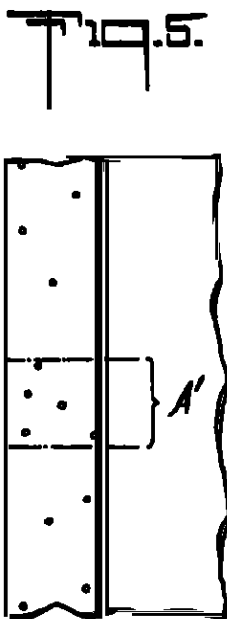
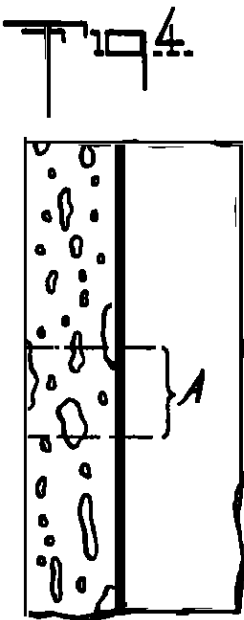
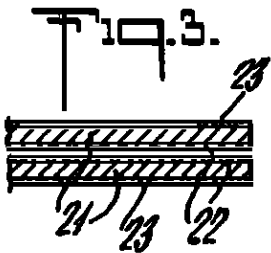
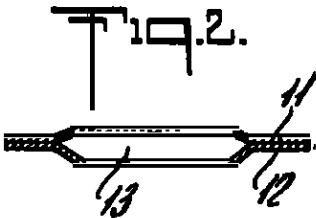
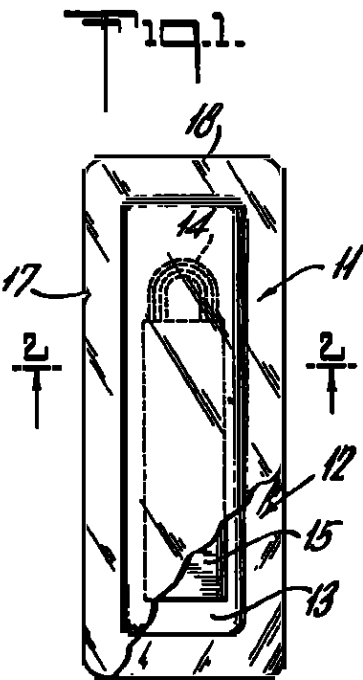
Primary Examiner—Steven E. Lipman
Attorney, Agent, or Firm—Wayne R. Eberhardt

[57] ABSTRACT

A laminated package comprising two panels of a moisture impervious material such as aluminum foil coated on adjacent interior surfaces with a heat sealable resin such as polypropylene, and peripherally heat sealed at the edge margins with a continuous and substantially bubble free seal to enclose a moisture sensitive suture within the package. The package is highly resistant to penetration by water vapor, and moisture sensitive sutures thus packaged are well protected against degradation by atmospheric moisture diffusing into the package through the heat seal layer during storage.

26 Claims, 5 Drawing Figures





PACKAGE FOR MOISTURE SENSITIVE SUTURES AND METHOD FOR MAKING SAME

BACKGROUND OF INVENTION

1. Field of the Invention

This invention relates to suture packages and more particularly to moisture permeation resistant packages for moisture sensitive suture materials.

2. Description of Prior Art

Heat sealed laminated packages have been used to package sterile sutures for a number of years. The packages are hermetically sealed to provide a perfect barrier against the transmission of bacteria and microorganisms and preserve the sterility of the suture contained therein indefinitely.

A commonly used package construction is one comprising an outside layer of aluminum foil and an inside layer of a thermoplastic heat sealable material. The aluminum may additionally be covered with a paper or plastic film to reinforce and protect the metal from corrosion and/or to provide a label on the package.

Synthetic absorbable sutures such as homopolymers and copolymers of lactide and glycolide are known to be susceptible to hydrolytic degradation by even minute amounts of water vapor. Great care is accordingly taken during packaging to remove substantially all traces of moisture from the suture and the interior of the package in order to seal the suture in a substantially anhydrous environment. Conventional laminated packages however, while providing a perfect barrier against biological contamination of the suture, have been discovered to provide less than adequate protection against permeation by water vapor. When a conventional package is stored for extended periods of time under condition of ambient temperature and humidity, a significant amount of water vapor is characteristically able to diffuse into the package through the heat seal layer to attack and degrade the moisture sensitive suture material.

It is accordingly an object of the present invention to provide an improved package for moisture sensitive sutures. It is a further object of this invention to provide a metal foil/polymeric film laminate package having great resistance to penetration by water vapor. It is another object of this invention to provide a method whereby the resistance to water vapor permeation of laminate packages constructed of conventional materials may be improved. Yet other objects of this invention will be apparent from the ensuing description and claims.

SUMMARY

In accordance with the present invention, the resistance to water vapor permeability of laminated and heat sealed suture packages is significantly improved by providing the package with a heat seal characterized by a substantial absence of bubbles within the seal area. Continuous and substantially bubble free seals in combination with metal foil of sufficient thickness to eliminate or minimize the existence of pinholes, and a heat sealable polymeric film having inherently high resistance to water vapor transmission, provide a suture package which is substantially impervious to penetration by water vapor.

DESCRIPTION OF DRAWING

FIG. 1 is a partially broken away plan view of a representative laminated sterile suture package.

FIG. 2 is a cross-sectional view of the package of FIG. 1 taken along the line 2—2 of FIG. 1 with the enclosed suture omitted for clarity.

FIG. 3 is a greatly enlarged sectional view of the laminates forming the top and bottom panels of the package before heat sealing.

