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www.cavelier.com
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EDIFICIO SISKI
CARRERA 4 No. 72 - 35
BOGOTÁ 8, COLOMBIA

Teléfono: (57-1) 347 3611
Telefax: (57-1) 211 8650
(57-1) 700 4814
Fax in U.S.A.: (1-305) 675 7743

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO



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Señor Superintendente

Superintendencia de Industria y Comercio

E. S. D.

Trámite : 011

Evento : 378

Actuación : 412

Referencia : Expediente No. 07.135.407

Asunto : Solicitud de Patente para:

CÁPSULA DE GELÁN ROMPIBLE SIN UNIÓN Y PROCESO PARA SU FABRICACIÓN

Solicitante : V. MANE FILS

Fecha de Solicitud : 21 de Diciembre de 2007



I. RECURSO VÍA GUBERNATIVA

Yo, Luz Clemencia DE PÁEZ, abogada con Tarjeta Profesional No. 23.555, obrando como apoderada de V. MANE FILS, solicitante de la patente de la referencia, por el presente escrito atentamente manifiesto a usted que debidamente notificada de la Resolución No. 36598 de fecha 15 de Junio de 2012, interpongo en su contra el recurso de **REPOSICIÓN**, para que sea revocada y en consecuencia se conceda el privilegio de patente de invención para "**CÁPSULA DE GELÁN ROMPIBLE SIN UNIÓN Y PROCESO PARA SU FABRICACIÓN**" a favor de V. MANE FILS.

II. OPORTUNIDAD DE LA IMPUGNACIÓN

La Resolución No. 36598 de fecha 15 de Junio de 2012, fue notificada mediante edicto No. 18088 desfijado el dieciocho (18) de Julio de dos mil doce (2012), por lo que el término para interponer el recurso de reposición vence el veintiséis (26) de Julio de dos mil doce (2012). En consecuencia, me encuentro dentro de la oportunidad legal.

III. FUNDAMENTO DE LA RESOLUCIÓN No. 36598

Mediante la Resolución objeto de la presente impugnación, el Superintendente de Industria y Comercio decidió:

3.1. Negar el privilegio de patente para la invención **“CÁPSULA DE GELÁN ROMPIBLE SIN UNIÓN Y PROCESO PARA SU FABRICACIÓN”**.

3.2. En la parte motiva de la providencia, se mencionaron los siguientes fundamentos:

“No hay evidencia de que la presencia del agente gelificante en una proporción del 4 al 95% en la cubierta y el agente de secuestro en una proporción de hasta 2% causen efectos o propiedades adicionales a lo divulgado por el documento D1 por cuanto las formulaciones que definen como rellenos componentes derivados de almidón no muestran evidencia técnica de que las cápsulas tengan mayor homogeneidad o esfericidad, tal como lo afirma el solicitante (Fl. 130).”

“En consecuencia, la persona del oficio normalmente versada en la materia enfrentada a la tarea de fabricar una cápsula de gelán rompible alternativa tendría una motivación razonable en incluir la presencia del agente gelificante ya conocido en una proporción del 10 al 100% del peso seco total de la cápsula; además de iones multivalentes reactivos en una proporción que varíe entre el 0 y 30% del peso total de la cubierta, así como el relleno en una cantidad que varía entre el 0 al 90% de acuerdo con las enseñanzas de los documentos D2 y D3 para llegar así al objeto de la reivindicación 1 de la solicitud; por lo cual, se considera que carece de nivel inventivo.”

“Aunque se menciona un aumento de la homogeneidad y esfericidad de las cápsulas producidas por el método reclamado en la reivindicación 19, este efecto es asociado a la presencia del agente de secuestro divalente que permite que no haya gelificación indeseable (Fl. 130) y dado que esta característica ya es conocida en el documento D3 por lo que no hay evidencia de que la diferencia encontrada, es decir, la presencia adicional de un relleno tenga un efecto o propiedad adicional a lo enseñado por el documento D3.”

“En consecuencia, una persona normalmente versada en la materia tendría una motivación razonable de incluir en el proceso de obtención de la cápsula, enseñado por el documento D3, el componente relleno, de acuerdo a lo divulgado por el documento D2 llegando de esta manera al objeto de las reivindicación 19, por lo cual la materia reclamada es considerada obvia y por lo tanto, sin altura inventiva.”

“Ahora bien, es oportuno aclarar que la presencia de un agente antigelante en las cápsulas ya era conocido en el documento D2 (párrafo 0086), por lo que la presencia de las sales antigelantes en las cápsulas del documento D3 con un objetivo diferente (disminuir más no eliminar el fenómeno de

sinéresis del producto lácteo contenido) es indiferentes, puesto que un técnico medio versado en la materia reconocería el carácter antigelante de los iones de calcio y por tal motivo tendría una motivación razonable en combinar las enseñanzas de los documentos D2 y D3."

"Asimismo, aunque el solicitante establece que el documento D3 es el estado de la técnica más cercano a la invención y la diferencia con la invención radica en la presencia adicional de un relleno, por el cual presentaría el efecto técnico alcanzado, el documento D2 anticipaba la presencia de un relleno (párrafo 90) con el objetivo de cambiar las características mecánicas de la cápsula debido a su inclusión en la estructura abierta del gel formado, por lo cual, los documentos D2 y D3 constituyen el estado de la técnica cercano a la invención y la combinación de sus enseñanzas le permiten a la persona versada en la materia inferir las características del objeto reclamado, por lo cual es considerado obvio y carente de nivel inventivo."

IV. OBJETO DEL RECURSO

De acuerdo con los argumentos que expongo a continuación, solicito atentamente a su Despacho lo siguiente:

- 4.1. Revocar la Resolución No. 36598 de fecha 15 de Junio de 2012, en el sentido de:

Conceder el privilegio de patente de invención para **"CÁPSULA DE GELÁN ROMPIBLE SIN UNIÓN Y PROCESO PARA SU FABRICACIÓN"** a favor de **V. MANE FILS.**

V. FUNDAMENTOS DEL RECURSO

Respetuosamente me permito disentir de lo expuesto por ese Despacho en la Resolución objeto del presente recurso, ya que la conclusión que la invención carece de nivel inventivo frente a los documentos D2 (US 2004/0191366) y D3 (US 6 627 236) no corresponde a los hechos del caso.

- 5.1. **Violación del artículo 18 de la Decisión 486 de la Comisión de la Comunidad Andina:**

De acuerdo con el artículo 18 de la Decisión 486:

"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."

Ahora bien, con relación al artículo 18 de la Decisión 486, una invención se considerará inventiva si la misma no hubiese resultado obvia a partir del arte previo, para una persona del oficio normalmente versada en la materia. Esto a su vez implica que el Examinador a cargo de esta evaluación debe colocarse en el momento exacto en el que el inventor buscaba resolver el problema técnico contemplado en la solicitud y para el cual poseía la literatura y el conocimiento disponibles en dicho momento.

Siguiendo entonces los lineamientos de la Jurisprudencia aplicable al análisis del nivel inventivo de una solicitud de patente, se considera que una anterioridad o una combinación de dos anterioridades puede afectar dicho requerimiento de patentabilidad, si una persona medianamente versada en la materia encuentra enseñanzas o sugerencias claras que, a partir de un conocimiento medio en dicho campo, le permitan llegar de manera obvia a la invención reivindicada.

Adicionalmente se considera que una mejora sustancial, un efecto inesperado o una ventaja con respecto al arte previo es un indicio de nivel inventivo, por cuanto aportan un salto tecnológico en la regla técnica.

A este respecto manifestamos nuestro desacuerdo con el análisis llevado a cabo por el Examinador y con las conclusiones del mismo y solicitamos atentamente la reconsideración de las razones por las cuales se decidió negar la patente, con base en la siguiente información:

El documento D2, correspondiente a US 2004/0191366: "*Mononuclearly filled microcapsule*", enseña formulaciones en cápsula que comprenden una cubierta de un material endurecedor de cápsulas basado en un polisacárido ácido, y un material de relleno rodeado por una cubierta de cápsula, el cual incluye una cantidad efectiva de un saborizante organoléptico. Dichas formulaciones resultan útiles para enmascarar el sabor del aceite de pescado.

Frente a lo anterior, el Examinador indica en la página 4 de la resolución impugnada que las diferencias existentes entre la invención como es definida en la reivindicación 1 y la cápsula del documento D2 consiste en que se especifica la presencia del agente gelificante en una proporción del 4 al 95% en la cubierta, el relleno estando a una proporción entre 25 y 95%, y el agente de secuestro en una proporción de hasta el 2%. Es así como el Examinador considera que los iones antigelantes de sodio, magnesio y complejos de calcio enseñados en el párrafo [0086] de D2 resultan equivalentes a los agentes secuestrantes de iones divalentes presentes en las cápsulas rompibles de acuerdo a la invención.

Es así como resulta necesario llamar la atención de su Despacho al párrafo [0085] del documento D2 antecediendo la referencia hecha en la tabla comparativa, en donde se indica que los materiales de cápsula particularmente adecuados corresponden a los alginatos, los cuales son copolímeros

lineales de L-guluronato (G) y D manuronato-(M). Sin embargo, y como es del entendimiento de una persona conocedora de la técnica, el alginato un término genérico que abarca toda una familia de polímeros, en donde las características de cada uno de ellos dependen de su estructura de bloque y su peso molecular.



Ahora bien, el párrafo [0086] mencionado por el Señor Examinador indica que *"en general, un aumento en el contenido de guluronato conduce a un aumento en geles mecánicamente estables con estabilidad elevada en presencia de los iones no- ó anti-gelantes, como lo son los compuestos complejantes de sodio y magnesio, así como de calcio"*, por lo que se puede concluir que lo que el documento D2 enseña en dichos párrafos es que **en el caso de la incorporación de alginatos, a un mayor contenido de guluronato, mayor la estabilidad mecánica del gel obtenido, y que dicha estabilidad se eleva bajo la presencia de iones anti-gelantes.**

De esta manera, resulta claro que la incorporación de un agente secuestrante de un metal divalente no puede ser deridado a partir de las características de los alginatos en presencia de iones antigelantes enseñados en D2, ya que en dicha anterioridad, se parte de una cubierta de cápsula que comprende iones de calcio, es decir, cationes multivalentes, que se utilizan para el endurecimiento del gel de alginato de cápsula (como es indicado en el párrafo [0083] de la anterioridad citada).