FIG. 4 is a greatly enlarged transparent view of a section of a conventional seal area illustrating bubbles within the seal area. FIG. 5 is a greatly enlarged transparent view of a section of a substantially bubble free seal area in accordance with the present invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

FIG. 1 illustrates a representative suture package comprising a top panel 11 and a bottom panel 12 which are superimposed and sealed to one another along their edge margins to completely enclose and hermetically seal off central space 13. A coiled sterile surgical suture 14 inside a paper sleeve 15 is enclosed within central space 13. A tearing notch 17 is located adjacent one end 18 of the package along its top edge to permit the package to be opened by tearing from notch 17 to the opposite side of the package.

The package is of a laminated construction as illustrated in FIG. 2 and FIG. 3. Both top and bottom panels consist of a metal foil layer 21 coated on the inner surface thereof with a heat sealable polymer layer 22. In addition, the outer surface of the metal foil is covered with paper or plastic layer 23 to reinforce and protect the metal layer during handling and to provide a printing surface for the package label. In the assembly of the package, the top and bottom panels are placed together and sealed by the application of heat and pressure to unify plastic layers 22 and form a single layer in the seal area. Conventional heat seals characteristically contain a significant proportion of bubbles within the borders of the seal as illustrated in FIG. 4, and the presence of these bubbles has now been discovered to increase the rate of water vapor transmission through the seal area. It has further been discovered that by providing the package with seals that are substantially bubble free as illustrated in FIG. 5, the resistance of the suture package to permeation by water vapor is significantly increased.

The extent to which a seal is free of bubbles is defined as "seal integrity", a high seal integrity indicating a relatively low proportion of bubble area, and a low seal integrity indicating a higher proportion of bubble area. A numerical value for seal integrity is obtained by comparing the area of bubbles relative to total seal area according to the following relationship:

$$\text{Seal Integrity (\%)} = \left(1 - \frac{\text{bubble area}}{\text{seal area}} \right) \times 100$$

The suture packages of the present invention are best characterized in terms of square seal integrity which is defined as the seal integrity of a square increment of the seal. In determining "minimum square seal integrity" for a given package, the seal integrity is determined for that square portion of the seal containing the highest relative bubble area. Determination of square

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seal integrity is illustrated in FIOS. 4 and 5 where square seal areas A and A' respectively each contain the highest relative bubble area in their respective seals.

The determination of square seal integrity has the advantage of reflecting bubble distribution and is in effect a measurement of the weakest section of the seal. A seal having a high overall seal integrity may nevertheless provide poor protection against water vapor permeation if the total bubble area is concentrated in a small area of the seal. Square seal integrity highlights weak seal areas and provides a reliable indication of the actual permeation resistance of the suture package.

Seal integrity of a metal laminated package may be determined by chemically stripping the metal foil from the package to reveal the transparent film, and then simply measuring the bubble area in any selected area of the seal. Aluminum foil packages, for example, are readily stripped of the metal by immersing the package in a solution of about 6N hydrochloric acid for about

of the package and became hydrated with the glycerol during each week was determined using liquid scintillation counting. The method allowed the water permeation rate to be followed over a period of several weeks without disturbing the test packages. Since the packages were identical except for polymer composition and seal integrity, differences in water permeation rates were directly relatable to these variables. The data obtained over a 10 week test period are presented in TABLE I. Minimum square seal bubble integrity of each package in TABLE I was objectively determined using a Quantimet 720 Image Analyzing Computer manufactured by IMANCO, Monsey, N.Y. The test packages were stripped of metal foil and photographic prints made of the heat seal areas as above described. The photographs were placed in the Epidiascope attachment of the image analyzer and the square seal area containing the highest proportion of bubble area selected and displayed on the visual scope of the instrument for analysis by the computer.

TABLE I

Package	SSI	Package Permeation, Micrograms of Water Per Week							10 week cumulative permeation
		1st wk.	2nd wk	3rd wk	4th wk	5th wk	6th wk	7-10 wks	
A. Polyvinyl chloride conventional seal	80	0.05	0.53	1.31	1.71	1.88	2.22	9.94	17.64
bubble free seal	90	.04	.04	.11	.29	.55	.56	3.64	7.53
B. Ionomer conventional seal	32	0.09	0.17	0.28	0.36	0.39	0.59	2.34	4.22
bubble free seal	100	.05	.04	.05	.04	.05	.05	.09	.37
C. Polypropylene bubble free seal (a)	93	0.06	0.09	0.38	0.73	0.93	1.09	5.93	9.21
bubble free seal (b)	100	.04	.05	.14	.33	.58	.70	4.07	5.91

SSI = Square Seal Integrity

15 to 30 minutes at room temperature. Measurement of bubble area in a selected area of the seal is facilitated by placing that portion of the seal including the area to be measured in a photographic enlarger and printing an enlarged image in which the bubbles are readily visible. Measurements can then readily be made from the photograph over any selected square seal area.

The improved suture packages of the present invention are characterized by a seal which is continuous around the perimeter of the package, and wherein the minimum square seal integrity of the seal is not less than about 90 percent. Such seals are defined as being "substantially bubble free". Most preferably, minimum square seal integrity is from 95 to 100 percent for maximum resistance to water vapor permeation.

The effect of square seal integrity on water vapor permeability through the seal was demonstrated by direct comparison testing of suture packages having conventional and bubble free seals. In each instance, test packages were constructed of an aluminum foil/polymer film laminate. Heat sealable polymers evaluated in the test included polyvinyl chloride, polypropylene, and Surlyn A, a DuPont ionomer resin which is an ionic cross-linked ethylene-acrylic copolymer containing metal ions. Ionomer resins are described in *Modern Packaging*, pp 157-161, May 1967 and pp 173-175, June 1967.

In the following examples, water vapor permeability was determined by sealing one milliliter of tritiated water equal to 0.01 curie inside each package. The sealed packages were hung in individual glass jars with a vial of anhydrous glycerol and maintained at 37° C. The glycerol vials were replaced at weekly intervals, and the amount of tritiated water which permeated out

It is apparent from the data in TABLE I that in packages A and B, the bubble free seal allowed significantly less water vapor permeation through the seal than did the conventional seal. Package C illustrates that even within the bubble free seal range, higher values of square seal integrity of from 95 to 100 percent are preferred to minimize water vapor permeability of the package. The data in TABLE I also illustrates innate differences between polymer types in water vapor permeability, and that a bubble free ionomer seal has exceptional resistance to water vapor transmission.

All of the above tests involved rectangular packages 3 1/8 x 1 1/8 inches (9.8 x 3.5 cm) having a seal width of 3/8 inch (0.95 cm) on three sides and 1/4 inch (0.63 cm) on one long side. The aluminum foil was 1.35 mils (0.035 mm) thick in the top panel, 2.0 mils (0.051 mm) thick in the bottom panel and nominally pinhole free. The polymer film was about 1.0 mil (0.025 mm) thick in each package and continuous over the entire inner surface of the aluminum foil. The packages were heat sealed to give a seal peel strength of at least 2 pounds per inch (357 g/cm).

In a preferred embodiment of the present invention, the minimum width of the seal is greater than about 1/4 inch (0.32 cm), and most preferably from about 5/32 to 1/2 inch (0.40 to 1.27 cm) to minimize water vapor permeation. The aluminum foil is preferably at least 1 mil (0.025 mm) thick, and most preferably from 1.25 to 2.0 mils (0.032 to 0.051 mm) thick in order to eliminate or minimize the incidence of pinholes. The heat sealing polymeric layer on the other hand, is preferably kept to a minimum thickness to reduce the edge thickness and area through which water vapor may penetrate the package. Preferred polymer film thickness is

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from about 0.25 to 1.5 mils (0.0064 to 0.038 mm) although even thinner films may be used in some instances. A particularly preferred suture package of the present invention is a package comprising a laminate of aluminum foil and ionomer resin of a preferred thickness and having a substantially bubble free seal as illustrated by package B of TABLE I.

Conventional suture packages are characterized by a high incidence of bubbles in the seal area, often the result of sealing by compression between two flat dies with the resulting entrapment of bubbles. The bubble free seals of the present invention may be obtained by using rolling or crowned dies which provide moving line sealing to the exclusion of bubbles. The present invention however, is not limited to any particular method of sealing and any convenient method which yields a bubble free seal may be used.

While the aforescribed water permeation test involves the diffusion of water vapor through the package from the inside to the outside, there is of course no significance to the direction of permeation. In the case of a sterile suture package where substantially all water has been removed from the inside of the package, the ambient moisture in the atmosphere surrounding the package provides the driving force for diffusion of water to the area of lower concentration inside the package.

Moisture diffusion rates into a conventional suture package for a synthetic absorbable suture of polyglycolic acid was determined by sealing individual suture packages in aluminum foil/ionomer film laminate pouches containing 1 ml of tritiated water equal to 0.01 curie. The sealed pouches were stored at 37° C. After 16 weeks, the pouches were opened and the suture packages removed and decontaminated. The packages were then opened and the paper folder and suture combusted in a Packard Sample Oxidizer. The products of combustion were collected and read in a liquid scintillation counter to determine the quantity of moisture which had permeated into the package. The procedure was repeated with suture packages having a substantially bubble free seal and preferred seal widths, aluminum foil thickness and polymer film thickness in accordance with the present invention. Package descriptions and water vapor permeation rates are presented in TABLE II below.

tures which do not affect considerations of seal integrity as described herein. The packages may also be formed of multi-layer laminates having layers of metal, plastic, paper and functional or decorative coatings, all in addition to the basic metal foil and heat sealable film of the laminates described herein. Metals other than aluminum, may also be used although aluminum is highly preferred for reasons of economy and availability.

Heat sealable thermoplastic polymers other than those illustrated in the examples may be used with good results. Representative examples of such thermoplastic polymers include other aliphatic polyolefins such as polyethylene, aromatic polyolefins such as styrene, other halogenated polyolefins such as polyvinylidene chloride, other carboxylated polyolefins such as polyacrylates and polyvinyl acetates, hydroxylated polyols such as polyvinyl alcohol, cellulose, polyurethanes, polyamides, polyesters, polycarbonates, polyethers, and acrylics, and various combinations of the above as copolymers, polymer blends and composite film laminates. Particularly preferred polymers are polypropylene, polyvinylchloride, polyvinylidene chloride, and ionomer.

The suture package may be laminated from two separate panels or formed by folding a single sheet of polymer coated aluminum so that only three sides are required to be heat sealed. The suture package may itself be packaged in a sterile or non-sterile overwrap which may or may not provide an additional barrier against water vapor permeability into the suture package. These and other variations are included within the scope of the present invention which is not to be limited except as defined by the following claims.

What is claimed is

1. A substantially water vapor impervious package for moisture sensitive materials comprising two panels of a water vapor impermeable material coated on at least the edge margins of adjacent interior surfaces with a heat sealable polymer, said panels being joined through said edge margins about the periphery of said package by a continuous seal to enclose the moisture sensitive material within the central space of said package, said seal being characterized by having a square seal integrity of at least about 90 percent.

2. A package of claim 1 wherein said water vapor

TABLE II

Suture Package	Aluminum Foil Thickness		Polymer Film		Seal Width	Moisture Permeation Micrograms A ₂ O
	(Top)	(Bottom)	Type	Thickness		
Conventional	1.3 (0.033)	1.3 mils (0.033 mm)	Polyethylene	1.1 mils (0.028 mm)	1/8 - 3/16 in. (0.32 - 0.48 cm)	5,958 (16 weeks)
This Invention	1.35 (0.034)	2.0 mils (0.050 mm)	Polyvinylchloride	0.5 mils (0.013 mm)	9/32 - 3/8 in. (0.71 - 0.95 cm)	41.6 (24 weeks)

Since it is known that moisture either sealed in the package with the suture or subsequently entering the package after sealing has an adverse effect upon the storage stability of the suture, the present invention includes a method for improving the storage stability of a moisture sensitive suture by providing a suture package having a high seal integrity and high resistance to moisture permeation as described herein.