Ahora bien, el Examinador considera que no existe evidencia alguna que la presencia del agente gelificante en una proporción del 4 a 95% en la cubierta y el agente de secuestro en una proporción de hasta el 2% causen efectos o propiedades adicionales a lo divulgado por el documento D2. No obstante, se trae a colación una vez más que tal como es afirmado en la memoria descriptiva en las líneas 17 a 24 de la página 6, **los agentes de secuestro de metal divalente de la invención logran atrapar los iones de metal divalentes que pueden estar presentes en los componentes de la fase líquida durante la etapa de co-extrusión.** Lo anterior es de gran importancia, ya que como fue determinado por los inventores, dichos iones de metal divalentes pueden tener un efecto perjudicial durante la etapa de co-extrusion, causando la gelificación de la goma de gelán. Dicha gelificación temprana afecta a la homogeneidad y esfericidad de las cápsulas (favor referirse a las líneas 17 a 22 de la página 2 de la memoria descriptiva). Con base en lo anterior, en la presente invención, el agente de secuestro de metal divalente permite la co-extrusión de gelán sin presentarse una gelificación indeseable o incontrolable durante dicha etapa del proceso para la fabricación de la cápsula (véase la memoria descriptiva entre la página 2 línea 24 hasta la página 3 línea 18, y página 6 línea 28 hastala página 7 línea 3).



Como prueba de lo anterior, se presenta a continuación los resultados obtenidos por el Solicitante al comparar las cápsulas rompibles según la invención con las cápsulas de acuerdo al documento D2. El Reporte de Prueba completo se presenta como anexo del presente recurso.

Es así como al partir de la composición según el documento D2, el Solicitante aplicó 2% de un polisacárido + 12% de un relleno, como se muestra en la tabla a continuación:

Tabla 1. Composiciones iniciales de la solución encapsulante líquida para producir las cápsulas rompibles según la invención y las cápsulas del arte previo.

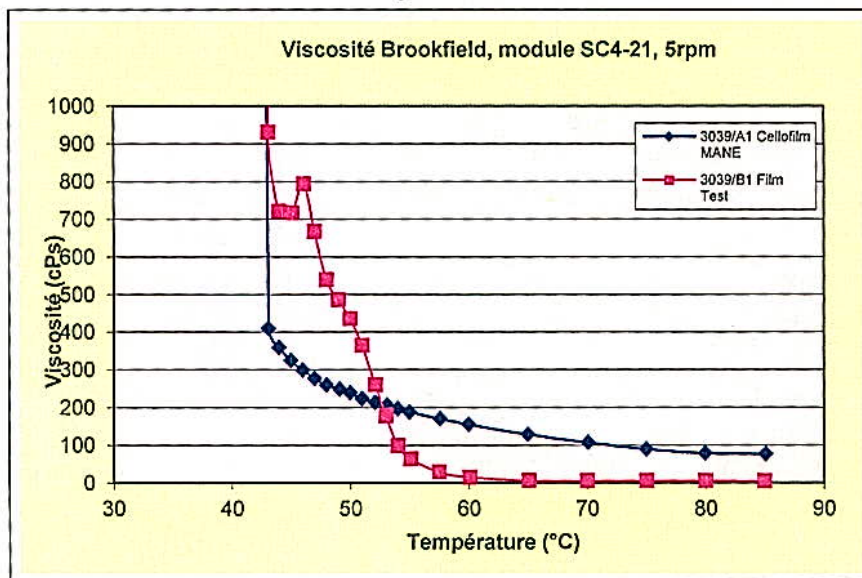
	Invención	Película de prueba (= arte previo)
	Solución Líquida	Solución Líquida
CITRATO DE SODIO (= secuestrante)	2 g	
LACTATO DE CALCIO (=iones gelantes)		1,5 g
GOMA GELAN KELCOF (= polisacarido)	20 g (= 2%)	10,0 g (= 0.99%)
SORBITOL EN POLVO (= relleno)	10 g	
DEXTRINA CRISTAL TEX 648 (= relleno)	115 g	
Agua de proceso	853 g	1000,0 g
Total	1000 g	1011,5 g
Materia seca	14,70%	1,14%

Siguiendo así lo enseñado en D2, la solución obtenida debe ser lo suficientemente concentrada para poder llevar a cabo el procesamiento, como lo indica el párrafo [0090] de dicho documento.

Sin embargo, y de manera sorprendente, se observó a partir de los perfiles de viscosidad de Brookfield, en el modula SC4-21, generados a 5 rpm, en donde la adición de un agente secuestrante permite que la solución resultante presente una viscosidad inferior a la normalmente observada. De manera más sorprendente aún, se observó que la solución de acuerdo a la invención tiene una viscosidad menor que la obtenida con la solución de D2, en donde el polisacárido se encuentra presente a una concentración de 1% y la composición no presenta un relleno o agente secuestrante.

Dichos resultados resultaron inesperados para los inventores, y resultan sorprendentes para cualquier persona medianamente versada en la materia, en la medida que la composición de la invención permite una rápida gelificación, la cual aparece a 43 °C, mientras que en D2 los primeros indicios de gelificación se empezaron a observar a 55 °C.

FIGURA 1: Perfil de viscosidad de la composición encapsulante usada para producir las cápsulas rompibles según la invención y las cápsulas del arte previo.



Otro resultado sorprendente frente al documento D2 se relaciona con la etapa de extrusión, la cual se da de manera regular siguiendo los parámetros de la invención bajo estudio, mientras que la extrusión de acuerdo al arte previo no se daba de manera regular y se presentaba la formación de satélites en las cápsulas en formación. Aún más, resulta necesario mencionar que la etapa de gelificación al seguir los métodos previamente conocidos no presenta resultados satisfactorios resultando las cápsulas obtenidas demasiado suaves, lo que dificulta su rompimiento. De forma contraria, las cápsulas de acuerdo a la presente solicitud presentan una forma regular y rompible, gracias a la gelificación dada.

Finalmente, y en la medida que el contenido de materia seca es mayor en las cápsulas de acuerdo a la reivindicación 1, que las cápsulas de la técnica anterior, se logra una etapa de secado rápido, siendo la etapa de secado en D2 de suma importancia, requiriendo del procesamiento de secado convectivo y de la presencia de sustancias adsorbentes de agua como dióxido de silicio (véase párrafo [0178].

Comparando las cápsulas secas de la invención con las enseñadas en la técnica anterior, se observa que:

- las cápsulas de la invención son regulares en su forma, frágiles, y no presentan filtraciones; mientras que
- las cápsulas de acuerdo a la anterioridad citada D2 no son regulares en su forma, resultan menos frágiles, y presentan algunas pérdidas de aceite por filtración del núcleo.

Lo anterior encuentra soporte experimental en las tablas 2 y 3 del Reporte de Prueba anexo al presente escrito, en donde se comparan las propiedades de las cápsulas después de la etapa de extrusión.