Many variations in the improved method and suture package of the present invention will be apparent to those skilled in the art. The package may for example, be formed in various shapes and sizes with design fea-

impermeable material is metal foil.

3. A package of claim 2 wherein said metal foil is aluminum foil.

4. A package of claim 3 wherein the aluminum foil is at least about 1.0 mil thick.

5. A package of claim 1 wherein the heat sealable polymer coating has a thickness of from about 0.25 to 1.5 mils.

6. A package of claim 1 wherein the heat sealable polymer is a polyolefin.

7. A package of claim 1 wherein the heat sealable polymer is polyvinyl chloride.

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from about 0.25 to 1.5 mils (0.0064 to 0.038 mm) although even thinner films may be used in some instances. A particularly preferred suture package of the present invention is a package comprising a laminate of aluminum foil and ionomer resin of a preferred thickness and having a substantially bubble free seal as illustrated by package B of TABLE I.

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1. A substantially water vapor impervious package for moisture sensitive materials comprising two panels of a water vapor impermeable material coated on at least the edge margins of adjacent interior surfaces with a heat sealable polymer, said panels being joined through said edge margins about the periphery of said package by a continuous seal to enclose the moisture sensitive material within the central space of said package, said seal being characterized by having a square seal integrity of at least about 90 percent.

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impermeable material is metal foil.

3. A package of claim 2 wherein said metal foil is aluminum foil.

4. A package of claim 3 wherein the aluminum foil is at least about 1.0 mil thick.

5. A package of claim 1 wherein the heat sealable polymer coating has a thickness of from about 0.25 to 1.5 mils.

6. A package of claim 1 wherein the heat sealable polymer is a polyolefin.

7. A package of claim 1 wherein the heat sealable polymer is polyvinyl chloride.

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8. A package of claim 1 wherein the heat sealable polymer is polyvinylidene chloride.
9. A package of claim 1 wherein the heat sealable polymer is ionomer.
10. A package of claim 1 wherein the width of the seal is greater than about 1/8 inch.
11. A package of claim 1 wherein the moisture sensitive material is a surgical suture.
12. A substantially water vapor impervious package for moisture sensitive suture materials comprising two panels of water vapor impermeable metal foil coated on at least the edge margins of adjacent interior surfaces with a heat sealable polymer, said panels being joined through said edge margins about the periphery of said package by a continuous seal to enclose the moisture sensitive suture material within the central space of said package, said seal being characterized by a square seal integrity of 95 to 100 percent.
13. A package of claim 12 wherein said metal foil is aluminum foil having a thickness of at least about 1.0 mil
14. A package of claim 12 wherein the minimum width of the seal is greater than about 1/8 inch
15. A package of claim 12 wherein the moisture sensitive suture material is a homopolymer or copolymer of lactide and glycolide
16. A package of claim 15 wherein the aluminum foil has a thickness of from about 1.25 to 2.0 mils.
17. A package of claim 16 wherein the minimum width of the seal is between about 5/32 and 1/4 inch.

18. A package of claim 17 wherein the heat sealable polymer is ionomer.
19. A package of claim 17 wherein the heat sealable polymer is polyvinyl chloride.
20. In a method for packaging moisture sensitive suture materials by enclosing said suture material in a hermetically sealed package formed by two panels of metal foil coated on at least the end margins of adjacent interior surfaces with a heat sealable polymer, said panels being joined through said heat sealable polymer in a continuous seal around the periphery of said panels to enclose the moisture sensitive suture material in the central space thereof, the improvement comprising increasing the storage stability of said suture material by sealing said package with a seal having a square seal integrity of at least about 90 percent.
21. A method of claim 20 wherein the minimum width of the seal is greater than about 1/8 inch.
22. A method of claim 20 wherein the minimum width of the seal is between about 5/32 and 1/4 inch
23. A method of claim 22 wherein the seal has a square seal integrity of 95 to 100 percent
24. A method of claim 20 wherein the suture material is a homopolymer or copolymer of lactide and glycolide
25. A method of claim 20 wherein the heat sealable polymer is ionomer.
26. A method of claim 20 wherein the heat sealable polymer is polyvinyl chloride.
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United States Patent [19]
Matsumoto et al.

[11] **Patent Number:** 5,763,028
[45] **Date of Patent:** Jun. 9, 1998

[54] **DOUBLY-PACKAGED EASILY OXIDIZABLE ARTICLE**

[75] **Inventors:** Shinichi Matsumoto; Norishige Matsuo; Sachiyo Ito, all of Kawasaki, Japan

[73] **Assignee:** Ajinomoto Co., Inc., Tokyo, Japan

[21] **Appl No :** 607,197

[22] **Filed:** Feb. 26, 1996

Related U.S. Application Data

[63] **Continuation of Ser No 257,192, Jun 8, 1994, abandoned.**

[30] **Foreign Application Priority Data**

Jun 8, 1993 [JP] Japan 5-163246
May 24, 1994 [JP] Japan 6-109902

[51] **Int. Cl.⁶** B65B 11/58; A23L 3/005

[52] **U.S. Cl.** 428/34.7; 428/35.2; 428/35.4; 428/336; 428/113; 428/124; 428/127; 428/412; 206/484.2; 53/425; 53/427; 53/449

[58] **Field of Search** 426/412, 124, 426/126, 127, 113, 107, 234; 428/34.6, 35.7, 35.2, 35.3, 349, 34.7, 35.4, 336, 53/425, 427, 440, 449; 206/484, 484.2; 604/403