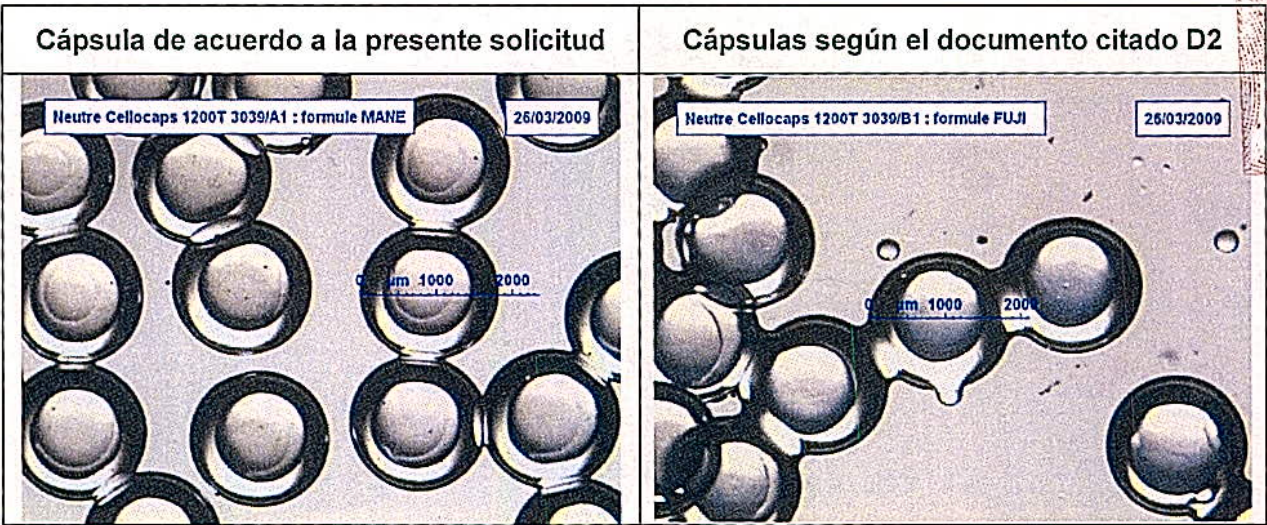
TABLA 2

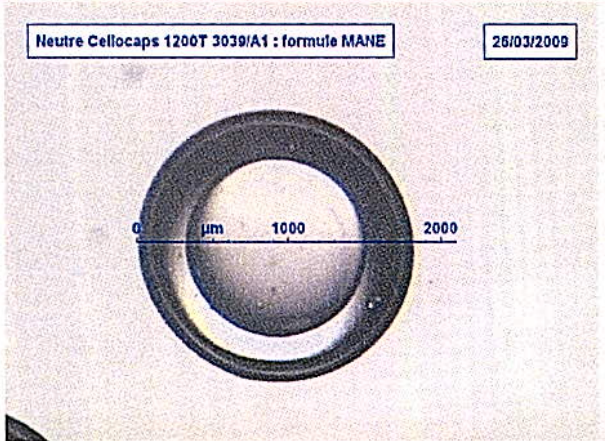
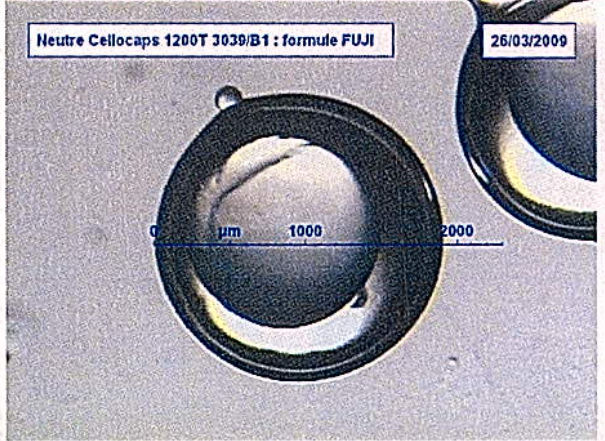
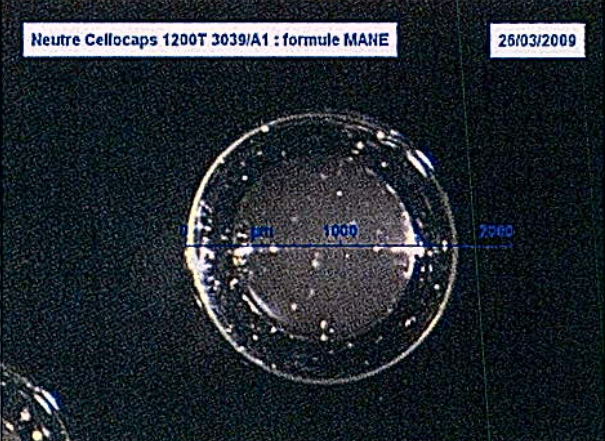
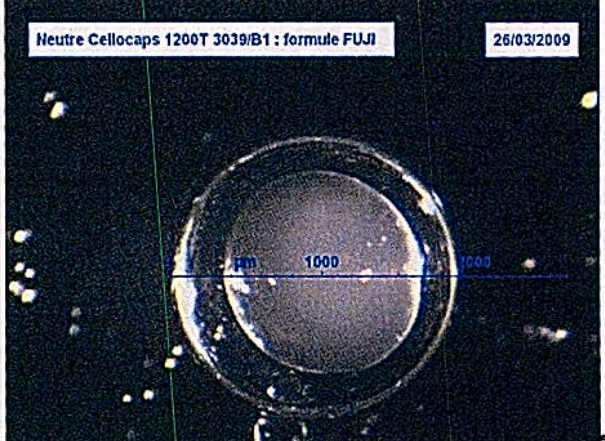
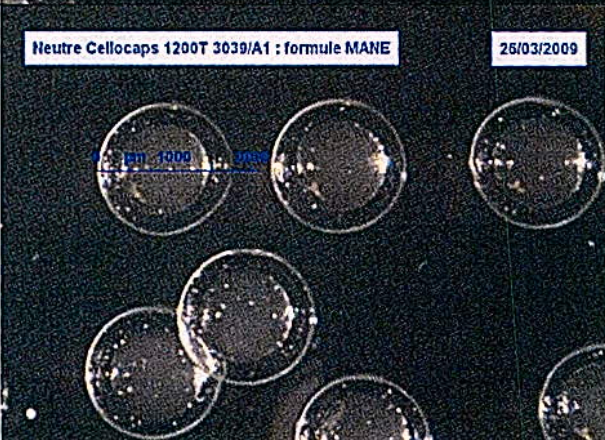
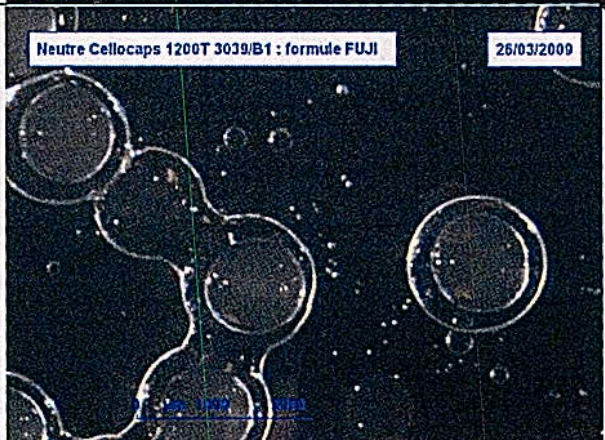
	Invencción	Película de prueba (= arte previo)
Núcleo de la cápsula húmeda	32,98%*	35,78%*
Diámetro de la cápsula húmeda	1,83 mm	1,90 mm
Grosor de la cápsula húmeda	0,262 mm	0,256 mm
Núcleo de la cápsula seca	77,00%**	98,00%**
Diámetro de la cápsula seca	1,400 mm	1,400 mm
Grosor de la cápsula seca	0,050 mm	0,004 mm

* en peso sobre el peso total de la cápsula húmeda

** en peso sobre el peso total de la cápsula seca

Así mismo, las imágenes a continuación demuestran la homogeneidad y esfericidad de las cápsulas según la invención, mientras que las cápsulas de acuerdo a D2 tienden a formar satélites, así como granos enteros. Adicionalmente, el cubrimiento de la cápsula de acuerdo a la presente solicitud presenta un grosor uniforme, mientras que las cápsulas según el documento citado tienden a presentar irregularidades en su grosor



Cápsula de acuerdo a la presente solicitud	Cápsulas según el documento citado D2
Neutre Cellocaps 1200T 3039/A1 : formule MANE26/03/2009 	Neutre Cellocaps 1200T 3039/B1 : formule FUJI26/03/2009 
Neutre Cellocaps 1200T 3039/A1 : formule MANE26/03/2009 	Neutre Cellocaps 1200T 3039/B1 : formule FUJI26/03/2009 
Neutre Cellocaps 1200T 3039/A1 : formule MANE26/03/2009 	Neutre Cellocaps 1200T 3039/B1 : formule FUJI26/03/2009 

Igualmente, las imágenes y las tablas a continuación muestran las propiedades físicas de las cápsulas secas de acuerdo a la presente solicitud y de acuerdo a lo enseñado en D2.

	Cápsula de acuerdo a la presente solicitud	Cápsulas según el documento citado D2
Diámetro promedio (µm)	1298	1376
Desviación estándar diámetro (µm)	17	35
Relación I/L	0,965	0,933
Fuerza aplastamiento (kp)	0.94	0.26
Desviación estándar fuerza aplastamiento (kp)	0.28	0.17
Aspecto	Neutre cellocaps 1200T 3039/A1 26/03/2009 Neutre Capsule Fuji 3039/B1 26/03/2009	
	Neutre cellocaps 1200T 3039/A1 26/03/2009 Neutre Capsule Fuji 3039/B1 26/03/2009	

Así las cosas, queda demostrado que las cápsulas siguiendo las enseñanzas de D2 se colapsan con facilidad al secarse, debido al bajo contenido de materia seca en la composición de la cubierta. Así mismo, las cápsulas de prueba se rompieron fácilmente al secarse, liberando así el núcleo líquido (filtración). Por el contrario, las cápsulas de acuerdo a la presente solicitud permanecieron esféricas y lo suficientemente fuertes para no romperse durante la manipulación.

Ahora bien, quedando demostradas las diferencias existentes entre la invención y el documento D2 así como el efecto superior alcanzado por dichas diferencias, unaa persona versada en la materia

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no se basaría en el documento D3 para mejorar las propiedades de las cápsulas. Lo anterior, por cuanto el documento D3 enseña una cápsula para almacenar un producto lácteo en un sobre, el cual comprende al menos un polímero que es reactivo con iones multivalentes y se selecciona del grupo compuesto de alginatos altamente gelificantes con un bajo peso molecular menor o igual a 100.000 (alginatos despolimerizado), goma de gelán ligeramente acetilada, y pectinas con un grado de esterificación menor o igual a 20.

Dichas cápsulas están diseñadas específicamente para productos lácteos fermentados o no fermentados, los cuales pueden ser seleccionados entre yogur, bebidas de yogur, leches fermentada, quesos frescos, y cremas, entre otros (columna 2, líneas 5 a 8, D3). Adicionalmente, se indica que el polímero de la cubierta puede comprender agentes de secuestro multi-iónicos, con el objetivo de reducir el fenómeno de sinéresis. Sin embargo, el fenómeno de sinéresis resulta propio de los lácteos.

Frente a lo anterior, se trae a colación el segmento de texto encontrado en la columna 6, líneas 1 a 4 de D3, en donde se enseña que el porcentaje de sinéresis se mide "*pesando el suero exudado por una 50 a 70 cápsulas después de su almacenamiento dentro un recipiente cerrado durante 24 horas a 4°C*". En el campo de lácteos, el término "*suero*" se refiere a la parte acuosa de la leche que se separa de la parte coagulable o cuajada. Por lo tanto, resulta claro que la sinéresis a la que se hace referencia en la columna 6, líneas 1 a 4 de D3 corresponde a la sinéresis de un producto lácteo y que el propósito de los agentes secuestrantes multi-iones de D3 es para reducir la sinéresis del producto lácteo confinado en el sobre.

Por lo tanto, la persona experta en la técnica no tendría ninguna razón para utilizar los agentes secuestrantes de D3 en las cápsulas de D2, ya que tratan problemas técnicos diferentes determinados por la naturaleza de los compuestos presentes en la cápsula, y no existe motivación alguna de aplicar el conocimiento que se tiene relacionado con la sinéresis en productos lácteos para ser aplicados en otros productos, como aquellos mencionados en el primer párrafo de la página 2 de la presente solicitud. Por consiguiente, una persona medianamente versada en la materia no tendría motivación alguna para incluir agentes de secuestro multi-iones en una cubierta de la cápsula para mejorar la homogeneidad y esfericidad.

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Por otro lado, y partiendo del documento D3 como el estado de la técnica más cercano, se tiene que la diferencia entre la invención y el documento citado consiste en que esta última no indica la presencia de un relleno. Frente a lo anterior, resulta necesario aclarar que, contrario a lo afirmado por el Señor Examinador en la resolución impugnada, los plastificantes de D3 no pueden ser comparados con el relleno mencionado en la reivindicación 1 de la presente solicitud, en la medida que los plastificantes de D3 se utilizan para ablandar el polímero. Por el contrario, el relleno incorporado en las cápsulas de acuerdo a la solicitud bajo estudio se utiliza para endurecer la



cápsula. Por lo tanto, los plastificantes de D3 realizan una función contraria a la función del relleno según la invención.

El efecto técnico alcanzado por la presencia de un relleno es el aumento en el porcentaje de materia seca en la fase líquida externa, logrando así las propiedades de formación de la película de la capsula, como es indicado en las líneas 7 a 9 de la página 6 de la memoria descriptiva. Por lo tanto, el problema técnico objetivo a resolver es cómo obtener cápsulas con una baja proporción de agua, de forma tal que estas sean rompibles con un mínimo de secado.

Si bien es cierto que D2 indica el uso de un relleno para mejorar las propiedades de la barrera, dicha anterioridad no incluye una preparación de una capsula que contenga un relleno. Lo que es más, no se indica cómo la incorporación de un relleno en la cubierta de una cápsula pueda disminuir el contenido de agua. Como ejemplo de lo anterior, se traen a colación los ejemplos 6 y 8 de dicho documento, en los que las cápsulas parten con un contenido de agua de 98% y 96,5%, y disminuyen a 49% y 4,6%, respectivamente, después a una etapa de secado extensa. No obstante, la etapa de secado de larga duración, como aquella requerida para la formación de las cápsulas de D2 afecta la forma esférica de las cápsulas. Lo anterior, debido a que el dióxido de silicio agrieta la cubierta a medida que esta se seca.

Por el contrario, la cápsula según la invención bajo estudio comprende goma de gelán, un relleno y un agente de secuestro de metal divalente, la cual presenta un contenido de agua alrededor del 85% después de la etapa de co-extrusión, reduciéndose a 0% después de la etapa de secado, como puede ser observado en el ejemplo 4 de la presente solicitud. Lo anterior demuestra que la presencia de un relleno permite lograr cápsulas con menor contenido de agua y que resulten rompibles.



De esta manera, se puede concluir que no existe enseñanza o sugerencia alguna en los documentos citados que llevara a la persona versada en la técnica a incorporar un relleno y un agente secuestrante en la composición de la cubierta de las cápsulas conocidas con anterioridad, con el fin de tener cápsulas regulares y homogéneas, caracterizadas por presentar un buen rompimiento y una estructura más resistente (debido a la mayor cantidad de materia seca). Por el contrario, las enseñanzas de los documentos citados por su Despacho se alejan de lo mencionado en la presente solicitud, y buscan limitar la cantidad del polisacárido a 0,5 a 4% en peso sobre el peso total de la cubierta, mientras que la cápsula según la invención pueden comprender de 25 a 95% de un relleno derivado de almidón, junto con un agente secuestrante, con el fin de reducir el contenido de agua, logrando así cápsulas rompibles que requieran menos secado cuando se compara con el arte previo

Así las cosas, resulta claro que los documentos D2 y D3 no presentan indicios suficientes que lleve a una persona versada en la materia a obtener las cápsulas rompibles sin unión de acuerdo a la



presente invención, que comprende un núcleo y una cubierta, en donde la cubierta incluye un agente gelificante presente en una cantidad entre 4 y 95% en peso sobre el peso seco total de la cubierta, un relleno, y un agente de secuestro de metal divalente, caracterizada porque: el agente gelificante es goma de gelán sola o en combinación con otro agente gelificante seleccionado del grupo que consiste de gelatina, ágar, carragenano, pectinas, goma de xantano, goma de celulosa, alginato, dextrano, curdlan, goma welan, goma rhamsan, o almidones modificados; el relleno es un derivado de almidón presente en la cubierta en una cantidad entre **25 y 95%** en peso sobre el peso seco total de la cubierta; y el agente de secuestro de metal divalente es una sal de metal presente en la cubierta **en hasta un 2%** en peso sobre el peso seco total de la cubierta.

Igualmente, la combinación de las enseñanzas de los documentos citados no permite obtener un proceso para la fabricación de una cápsula rompible sin unión, el cual comprende:

- co-extruir una fase líquida externa e hidrofílica, y una fase líquida interna y lipofílica, con el objeto de formar una cápsula constituida de un núcleo que comprende a la fase interna y lipofílica, y una cubierta que comprende a la fase externa y lipofílica;
- sumergir en una solución acuosa que contenga un agente de curado que comprende iones divalentes;

en donde la fase líquida externa incluye un agente gelificante que comprende goma de gelán sola o en combinación con otro agente gelificante, un relleno, y un agente de secuestro de metal divalente.

Por lo tanto, contrario a las consideraciones del Examinador, una persona versada en la materia no tendría ningún incentivo a considerar dichos documentos al estar enfrentado al problema que se presenta en la solicitud. De esta manera se desvirtúa lo manifestado por su Despacho con respecto a que la presente invención no había superado un prejuicio técnico y por ende, queda acreditado el nivel inventivo de la misma.



Por último, se desea poner de presente que aunque nos encontramos de acuerdo con la soberanía y autonomía de su Oficina para realizar el examen de patentabilidad de las solicitudes de patentes, consideramos relevantes tener de presente que la solicitud bajo estudio ha sido otorgada por la Oficina de Patentes Europea, y por China, Indonesia, México, Nueva Zelanda, Filipinas, Rusia, Singapur, Ucrania y Sur África.

5.2. Conclusión

En línea con los argumentos presentados y con las disposiciones de la legislación actual en materia de patentes, consideramos que el estudio de patentabilidad no fue correctamente realizado y que contrario a lo que afirma el Examinador, la cápsula y su proceso de fabricación reivindicados sí presentan nivel inventivo, teniendo en cuenta que la presente invención responde a una necesidad, presenta ventajas reales y que las enseñanzas de las anterioridades citadas no llevan a un técnico



versado en la materia a resolver el problema acá planteado y a obtener la presente invención ya que no enseñan o sugieren las características técnicas esenciales relacionadas con la misma. Por lo tanto es claro que a partir de las anterioridades citadas no era posible para un técnico medio obtener de manera obvia y/o evidente la materia acá reivindicada.

Por lo tanto, la decisión tomada en este sentido debe ser revocada, dado que la solicitud en estudio cumple con los requerimientos de patentabilidad tal como exige la Decisión 486 de la Comunidad Andina.

VI. PETICIONES

Ruego a Usted entonces, lo siguiente:

- 6.1. Que se revoque el artículo PRIMERO de la Resolución No. 36598 en cuanto niega el privilegio de patente para el capítulo reivindicatorio de la presente invención.
- 6.2. Que en consecuencia se otorgue el privilegio de patente de invención **"CÁPSULA DE GELÁN ROMPIBLE SIN UNIÓN Y PROCESO PARA SU FABRICACIÓN"** a favor de V. **MANE FILS.**

VII. NOMBRE Y DIRECCIÓN DEL RECURRENTE

El nombre y la dirección del recurrente son:

V. MANE FILS
620 route de Grasse
06620 Bar sur Loup,
Francia



VIII. ANEXOS

- 8.1. Reporte de Prueba en el que se comparan las cápsulas según la presente solicitud y aquellas enseñadas en el documento D2: US 2004/0191366.
- 8.2. Copia de los pliegos reivindicatorios concedidos por la Oficina de Patentes Europea, y por China, Nueva Zelanda y Rusia. En este sentido resulta necesario poner de presente que las reivindicaciones concedidas en México, Indonesia, Filipinas y Singapur son las mismas a aquellas concedidas por la Oficina de Patentes Europea.



VIII. NOTIFICACIONES

Atentamente manifiesto a usted que recibiré notificaciones en la Secretaria de su Despacho o en mi oficina de abogada situada en la Carrera 4ª. No. 72-35, piso 4º, de esta ciudad de Bogotá, D.C.

Señor Superintendente,

Luz Clemencia de Paez
LUZ CLEMENCIA DE PAEZ

C.C. 35.456.344 de Usaquén
T.P.A. No. 23.555

COLO-16271-841-002-8
LLG\LLG\ID-222048\WPC16271
No. M-2012-222048\LLG



NOTARIA SEXTA DE BOGOTÁ
RECONOCIMIENTO Y PRESENTACION PERSONAL
Bogotá, D.C.
25 JUL 2012
Ante mí AMPARO QUINTERO ARTURO,
NOTARIA SEXTA DEL CÍRCULO DE
BOGOTÁ, D.C.
Compareció(en)

*Luz Clemencia
Suarez de paez*

C.C. 35.456.244 y 4549
TP # 23 555

Y declaró(en), que la(s) firmante(s) que aparece(n)
en el presente documento es(son) la(s) suya(s) y
que el contenido del mismo es cierto.
En constancia se firma esta diligencia.

*Luz Clemencia Suarez
TP # 23 555 ASJ.*



TEST REPORT

In the following test report, the seamless capsules of the invention are compared to the capsules according Mangos US patent n°2004/0191366.

Starting compositions and process parameters

a. Protocols

The starting compositions for the encapsulating liquid solution are detailed in Table 1 below.

	Cellofilm MANE	Film Test (= prior art)
	Liquid solution	Liquid solution
SODIUM CITRATE (= sequestrant)	2 g	
CALCIUM LACTATE (=gelling ions)		1,5 g
GOMME GELLANE KELCOF (= polysaccharide)	20 g (= 2%)	10,0 g (= 0.99%)
SORBITOL POUDRE (= filler)	10 g	
DEXTRINE CRISTAL TEX 648 (= filler)	115 g	
Process water	853 g	1000,0 g
Total	1000 g	1011,5 g
Dry matter	14,70%	1,14%

TABLE 1

There is a big difference between the dry matter content in the encapsulating composition used to produce the seamless capsules of the invention compared to the encapsulating composition used to produce the prior art capsules (i.e. Mangos capsules).
The co-extrusion is carried out in a seamless capsule apparatus as described in EP0513603. The extrusion temperature of the shell composition is 85-90°C and the core composition is at room temperature.

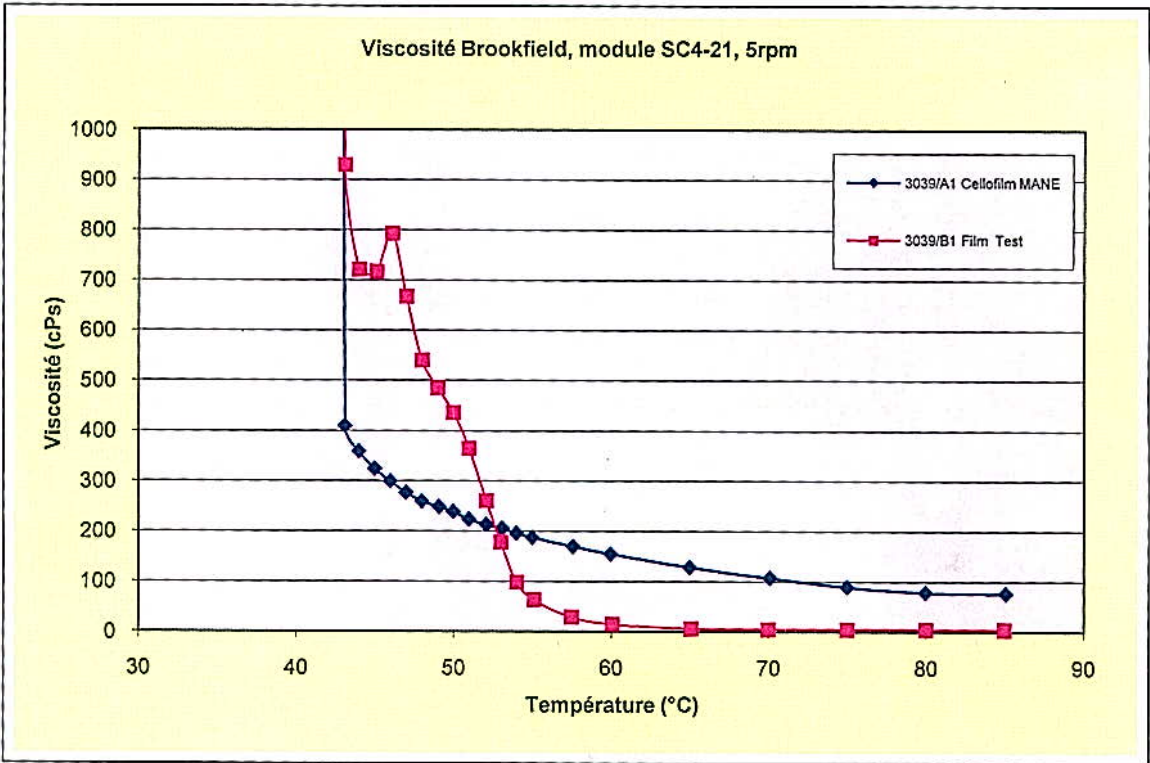


FIGURE 1: viscosity profile of the encapsulating composition used to produce the seamless capsule of the invention and the capsule of the prior art.