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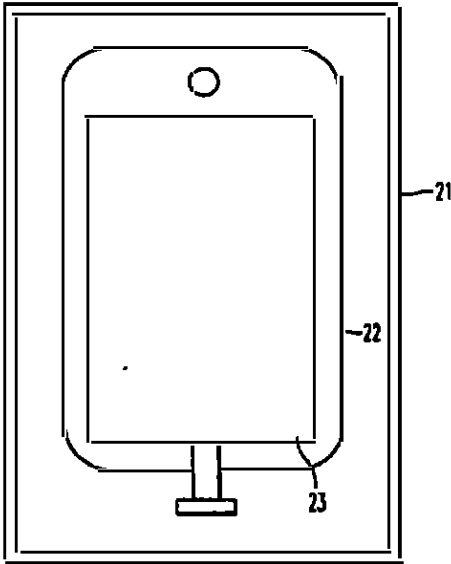
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Primary Examiner—Rena Dye
Attorney, Agent, or Firm—Obion, Spivak, McClelland, Maier, & Neustadt, P.C.

[57] **ABSTRACT**

A doubly-packaged easily oxidizable article and a process for packaging the article are provided, wherein the deterioration of the easily oxidizable article during heat sterilization or storage is prevented. A hermetically sealed plastic vessel filled with an easily oxidizable article is double-packaged in a flexible packaging bag. The bag is made of a plastic layer having heat-sealing characteristics, an inorganic oxide layer and a plastic layer laminated in order from the inside to the outside.

24 Claims, 1 Drawing Sheet



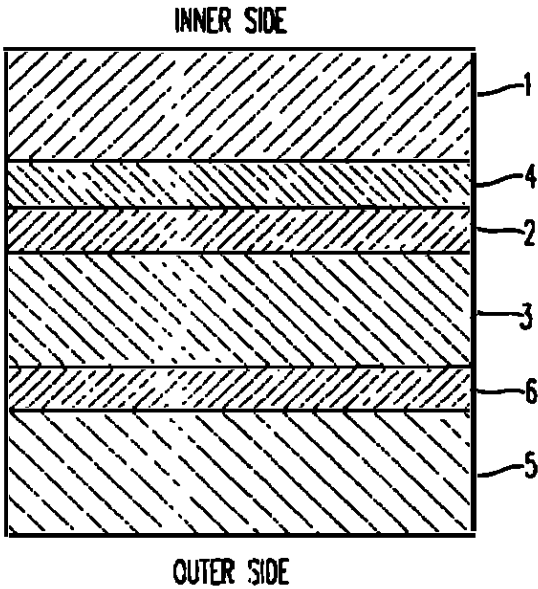


FIG. 1

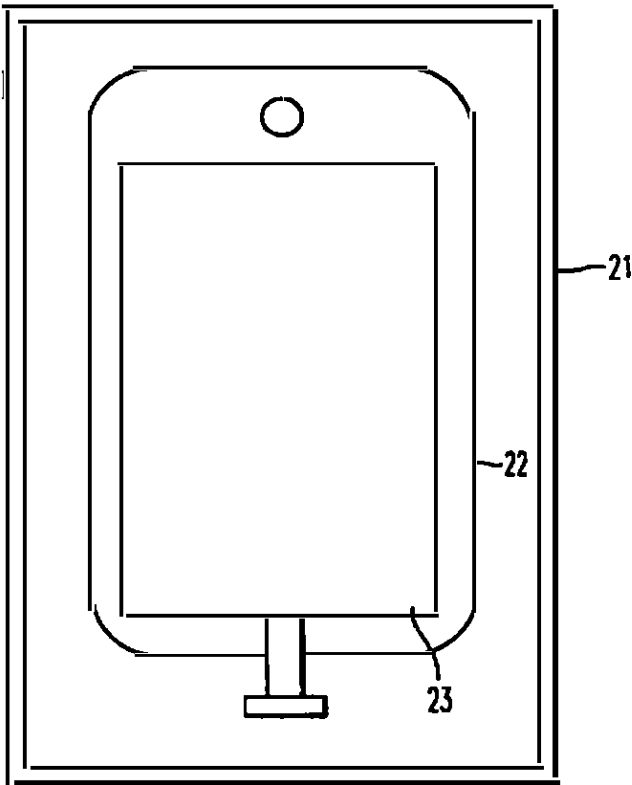


FIG. 2

DOUBLY-PACKAGED EASILY OXIDIZABLE ARTICLE

This application is a continuation of application Ser. No. 08/257,192, filed on Jun. 8, 1994, now abandoned.

BACKGROUND OF THE INVENTION

1 Field of the Invention

The present invention relates to a doubly-packaged easily oxidizable article comprising a hermetically sealed plastic vessel filled with an easily oxidizable article which requires heating and/or sterilization such as an easily oxidizable medical or pharmaceutical product, medical equipment, a cosmetic product, food or drugs, which is packaged with a packaging material having high oxygen barrier properties as well as resistance to heat sterilization. The invention also relates to a packaging process for preparing a doubly-packaged easily oxidizable article.

2. Description of the Related Art

Recently, many easily oxidizable articles which require heating and/or sterilizing treatment have been packed in plastic vessels, and made available after being subjected to heat sterilization treatment. However, due to insufficient oxygen barrier properties of the vessel, the easily oxidizable article is degenerated or degraded by oxygen permeating into the vessel during the heat sterilization treatment or subsequent storage.

For example, a material such as an amino acid transfusion solution containing tryptophan undergoes browning or the generation of a foreign odor and the like by oxidation. Accordingly, when a vessel filled with a medical or pharmaceutical liquid drug which is susceptible to oxidation is required to be sterilized by heating a method as described in Japanese Patent Laid Open Hei 57-206447 is employed wherein a retort is pressurized with an inactive gas to carry out high pressure sterilization in a saturated steam atmosphere which is essentially free from oxygen so that the sample content is neither oxidized nor degenerated during heat sterilization. This method of heat sterilization however, is disadvantageous because it requires a special apparatus, a complicated procedure and high cost.