The gelling of the encapsulating composition of the invention is very quick and occurs at 43°C while the gelling occurs gradually from 55°C for the encapsulating composition of the prior art. Then, the encapsulating composition of the prior art is not suitable for a regular and homogeneous extrusion.

b. Capsules properties after extrusion

Table 2 shows the properties of the seamless capsules of the invention compared to the seamless capsules according the prior art of Mangos.

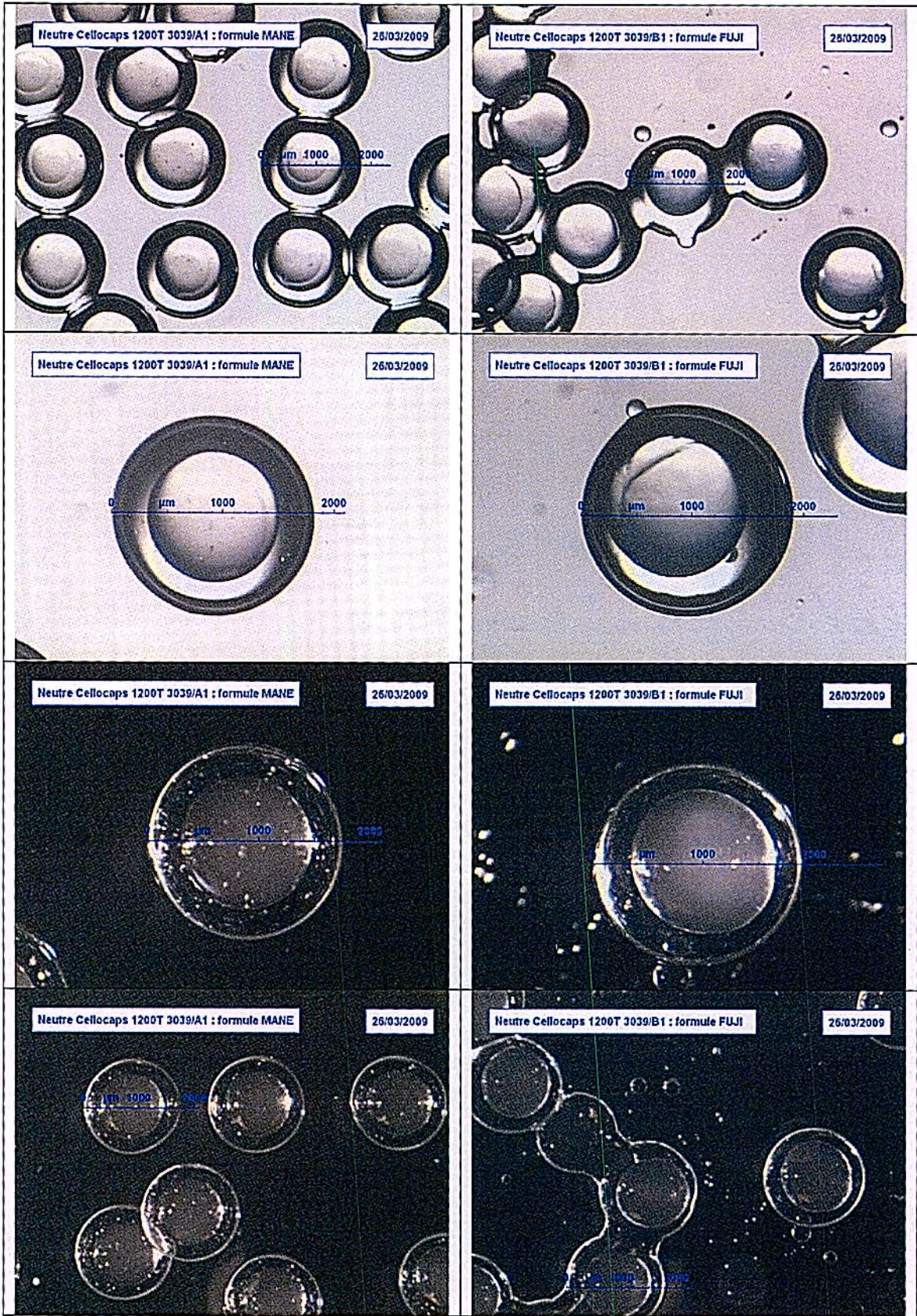
	Cellofilm MANE	Film Test (= prior art)
Core of wet capsule	32,98%*	35,78%*
Wet capsule diameter	1,83 mm	1,90 mm
Wet shell thickness	0,262 mm	0,256 mm
Core of dry capsule	77,00%**	98,00%**
Dry capsule diameter	1,400 mm	1,400 mm
Dry shell thickness	0,050 mm	0,004 mm

TABLE 2

* by weight of the total weight of the wet capsule
 ** by weight of the total weight of the dry capsule

As it can be seen from the figure below, the capsules of the invention are regular in shape while the capsules of the prior art tend to form satellites as well as full beads. In addition, the shell of the capsules of the invention have a uniform thickness while the shell of the capsules of the prior art often shows irregular thickness.

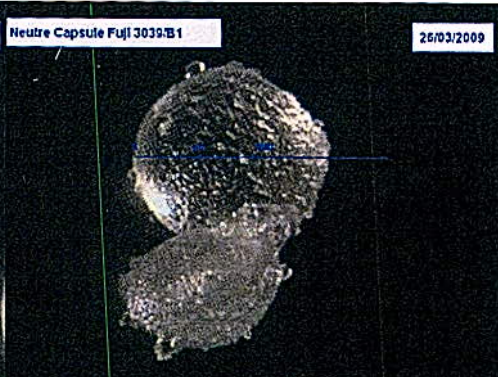
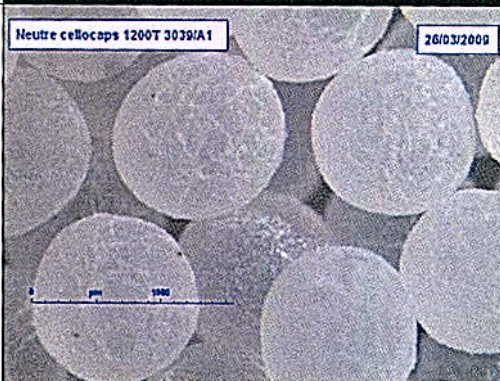
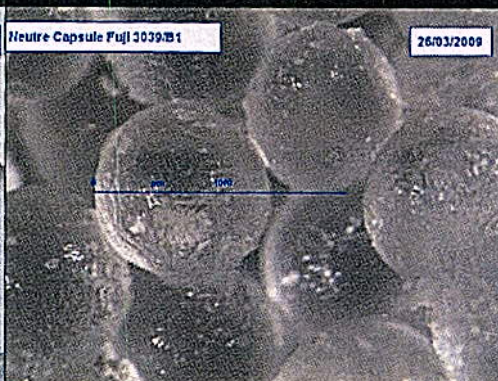
Capsules of the invention	Capsules of prior art
---------------------------	-----------------------



c. Dried capsules

Picture and Table below show the physical properties of the dried capsules of the invention and the dried capsules of prior art.

	Capsules of the invention	Capsules of prior art
--	---------------------------	-----------------------

Aspect		
		
Average diameter (µm)	1298	1376
Diameter standard deviation (µm)	17	35
I/L ratio	0,965	0,933
Crush strength (kp)	0.94	0.26
Crush strength standard deviation (kp)	0.28	0.17

From the pictures above, it can be seen that the capsules prior art collapse easily when dried because of the low content of dry matter in the shell composition. Moreover, the capsules Test broke easily when dried, resulting in the release of the core liquid. On the contrary, the capsules of the present invention remain spherical and sufficiently strong so as not to break upon manipulation.

Table 3 below shows the physical properties of the dried capsules of the invention and the dried capsules of the prior art

	Cellofilm MANE	Film Test (= prior art)
Average diameter (µm)	1298	1376
Diameter standard deviation (µm)	17	35
I/L	0.965	0.933
Crush strength (kp)	0.94	0.26
Crush strength standard deviation (kp)	0.28	0.17

TABLE 3



European Patent Office
80298 MUNICH
GERMANY
Tel: +49 89 2399 0
Fax: +49 89 2399 4465



Cabinet Plasseraud
52, rue de la Victoire
75440 Paris Cedex 09
FRANCE

REÇU LE

28 MAI 2009

CABINET PLASSERAUD

Formalities Officer
Name: Christensen, Jette
Tel: +49 89 2399 - 8052
or call
+31 (0)70 340 45 00

Application No. 06 809 049.7 - 2112	Ref. DZ06002905CMV	Date 25.05.2009
Applicant V. Mane Fils		

Communication under Rule 71(3) EPC

You are informed that the Examining Division intends to grant a European patent on the basis of the above application with the text and drawings as indicated below:

In the text for the Contracting States:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC NL PL PT RO SE SI SK TR

Description, Pages

1, 2, 4, 5, 11-21 as published
3, 6-10 filed with telefax on 08.04.2009

Claims, Numbers

1-22 filed with telefax on 08.04.2009

Drawings, Sheets

1/1 as published

A copy of the relevant documents is enclosed

The title of the invention in the three official languages of the European Patent Office, the international patent classification, the designated Contracting States, the registered name of the applicant and the bibliographic data are shown on the attached EPO Form 2056.

You are requested within a non-extendable period of **four months** of notification of this communication

1.	to file 1 set of translations of the claim(s) in the two other EPO official languages;		EUR
2a.	to pay the fee for grant including the fee for printing up to and including 35 pages; Reference 007		790.00
2b.	to pay the printing fee for the 36th and each subsequent page; number of pages: 0	Reference 008	0.00
3.	to pay the additional claim fee(s) (R. 71(6) EPC); number of claims fees payable:	Reference 016	0.00
		Total amount	790.00

The mention of the grant of the patent shall be published in the European Patent Bulletin as soon as possible after the requirements concerning the translation of the claims and the payment of the fees for grant and printing, claims fees, designation fees and renewal fees as laid down in Rule 71(3), (4), (6) and (8) and (9) EPC are fulfilled.