After carrying out sterilization by heat, in order to prevent the oxidation and deterioration of the desired content during storage the vessel filled with the easily oxidizable medical or pharmaceutical liquid drug is typically covered and hermetically sealed in a bag made of a laminated film having an intermediate layer that has high oxygen barrier properties, such as polyvinyl alcohol, ethylene-vinyl alcohol copolymer, polyvinylidene chloride, aluminum foil or an aluminum deposited layer and the like (Japanese Patent Laid-Open Sho 59-80256, Japanese Patent Laid-Open Hei 02-180129).

In addition in Japanese Patent Publication No. Hei 03-1021, a vessel filled with an easily oxidizable liquid drug is packaged in a sheathing bag made of a laminate having polyvinylidene chloride as an oxygen barrier layer, and sterilized by heating under that condition.

Polyvinyl alcohol and ethylene-vinyl alcohol copolymers lower their oxygen barrier properties significantly under high humidity conditions, however, and polyvinylidene chloride lowers its oxygen barrier properties significantly under high temperature conditions. When a vessel is previously packaged in a flexible packaging bag containing these materials and then heat sterilization is carried out in a retort without replacing the atmosphere with an inactive gas, it is

very difficult to control the oxidation deterioration of the content during heat sterilization. In addition, the material using the polyvinyl alcohol or ethylene-vinyl alcohol copolymer attains an extremely low oxygen barrier property after heat sterilization treatment; thus the oxidation deterioration controlling capability available to protect the liquid drug during storage is very much lowered as well.

Since a product using polyvinylidene chloride also lowers the oxygen barrier properties with heat sterilization treatment considerably as shown in Japanese Patent Publication No. Hei 03-1021, though not so much as that of polyvinyl alcohol or ethylene-vinyl alcohol copolymer, it is not favorable to carry out heat sterilization treatment of the vessel while it is packaged in such a sheathing bag and to store it in such a bag, at least from the viewpoint of preventing the easily oxidizable article from being oxidized and deteriorated.

On the other hand, when a metal foil such as aluminum foil, or a film where a metal such as aluminum is deposited is used for the flexible packaging bag to carry out the sterilization by heat, the inside of the vessel cannot be seen, and visual inspection of the content for determining a foreign matter after the heat sterilization treatment is impossible. Moreover, the heat sterilization treatment tends to generate pin holes etc which lowers the oxygen barrier properties thereof.

For the above reasons, the packing of a vessel in a flexible packaging bag having an oxygen barrier material therein is practically required to be carried out after heat sterilization treatment. Accordingly, processes for packaging a vessel in a flexible packaging bag generally comprise the steps of waiting until the vessel is cooled after heat treatment, wiping off the water on the surface, and packaging it in an inactive gas atmosphere. Such a method is disadvantageous since it is complicated, time-consuming and requires a special apparatus.

Also known in the art is a flexible plastic bag in which a film having high oxygen barrier properties, such as polyvinylidene chloride, is laminated, directly filled with a medical and pharmaceutical liquid drug, and then subjected to heat sterilization treatment (Japanese Patent Laid-Open Sho 63-164950, Japanese Patent Laid-Open Hei 02-204033). As mentioned before, however, a product utilizing polyvinylidene chloride has lowered oxygen barrier properties during and after heat sterilization. Also, when the plastic bag is contacted directly with a medical or pharmaceutical liquid drug, its ingredients migrate into the liquid drug.

There is another known process (Japanese Patent Laid-Open Sho 60-236651) wherein a silicone layer having oxygen barrier properties is formed on an external surface or an internal surface of a vessel, then the vessel is filled with a liquid drug and heat sterilization treatment is carried out under pressure after replacing the atmosphere of the autoclave with an inactive gas.

However, the oxygen permeability of such a vessel is high and is insufficient to prevent the oxidation of an easily oxidizable article. Further, the silicone layer existing on the surface of the vessel under unprotected conditions tends to be damaged, and that increases oxygen permeability. For heat sterilization, the atmosphere of the autoclave must be replaced with an inactive gas and the autoclave must be pressurized, thus the procedure is complicated and requires a special apparatus.

There is still another known process (Japanese Patent Laid-Open Sho 62-103139, Japanese Patent Laid-Open Sho 63-186652, Japanese Patent Laid-Open Hei 03-244535)

wherein a plastic bag or pouch having oxygen barrier properties in which silicon oxide layer or aluminum oxide layer is laminated, is directly filled with a medical and pharmaceutical liquid drug or food and subjected to heat sterilization treatment. In such a case, however, when the plastic bag or pouch is directly contacted with the medical and pharmaceutical liquid drug or food, the components of the plastic bag or pouch migrate into the medical and pharmaceutical liquid drug or food and lower safety, or cause a foreign taste or foreign odor. Since a material having the silicon oxide layer or aluminum oxide layer cannot be processed by blow molding, when a plastic bag for transfusion is to be produced, for example, a stick-shaped liquid drug injection nozzle must be attached later, and the attachment step tends to provide pin holes in the silicon oxide layer or aluminum oxide layer which results in lowering oxygen barrier properties.

OBJECTS OF THE PRESENT INVENTION

One object of the present invention is to provide a packaged easily oxidizable article, comprising a hermetically sealed vessel filled with the easily oxidizable article which allows for sterilization by heat under oxygen barrier conditions, prevents the components of the vessel from migrating to the easily oxidizable article, and has high inhibitory power on the oxidation deterioration of the easily oxidizable article during storage since the oxygen barrier properties are maintained at a high level even after the heat sterilization.