Any divisional applications relating to this European patent application must be filed directly at the European Patent Office in Munich, The Hague or Berlin in accordance with Article 76(1) and Rule 36 EPC **before** the date on which the European Patent Bulletin mentions the grant of the patent (see Guidelines for Examination in the EPO, A-IV, 1.1.1).

If you do not approve the text intended for grant but wish to request amendments or corrections, the procedure described in Rule 71(4) EPC is to be followed.

If this communication is based upon an auxiliary request, and you reply within the time limit set that you maintain the main or a higher ranking request which is not allowable, the application will be refused (Art. 97(2) EPC).

If the enclosed claims contain amendments proposed by the Examining Division, and you reply within the time limit set that you cannot accept these amendments, refusal of the application under Article 97(2) EPC will result if agreement cannot be reached on the text for grant.

In all cases except those of the previous two paragraphs, if the fees for grant and printing or claims fees are not paid, or the translations are not filed, in due time, the European patent application will be deemed to be withdrawn (R. 71(7) EPC).

For all payments you are requested to use EPO Form 1010 or EPO Form 1010E or to refer to the relevant reference number.

After publication, the European patent specification can be downloaded free of charge from the EPO publication server <https://publications.european-patent-office.org> or ordered from the Vienna sub-office upon payment of a fee (OJ EPO 2005, 126).

Upon request in writing each proprietor will receive the certificate for the European patent **together with one copy** of the patent specification provided that the request is filed within the time limit of Rule 71(3) EPC. If

such request has been previously filed, it has to be confirmed within the time limit of Rule 71(3) EPC. The requested copy is free of charge. If the request is filed after expiry of the Rule 71(3) EPC time limit, the certificate will be delivered without a copy of the patent specification (R.74 EPC, Decision of the President of the EPO, Special edition No.3, OJ EPO 2007, D.2).

Note on payment of renewal fees

If a renewal fee falls due between notification of the present communication and the proposed date of publication of the mention of the grant of the European patent, publication will be effected only after the renewal fee and any additional fee have been paid (R. 71(9) EPC).

Under Article 86(2) EPC, the obligation to pay renewal fees to the European Patent Office terminates with the payment of the renewal fee due in respect of the year in which the mention of the grant of the European patent is published.

Filing of translations in the Contracting States

As regards translation requirements prescribed by the Contracting States under Article 65(1) EPC, please consult the website of the European Patent Office

www.epo.org → Patents → Law → Legal texts → National law relating to the EPC

www.epo.org → Patents → Law → Legal texts → London Agreement

In case of a valid extension

As regards translation requirements prescribed by the Extension States, please consult the website of the European Patent Office

www.epo.org → Patents → Law → Legal texts → National law relating to the EPC

Failure to supply a prescribed translation in a Contracting State or an Extension State may result in the patent being deemed to be void *ab initio* in the State concerned (Article 65(3) EPC).

Important note to users of the automatic debiting procedure

The fees for grant and printing and also any additional claims fees due under Rule 71(6) EPC will be debited automatically on the date of filing of the translation of the (relevant) claims, or on the last day of the period of this communication. However, if the designation fees become due as set out in Rule 71(8) EPC and/or a renewal fee becomes due as set out in Rule 71(9) EPC, these should be paid separately by another permitted means of payment in order not to delay the publication of the mention of grant. The same applies in these circumstances to the payment of extension fees. For further details see the Arrangements for the automatic debiting procedure (AAD) and accompanying Information from the EPO concerning the automatic debiting procedure (Annexes A.1 and A.2 to the Arrangements for deposit accounts (ADA) in Supplement to OJ EPO 3/2009).

Date 25.05.2009

Sheet 4

Application No.: 06 809 049.7

Examining Division:

Chairman: S. von Eggelkraut-G.
2nd Examiner: Schüle, Stefanie
1st Examiner: Villa Riva, A



Christensen, Jette
For the Examining Division
Tel. No.: +49 89 2399 - 8052

Enclosure(s): Form 2056
28 Copies of the relevant documents



European Patent Office
80298 MUNICH
GERMANY
Tel: +49 89 2399 0
Fax: +49 89 2399 4465

Annex to EPO Form 2004, Communication pursuant to Rule 71(3) EPC

Bibliographical data of European patent application No. 06 809 049.7

For the intended grant of the European patent, the bibliographical data are set out below, for information:

Title of invention:

- NAHTLOSE BRECHBARE GELLANKAPSEL UND HERSTELLUNGSVERFAHREN DAFÜR
- GELLAN SEAMLESS BREAKABLE CAPSULE AND PROCESS FOR MANUFACTURING THEREOF
- CAPSULE RUPTURABLE DE GÉLLANE SANS SOUDURE ET SON PROCÉDÉ DE FABRICATION

Classification:

INV. A61K9/48 A61K8/11 B01J13/04 A23L1/00

Date of filing:

21.06.2006

Priority claimed:

EP / 21.06.2005 / EPW2005008502
EP / 05.08.2005 / EPW2005009226

Contracting States*
for which fees have
been paid:

AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HU IE IS IT LI LT LU LV MC
NL PL PT RO SE SI SK TR

Extension States*
for which fees have
been paid:

Applicant(s):**

V. Mane Fils
620, route de Grasse
06620 Bar sur Loup
FR

Inventor(s):

HARTMANN, Didier
83, avenue Maurice Chevalier,
Résidence La Boissière, Bat. Bambou
F-06150 Cannes La Bocca
FR

HANNETEL, Jean-Michel
6, rue Jeanne Jugan
F-06130 Grasse
FR

COURSIERES, Nathalie
580 chemin de la Stèle
F-06530 St Cezaire sur Siagne
FR



European Patent Office
80298 MUNICH
GERMANY
Tel: +49 89 2399 0
Fax: +49 89 2399 4465

MANE, Jean
Domaine Saint-Mathieu,
290, route de Saint-Mathieu
F-06130 Grasse
FR

- *) If the time limit for the payment of designation fees according to Rule 39(1) EPC has not yet expired and the applicant has not withdrawn any designation, **all Contracting States/Extension States** are currently still deemed to be designated. See also Rule 71(8) EPC and, if applicable, the above Note to users of the automatic debiting procedure.
- **) If two or more applicants have designated different Contracting States, this is indicated here.

~~GELLAN SEAMLESS BREAKABLE CAPSULE AND PROCESS FOR
MANUFACTURING THEREOF.~~

The present invention relates to a breakable
5 capsule having a fluid core and a solid or fluid breakable
shell.

In this invention, the term "capsule" means a
spherical or substantially spherical delivery system of a
substance, said substance being hereinafter referred to as
10 "the core", and said substance being encapsulated into a
shell, the shell being breakable and releasing the core
when broken or ruptured. The term fluid means flowing as
opposed to being in a solid state. According to the
invention, the term fluid includes finely divided solids,
15 such as a powder, and also gel, or any physical state of a
product wherein said product changes shape or direction
uniformly, in response to an external force imposed upon
it. According to the invention, fluid preferably refers to
a flowable or gellified product.

20

The term "breakable capsule" refers to a capsule
as hereabove defined, wherein the shell can be ruptured by
means of a pressure, which results in the release of the
core. According to an embodiment, the capsule of the
25 invention may be specifically designed to be incorporated
into a fluid medium such as for example a gel, a pasty or a
liquid medium containing water; in this embodiment, the
capsules may be suspended or mixed by any suitable means in
order to bring an visual effect of homogeneous dispersion
30 of the capsules in the medium; advantageously, the shell
and/or the core of the capsule is coloured. According to
another embodiment, the capsule of the invention is

dispersed into a solid or fluid medium, such as for example a powder; advantageously, the shell and/or the core of the capsule is coloured.

Such capsules are useful for numerous applications, such as in oral care application (toothpaste, mouthwash, gums...), in food applications such as confectionary, dairy, bakery, savory, in nutraceutical applications or in pharmaceutical or in personal care products such as cosmetic products and the like.

10 In the present patent application, the term "capsule" will be used to designate any size of capsules, including macrocapsules and microcapsules and preferably capsule which larger diameter is from 0.5 mm up to 8 mm, preferably 1 to 5 mm; more preferably 1.2 to 3 mm.

15 It is of particular interest to obtain seamless capsules, as the breakability of a welded capsule (also designated in the prior art as softgel or hard capsule) may be influenced by the easy or unwanted rupture of the weld.

Fuji patent application JP10291928 describes a capsule obtained through a co-extrusion process, wherein the external liquid phase comprises gellan and calcium salts. Gellan gum, first discovered in 1978, is produced by the microorganism *Sphingomonas elodea*.

25 The Applicant has found that the production of gellan capsule through the Fuji process was not satisfactory and resulted in poor quality capsules and in processing difficulties, because the gellan was actually gelling during the co-extrusion, and it was not possible to obtain spherical and homogeneous breakable capsules.

WO 2007/012981

PCT/IB2006/002905

3

For this reason, the Applicant tried to improve the Fuji process and found that the drawbacks of the prior art process may be due to the presence of calcium salts, and more generally to divalent metal salts in gellan during the co-extrusion step. Thus, the Applicant carried out a process wherein the co-extrusion liquid phase containing gellan was performed in absence of calcium salts, and observed that, surprisingly, the resulting capsules had the required spherical or substantially spherical shape and homogeneous sizes. However, the capsules thus obtained could not be used as such, because the shell was too soft and the resulting capsules were not breakable capsules; the Applicant found a solution to this subsequent technical problem by contacting the capsules with divalent metal ions, preferably calcium or magnesium ions, or by using organic acid solution, once the co-extrusion process is finished, and this finally lead to satisfactory breakable capsules.

Thus, this invention relates to a process for manufacturing seamless breakable capsules and to new seamless breakable capsules, as defined in claim 1,

The process of the invention comprises a step (A) of co-extrusion of an external and hydrophilic liquid phase and an internal and lipophilic liquid phase, in order to form a capsule having a core comprising the internal and lipophilic phase and a shell comprising the external and hydrophilic phase; and a step (B) of washing and immersing the capsules into an aqueous solution preferably containing a curing agent, the curing agent being one of the means for making the shell breakable as required for the intended use; optionally a step (C) of drying the obtained capsules

IDS
8/04/09

or optionally a step (D) of suspending the capsules into an fluid medium.

The co-extrusion process comprises three main stages: compound drop formation, shell solidification and capsule collection. The compound drop is a sphere of the liquid fill phase inside the shell phase. The liquid fill phase is hereinafter referred to as "the core". The shell phase is hereinafter referred to as "the shell".

According to the invention, the external liquid phase includes a gelling agent comprising gellan gum, alone or in combination with at least one suitable gelling agent, a filler, and a metal sequestering agent, the liquid preferably being aqueous, more preferably the liquid is water, preferably desionized or osmozed water.

By "gelling agent" in the meaning of this invention, it is referred to an agent able to convert an aqueous phase from a flowable or fluid liquid to a solid or a gel.

By "sequestering agent" in the meaning of this invention it is referred to any agent complexing, chelating or sequestering bivalent ions such as calcium or magnesium ions.

The term "substantially", when referring to a number or value, means + or - 10 % of the value; when referring to a sphere, it means a distorted sphere which larger diameter is + or - 10 % of the diameter of the expected sphere.

The term "wet capsule" in the meaning of this invention, refers to a capsule which shell includes a positive amount of water. The term wet capsule is used for the calculation of percentages of ingredients in the final

product or shell, as opposed to the calculation based on the dry weight of said final product or shell.

The breakable capsule according to the invention preferably has a crush strength from 0.01 to 5 kp, preferably from 0.1 to 2.5 kp, edge values being included. The crush strength of the capsule is measured by continuously applying a load vertically onto one particle until rupture. The crush strength of the capsules in the present invention is measured by using a texturometer TA.XT plus from Micro Stable System in compression mode or a LLOYD - CHATILLON Digital Force Gauge, Model DFIS 50, having a capacity of 25Kg, a resolution of 0.02 Kg, and an accuracy of +/- 0,15 %. The force gauge is attached to a stand; the capsule is positioned in the middle of a plate that is moved up with a manual thread screw device. Pressure is then applied manually and the gauge records the maximum force applied at the very moment of the rupture of the capsule, (measured in Kg or in Lb). Rupture of the capsule results in the release of the core.

Gellan gum is a hydrocolloid which, according to the invention, can be used as the sole gelling agent of the external liquid phase, or in combination with at least one other gelling agent. Other suitable gelling agents may be alginates, agar, carragheenan, pectines, xanthan gum, Arabic gum, tara gum, ghatti gum, karaya gum, dextran, curdlan, welan gum, rhamsan gum or modified starches. Suitable gellan gums are for example, but not limited to deacylated gellan gum. Kelcogel® can be mentioned as a suitable gellan gum.

The amount of gelling agent present in the shell is 4 to 95%, preferably 5 to 75%, even more preferably is

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10 to 50%, more preferably 12 to 40 % by weight of the total dry weight of the shell.

When used in combination with at least another gelling agent, the weight ratio between gellan gum and the
5 other gelling agent(s) is from 80/20 to 20/80, preferably 75/25 to 25/75, and even more preferably from 60/40 to 50/50.

Preferably, the weight ratio of gelling agent / dried shell is greater than 10%, preferably greater than
10 12, more preferably greater than 15%.

The filler is any suitable material that can increase the percentage of dry material in the external liquid phase or bring filming properties. Increasing the dry material amount in a shell results in solidifying the
15 shell, and in making it physically more resistant or impermeable. Preferably, the filler is selected from the group comprising starch derivatives such as dextrin, maltodextrin, polyol, cyclodextrin (alpha, beta or gamma), or cellulose derivatives such as
20 hydroxypropylmethylcellulose (HPMC), hydroxypropylcellulose (HPC), methylcellulose (MC), carboxymethylcellulose (CMC), polyethylene glycol derivatives, polyvinyl alcohol, polyols or mixture thereof.

The amount of filler in the shell is at most
25 ~~98.5%, preferably from 25 to 95% and even more preferably from 50 to 80%~~ ⁵⁰ by weight on the total dry weight of the shell.

Using a divalent metal sequestering or complexing agent allows trapping the divalent metal ions which are
30 possibly present in the components of the liquid phase including water and which have a gelling effect on gellan. Thus, the use of a divalent metal sequestering agent,

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preferably of a calcium ion sequestering agent, allows the gellan to be co-extruded without undesirable or uncontrollable gelling during the co-extrusion.

The amount of sequestering agent is at most 2%, preferably at most 1% and even more preferably at most 0.5% by weight of the total dry weight of the shell.

Preferably, the water used for the external phase is deionized water and/or osmized water; using processing water remains possible but needs adjusting the amount of divalent metal sequestering agent.

The sequestering agent is a metal salt, preferably selected from the group comprising trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

The hydrophilic external liquid phase may further comprise at least one plasticizer, which may be at least one of glycerol, sorbitol, maltitol, triacetina or polyethylene glycol type product, or a polyalcohol with plasticizing or humectant properties. Advantageously, the hydrophilic external liquid phase further comprises at least one colouring agent or pigment; according to a first embodiment, the colouring agent or the pigment is in a form of a powder or a suspension stable in an aqueous medium. According to another embodiment of the invention, the liquid phase may include perfumes, aromas, fragrances or any odoring agent.

According to one embodiment of the invention, the co-extrusion step (A) of the process can be performed at a temperature being from room temperature to 100°C. Advantageously, it is performed at room temperature, which means between 18 and 30°C, preferably 20-25 °C under atmospheric pressure.

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The co-extrusion step is a synchronous extrusion of two liquids: the external and hydrophilic liquid phase, and the internal and lipophilic liquid phase which can be performed using an apparatus and a process as described in EP 513603, the disclosure of which is herein incorporated by reference.

According to an embodiment of the invention, after the co-extrusion step (A), the solidification step is performed by keeping cold the capsules in order to ensure correct gelling of the shell, for example by contacting them with a cold bath. The cold bath may preferably be cold oil or cold emulsion. Cold means any temperature below 18 °C, preferably the temperature is from 2 to 10 °C, more preferably 4 to 6 °C.

According to an embodiment of the invention, the capsules may then be centrifuged in order to remove the surplus oil, and/or washed with organic solvent (such as acetone, ethyl acetate, ethanol, petroleum ether, etc.) also to remove the surplus oil, and optionally dried in a air flow at controlled temperature and humidity. The relative humidity of the drying air is 20% to 60%, preferably 30 to 50%; the temperature of the drying air is of 15 to 60 °C, preferably 35 to 45 °C.

~~According to another embodiment,~~ The capsules are preferably immersed into an aqueous solution or an emulsion containing a curing agent which comprises a divalent salt and optionally an acid. The effect of the immersion step is to wash out the oil remaining at the periphery of the capsule, and to gradually strengthen the shell, notably through dehydration and osmotic equilibrium.

According to one embodiment of the invention, after immersion, the capsules are dried in the same

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conditions as mentioned above. According to another embodiment of the invention, after immersion, the capsules are not dried.

5 The curing agent ~~preferably~~ comprises ~~divalent metal ions, or a mixture of divalent metal ions, such as calcium ions or magnesium ions.~~

 The aqueous solution or emulsion containing the curing agent is preferably a divalent metal salt solution, preferably containing calcium ~~or magnesium~~ salts, more preferably, calcium dichloride, calcium carbonate, calcium sulfate or dicalcium phosphate. This solution may be the aqueous phase of an oil-in-water emulsion. This solution can be at a temperature comprised between 2°C and room temperature. Advantageously, the aqueous solution containing the curing agent is maintained under acid conditions of pH, and preferably at a pH less than 5, more preferably from 2 to 4. According to a preferred embodiment of the invention, the aqueous solution or emulsion containing a curing agent is a calcium chloride solution having a pH of 3 to 4.

 The aqueous solution containing the curing agent can also contain preservatives or bactericides such as benzoate, parabens, diols, cetylpyridinium chloride, diazolidinyl urea or any preservatives used for food, pharmaceutical or cosmetic products.

 According to one embodiment of the invention, the process comprises the steps of co-extruding the above mentioned external and internal liquid phases, optionally solidifying and/or gelling the surface of the shell by keeping the capsule under cold conditions, as explained herein above, optionally centrifugating, optionally washing

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the so-obtained capsules with an organic solvent, immersing the resulting capsules into an aqueous solution containing a curing agent, and optionally drying the capsules.

According to one embodiment of the invention, the solidifying/gelling/curing steps can be gathered into a single step, for example by dipping the capsules into a bath, under cold conditions, containing the ~~divalent metal salts, preferably calcium or magnesium salts,~~ more preferably, calcium dichloride, calcium sulfate or dicalcium phosphate. This bath may be an oil-in-water emulsion.

The capsules manufactured through the process according to the invention are substantially or perfectly spherical and very homogeneous in size.

This invention also relates to breakable capsules which are preferably seamless capsules susceptible to be obtained through the process according to the invention.

The capsule of the invention comprises a core and a shell, and said shell includes a gelling agent comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent.

Preferably the gelling agent of the shell is a combination of gellan and of at least one other gelling agent selected from the group consisting of gelatin and hydrocolloids such as agar, carragheenan, pectins, xanthan gum, alginate, tara gum, arabic gum, ghatti gum, caroub gum, cellulose gum, dextran, curdlan, welan gum, rhamnan gum or modified starches.

According to a preferred embodiment of the invention the filler and the sequestering agent, are as described hereinabove.

According to another embodiment, the shell further comprises a plasticizer as described hereinabove.

The amount of plasticizer ranges from 0.1% to 30% by weight, preferably from 2% to 15% by weight, and even
5 more preferably from 3 to 10% by weight of the total dry weight of the shell.

According to the intended use of said capsules, the shell may contain other additives such as perfumes, aromas, or any flavoring agent.

10 According to the intended use of said capsule, the shell may comprise coloring agent such as pigments, titanium dioxide, iron oxides, carbon black, or any type of food, oral care, cosmetic or pharmaceutical pigment such as Covasorb colors distributed by LCW.

15 The shell of a breakable capsule according to the invention represents by weight 8 to 50% of the total weight of said capsule, preferably 10 to 40%, more preferably 20 to 30%.

The amount of water present in the shell is of
20 1 to 60 %, preferably 5 to 40 % the capsule remaining breakable even at the higher percentages.

According to a preferred embodiment, the breakable capsule according to the invention has a crush strength of
25 from 0.01 to 5, preferably from 0.01 to 2.5 kp.

Advantageously, the shell thickness of the capsule is 10-500 microns, preferably 30-150 microns, more preferably 50-60 microns. The ratio diameter of the

capsule/thickness of the shell is in the range of 1 to 100, preferably 5 to 30.

The core of the capsule is preferentially composed of a mixture of materials or products which are lipophilic or partially soluble in ethanol, or of molecules formulated as oil/water/oil emulsions.

The core of a breakable capsule according to the invention represents by weight 50 to 92% of the total weight of said capsule, preferably 60 to 90%, more preferably 70 to 80%.