Another object of the present invention is to provide a process of making the packaged easily oxidizable article

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention is achieved by filling a vessel which has heat resistance, which does not, or only minimally allows its components to migrate to its contents, and which can firmly prevent components outside from permeating into it, with an easily oxidizable article and packaging the vessel in a flexible packaging bag which has high heat resistance and high oxygen barrier properties, keeps the oxygen barrier properties at a high level even under conditions of high humidity and high temperature such as during sterilization by heat, and which does not lose its high oxygen barrier properties even after, e.g., heat sterilization.

More particularly, the present invention provides a double-packaged easily oxidizable article comprising a flexible packaging bag in which one or more plastic vessels, each filled with an easily oxidizable article, are packaged and hermetically sealed. The flexible packaging bag is flexible and comprises a plastic layer having at least heat-sealing characteristics, an inorganic oxide layer and a plastic layer laminated in an ascending order from the inside of the bag, to provide a doubly-packaged easily oxidizable article. Subjecting the doubly-packaged easily oxidizable article to heat sterilization to provide a sterilized article is also part of the invention, as is a packaging process for making the doubly-packaged easily oxidizable article.

Easily oxidizable articles to be used in the present invention are not specifically limited. Such articles contain an oxidizable component and may be articles that require heating and/or sterilization. For example, they include medical and pharmaceutical liquid drugs such as amino acid preparations, fat emulsion preparations, vitamin preparations, nucleic acid preparations, enteral feeding nutrient preparations, tube feeding nutrient preparations, and

ophthalmic solutions. A representative example includes amino acid transfusion solutions. Medical equipment includes a tube to be introduced into a body cavity or an instrument for blood transfusion which is made of a material susceptible to oxidation. Cosmetic products are also included, such as milky lotions, lotions and creams containing proteins such as collagen and chitin, amino acids, amino acid derivatives, unsaturated fatty acids and vitamins. Foods are included, for example, margarine, mayonnaise and beverages and the like which may optionally be enriched with vitamin E or unsaturated fatty acids. In addition to these, drugs and foods which require heat reaction are also included as examples.

The vessel to be filled with the easily oxidizable article is preferably a vessel made of a transparent plastic which allows visual observation of the contents. The hardness of the vessel depends on the use. Soft bags are appropriate for transfusion solutions, for example, and hard vessels are appropriate for ophthalmic solutions and the like. As the vessel material, any material can be used as long as it has such heat resistance that can resist sterilization by heat, as long as it allows little or no migration of its components into the easily oxidizable article filled in the vessel, and as long as it can prevent any component other than a gas from migrating from the outside to the easily oxidizable article through the vessel. Such a material includes, for example, a single layer or a laminated layer of a polyolefin material such as polyethylene, polypropylene, polybutene or their copolymers, as well as that of vinyl chloride, crosslinked ethylene-vinyl acetate copolymer resin, polyester, polycarbonate, polyacrylate, polyamide, and fluorine resin and the like. The vessel can be made by molding, by heat sealing, blow molding, orientation-blow molding and the like.

The flexible packaging bag is made of a laminate comprising a plastic layer having at least heat-sealing characteristics, an inorganic oxide layer and a plastic layer laminated in ascending order from the inside of the bag. The flexible packaging bag is preferably transparent to allow for visual recognition of the contents and has resistance to sterilization by heat. The oxygen permeability of the flexible packaging bag before and after typical heat sterilization treatment is not more than 4.0 ml/m^2 measured over 24 hours under conditions of 25°C ., relative humidity of 100% and 1 atmospheric pressure (in conformance with ASTM D 3985), preferably not more than 2.0 ml/m^2 over 24 hours, and most preferably not more than 1.0 ml/m^2 over 24 hours.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an illustrative example of a sectional view of a laminate of the present invention, but the present invention is not limited to it.

FIG. 2 is an illustrative example of the invention doubly-packaged easily oxidizable article.

Referring to FIG. 1, reference number 1 refers to a plastic layer having heat-sealing characteristics, which comprises a single layer or two or more layers of a polyolefin such as polyethylene, polypropylene, polybutylene or their copolymers, as well as vinyl chloride, ethylene-vinyl acetate copolymer.

Reference number 2 refers to an inorganic oxide layer which is formed on a plastic layer 3 made of a polyester film such as biaxially oriented polyethylene terephthalate or polycarbonate, as well as a polyamide film, a polyolefin film, and a polyacrylonitrile film. As an inorganic oxide layer, any film as may be used as it has high transparency in the visible

continuously, the production amount can be increased to lower the cost. The product can be supplied to hospitals as it is or after packed in a box.

As described above, the flexible packaging bag of the doubly-packaged easily oxidizable article of the present invention has high oxygen barrier properties, allows for the heat sterilization of the contents while they are packaged in the flexible packaging bag since it shows no or almost no change in the oxygen barrier properties before and after the heat sterilization treatment, and has a high inhibitory power on oxidation and deterioration of the easily oxidizable article during heat sterilization and storage. By providing a vessel filled with the easily oxidizable article in the flexible packaging bag, the migration of the components of the bag material into the contents can be completely or almost completely eliminated; thus the migration of the components of the bag material into the contents, that is seen when the easily oxidizable article is directly packed in a bag of high oxygen barrier capacity and then subjected to sterilization by heat, can be substantially prevented. In addition, the doubly-packaged easily oxidizable article can be made to have transparency, and the mixing of a foreign substance to the content can be easily seen from outside.

The process for packaging the doubly-packaged easily oxidizable article of the present invention does not need any complicated procedure nor any special apparatus, and requires few process steps.

This application claims priority to Japan 100902/1994, filed May 24, 1994 and Japan 163246/1993, filed Jun. 8, 1993, both incorporated herein by reference.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore to be understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed as new and desired to be secured by Letters Patent of the United States is:

1. A doubly-packaged oxidizable article, comprising a flexible bag in which one or more hermetically sealed plastic vessels filled with an oxidizable article are contained;

said flexible packaging bag, comprising a laminate, comprising in ascending order:

a) an inner plastic base layer having a heat-sealing property;

b) a resin layer on said base layer a) having an oxygen-barrier property, which resin layer is a layer of polyvinyl alcohol, ethylene-vinyl alcohol copolymer, polyvinylidene chloride, biaxially-oriented polyethylene terephthalate, polyamide or polyester;

c) an inorganic layer having a steam barrier property on said resin layer (b); and

d) an outer plastic layer on said layer c);

wherein said flexible packaging bag has an oxygen permeability before and after heat sterilization of not more than 4.0 ml/m^2 measured over 24 hours under conditions of 25°C , relative humidity of 100% at a pressure of 1 atm.

2. The doubly-packaged oxidizable article according to claim 1, wherein said resin layer b) on said base layer a) is a layer of polyvinyl alcohol, ethylene-vinyl alcohol copolymer, polyvinylidene chloride, biaxially-oriented polyethylene terephthalate or polyamide.

3. The doubly-packaged oxidizable article according to claim 1, wherein the inorganic oxide layer is selected from the group consisting of a silicon oxide layer, an aluminum oxide layer, a titanium oxide layer and an indium oxide layer.

4. The doubly-packaged oxidizable article according to claim 1, wherein said article has undergone sterilization by heat.

5. The doubly-packaged oxidizable article according to claim 3, wherein said article has undergone sterilization by heat.

6. The doubly-packaged oxidizable article according to claim 1, wherein the flexible bag is hermetically sealed.

7. The doubly-packaged oxidizable article according to claim 1, wherein said vessels filled with said easily oxidizable article are transparent.

8. The doubly-packaged oxidizable article according to claim 1, wherein said vessels are made of a single layer or laminated layers of a polyolefin material.

9. The doubly-packaged oxidizable article according to claim 8, wherein said polyolefin material is selected from the group consisting of polyethylene, polypropylene, polybutene and copolymers of each, polyvinyl chloride, crosslinked ethylene-vinyl acetate copolymers resin, polyester, polycarbonate, polyacrylate and polyamide.

10. The doubly-packaged oxidizable article according to claim 3, wherein said inorganic oxide layer is a silicon oxide layer or an aluminum oxide layer.

11. The doubly-packaged oxidizable article according to claim 10, wherein said inorganic oxide layer is a silicon oxide layer comprising a mixture of silicon monoxide and silicon dioxide.

12. The doubly-packaged oxidizable article according to claim 11, wherein said silicon oxide layer is from 50 to $6,000 \text{ \AA}$ in thickness.

13. The doubly-packaged oxidizable article according to claim 12, wherein said silicon oxide layer is from 100 to $1,500 \text{ \AA}$ in thickness.

14. The doubly-packaged oxidizable article according to claim 10, wherein said inorganic oxide layer is non-crystalline aluminum oxide.

15. The doubly-packaged oxidizable article according to claim 14, wherein said non-crystalline aluminum oxide layer is 30 to $5,000 \text{ \AA}$ in thickness.

16. The doubly-packaged oxidizable article according to claim 1, wherein said resin layer b) having an oxygen-barrier property is a polyvinyl alcohol layer, an ethylene-vinyl alcohol copolymer layer or a polyvinylidene chloride layer.

17. The doubly-packaged oxidizable article according to claim 1, wherein said oxidizable article comprises amino acid preparations, fat emulsion preparations, vitamin preparations, nucleic acid preparations, enteric feeding nutrient preparations, tube feeding nutrient preparations, ophthalmic solutions and foods.

18. The doubly-packaged oxidizable article according to claim 17, wherein said foods comprise margarine, mayonnaise or beverages.

19. The doubly-packaged oxidizable article according to claim 1, wherein said oxygen permeability of said flexible packaging bag before and after heat treatment is 2.0 ml/m^2 over 24 hours.

20. The doubly-packaged oxidizable article according to claim 19, wherein said oxygen permeability of said flexible packaging bag before and after heat treatment is 1.0 ml/m^2 over 24 hours.

21. A process for preparing a sterilized doubly-packaged easily oxidizable article, comprising a flexible bag in which one or more hermetically sealed plastic vessels filled with an oxidizable article are contained and hermetically sealed, which process comprises:

a) charging the easily oxidizable article into the plastic vessel; and

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b) hermetically sealing the vessel and packaging the vessel in a flexible packaging bag;
said flexible packaging bag, comprising a laminate, comprising in ascending order
i) an inner plastic base layer having a heat-sealing property;
ii) a resin layer on said base layer i) having an oxygen-barrier property, which resin layer is a layer of polyvinyl alcohol, ethylene-vinyl alcohol copolymer, polyvinylidene chloride, biaxially-oriented polyethylene terephthalate, polyamide or polyester;
iii) an inorganic layer having a steam barrier property area on said resin ii), and
iv) a plastic layer on said layer iii);
wherein said flexible packaging bag has an oxygen permeability before and after heat sterilization of not more

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than 4.0 ml/m² measured over 24 hours under conditions of 25° C., relative humidity of 100% and a pressure of 1 atmosphere.
22. The process according to claim 21, wherein said resin layer b) on said base layer a) is a layer of polyvinyl alcohol, ethylene-vinyl alcohol copolymer, polyvinylidene chloride, biaxially-oriented polyethylene terephthalate or polyamide.
23. The process according to claim 21, wherein the oxygen permeability of said flexible packaging bag before and after heat treatment is 2.0 ml/m² over 24 hours.
24. The process according to claim 23, wherein the oxygen permeability of said flexible packaging bag before and after heat treatment is 1.0 ml/m² over 24 hours.

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