The core of the capsule may be composed of one or more lipophilic solvents conventionally used in the food, pharmaceutical or cosmetic industries. In a preferred embodiment, these lipophilic solvents may be triglycerides, especially medium chain triglycerides, and in particular triglycerides of caprylic and capric acid, or mixtures of triglycerides such as vegetable oil, hydrogenated oil, coconut oil, palm oil, olive oil, sunflower oil, corn oil, linseed oil, cottonseed oil, groundnut oil, grape seed oil, wheat germ oil, fish oil, beet fat, mineral oils and silicone oils. The amount of lipophilic solvent in the core of a capsule according to the invention is of the order of 0.01 to 90%, preferentially 25 to 75%, of the total weight of the capsule.

The core may also comprise one or more aromatic or fragrance molecules as conventionally used in the formulation of flavoring or fragrance compositions. Mention will in particular be made of aromatic, terpenic and/or sesquiterpenic hydrocarbons, and more particularly essential oils, alcohols, aldehydes, phenols, carboxylic acids in their various forms, aromatic acetals and ethers,

nitrogenous heterocycles, ketones, sulfides, disulfides and mercaptans which may be aromatic or non aromatic. It may also comprise one or more molecules or extracts for cosmetic use.

5 The core may also comprise one or more fillers as used in aromatic emulsions. Mention will be made of dammar gum, wood resins of the ester gum type, sucrose acetate isobutyrate (SAIB) or brominated vegetable oils. The function of these weighting agents is to adjust the
10 density of the liquid core.

 The core may also comprise one or more sweeteners, which may be provided in the form of a solution or suspension in ethanol. Examples of suitable sweeteners may be, but is not limited to, aspartame, saccharine, NHDC,
15 sucralose, acesulfame, neotame, thaumatin, steviosides, etc.

 The core may also comprise one or more "sensate" aromatic agents, which provide either a freshening effect or a hot effect in the mouth. Suitable freshening agents
20 may be, but are not limited to, menthyl succinate and derivatives thereof, in particular Physcool® marketed by the Applicant. A suitable hot effect agent may be, but is not limited to, vanillyl ethyl ether.

 The flavoring agents that can be solubilized in
25 the solvent of the core of the capsule include, but are not limited to, natural or synthetic aromas and/or fragrances. Examples of suitable fragrances are fruity, confectionery, floral, sweet, woody fragrances. Examples of suitable aromas are vanilla, coffee, chocolate, cinnamon, mint. The
30 core may also comprise a lipophilic color such as fake colors but also natural colors such as paprika oleoresin,

40
turmeric oleoresin, carotenes, chlorophyllin, or any other
suitable natural coloring product. The core may also
include lipophilic active agents, such as vitamins, more
preferably vitamin B; fatty acids, preferably omega 3 and
5 natural extracts of plants.

The capsules according to the invention can be
included in various products, such as food products, oral
care products, nutraceutical products, pharmaceutical
products, cleaning products and cosmetic products. The
10 invention thus relates to a food product including
breakable capsules according to the invention; an oral care
product including breakable capsules according to the
invention, preferably a toothpaste including breakable
capsules according to the invention; a pharmaceutical
15 product including breakable capsules according to the
invention; a fragrance including breakable capsules
according to the invention.

The capsules of the invention may be within a
slurry, in suspension in a gel, preferably carried out with
20 a gel forming agent such as xanthan gum, gellan gum, CMC or
Carbopol, araboxymethyl cellulose, or any polymer commonly
used as suspending agent and optionally comprising
preservatives and stabilizers.

The total weight of the capsule of the invention
25 depends on its diameter and on the amount of core filling
the shell. According to an embodiment of the invention, the
total weight of the capsule is within the range of 0.1 to
50 mg, preferably 0.2 to 20 mg, more preferably 0.5 to 10
mg.

The invention is hereunder illustrated by the following examples, which should not be considered as limiting the scope of the invention.

5 EXAMPLES

Example 1

10 Menthol Capsules (referred as 3039/A1) are prepared by co-extruding an outer liquid phase and an internal liquid phase presenting the following compositions:

Outer liquid phase Dry matter: 15,0%	%/total weight	% / dry matter	% wet capsule
gellan	2.000%	13.33	1.482
Sorbitol	1.000%	6.67	0.741
Dextrin Cristal Tex 648	11.400%	76.00	8.445
Sodium citrate	0.200%	1.33	0.148
Citric acid	0.1%	0.67	0.074
unipure blue pigment CI77007	0.300%	2.00	0.222
Deionized water	85.000%		62.968
	100.000%	100	
Internal liquid phase	%	%	
Ethanol	5.0000%	5%	
Miglyol 812S	81.5000%	81.5%	22.245%
Menthol codex	13.5000%	13.5%	3.685%
	100.0000%	100.00%	100%

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The obtained capsules are separated into two batches referred as A1a and A1b. Capsules from each batch are cooled at 4°C for 1h, washed with desionised water and then
5 immersed in a bath containing an aqueous solution of calcium chloride (0.1% for A1a and 1% for A1b) at pH=3.5 at T=20°C during 15 minutes.

Wet capsule crush strength (gel strength) is then measured for both capsules A1a and A1b using a texturometer
10 TA.XT plus from Micro Stable System to compare influence of concentration of calcium (the results are presented on Figure 1).

Wet capsule strength is higher using 1% CaCl₂ solution than using 0.1% CaCl₂ solution.

15 After drying, crush strength of the capsules is measured using a texturometer in compression mode.

	3039/A1a	3039/A1b
Crush strength (dry capsules)	184g	186.6g

The obtained capsules present the following physical
20 characteristics:

diameter: 2mm,
thickness of the shell: 0.096mm,
total weight: 4mg,
weight of the core: 2.8mg (70%),
25 weight of the shell: 1.2mg (30%).

Such capsules are then placed into a clear toothgel and bring nice visual effect of spherical blue capsules liberating menthol when broken.

Example 2

Cinnamon Capsules (referenced as 4053/F1) are prepared by co-extruding an outer liquid phase and an internal liquid phase presenting the following compositions:

5.

Outer liquid phase	%/total	% / dry
Dry matter: 13.0%	weight	matter
gellan	2.000%	15.38%
Sorbitol	1.900%	14.62%
Dextrin Cristal Tex 648	8.500%	65.38%
Sodium citrate	0.200%	1.54%
Calcium citrate	0.100%	0.77%
Titanium dioxide	0.300%	2.31%
Osmosed water	87.000%	100%
	100.000%	
Internal liquid phase	%/total	% without
Ethanol	5,0000%	ethanol
Miglyol 812S	58.9000%	85,79%
Cinnamon	19.6000%	14,21%
Physcool	10.0000%	10.53%
N-ethyl-p-menthane- 3-carboxamide commercially available as WS3	6.5000%	6.84%
Total	100,0000%	100,00%

The obtained capsules are cooled at 4°C for 1h, washed with deionised water and then immersed in a bath containing an aqueous solution containing 1.25% of calcium chloride at pH=3 at T=20°C during 30 minutes.

5

The obtained capsules present the following physical characteristics:

diameter:	1.2mm,
thickness of the shell :	0.053mm,
10 total weight :	0.87mg,
weight of the core:	0.62mg (71.98%),
weight of the shell :	0.24mg (28.02%),

15 Capsules are then incorporated into a toothpaste base containing mint flavour and cinnamon capsules 4053/F1 at a 0.2% use level. During brushing, cinnamon flavour is clearly identified showing good breakability of the capsules.

20 Example 3

Orange capsules (referred as 5053/C1) are prepared by coextruding an outer liquid phase and an internal liquid phase presenting the following compositions:

25

Outer liquid phase	%/total	% / wet
Dry matter: 15.0%	weight	capsule
gellan	2.000%	0.95%
Sorbitol	1.000%	0.45%
Dextrin Cristal Tex	11.4%	5.36%

648		
Sodium citrate	0.200%	0.01%
water	84.5%	40%
	100.000%	
Internal liquid phase	%	%
Orange flavour	19.905%	5.47%
Coconut oil	80%	47.7%
Paprika color	0.095%	0.06%
Total	100,0000%	100,00%

Wet capsule crush strength (gel strength) is then measured using a texturometer TA.XT plus from Micro Stable System. Crushstrength value obtained is 15g and these capsules are easily broken under the teeth.

The obtained capsules present the following physical characteristics:

Diameter : 2.5 mm
 Thickness of the shell: 0.32 mm
 10 Total weight: 8.2 mg

Capsules are then placed into a suspension of xanthan gum to be applied to beverage application. Capsules can be swallowed or broken under the teeth to liberate the flavour into the mouth.

Example 4

Menthol capsules (referred as 5025/B1) are prepared by coextruding an outer liquid phase and an internal liquid phase presenting the following composition:

	% dry capsule		% wet capsule untreated		% wet capsule treated with acid as calcium releasing agent	
	% shell	%/total weight	% shell	%/total weight	% shell	%/total weight
Outer liquid phase						
gellan	13.333%	3.6%	2%	1.423%	2%	1.423%
Sorbitol	6.667%	1.8%	1%	0.712%	1%	0.712%
Dextrin Cristal Tex 648	76%	20.52%	11.4%	8.111%	11.4%	8.111%
Sodium citrate	1.333%	0.360%	0.2%	0.142%	0.2%	0.142%
Citric acid	0.667%	0.180%	0.1%	0.071%	0.1%	0.071%
Unipure blue pigment CI77007	2%	0.54%	0.3%	0.213%	0.3%	0.213%
water	0%	0%	85%	60.480%	85%	60.480%
Internal liquid phase						
ethanol	0%	0%	0%	0%	0%	0%
Miglyol 812S	47.368%	34.579%	47.368%	13.664%	47.368%	13.664%
Menthol codex	52.632%	38.421%	52.632%	15.183%	52.632%	15.183%
Total	100%	73%	100%	28.8%	100%	28.8%
Total		100%		100%		100%

Crush strength	94.31 g	5.09 g	15.09 g
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The treatment of wet capsules with an acid as calcium releasing agent allow the enhancing of the crush strength of the capsules.

*Claims*NEW MAIN REQUEST

1. A seamless breakable capsule comprising a core and a shell, wherein the shell includes a gelling agent comprising gellan gum alone or in combination with another gelling agent,

characterized in that the shell further includes a filler, and a divalent metal sequestering agent selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof, wherein the amount of the filler in the shell is from 50 to 95% by weight on the total dry weight of the shell, the amount of the sequestering agent is at most 2% by weight of the total dry weight of the shell.

2. The seamless breakable capsule according to claim 1, wherein the larger diameter of the capsule is 0.5 mm to 8 mm.

3. The seamless breakable capsule according to claim 1 or 2, wherein the gelling agent is a combination of gellan and one gelling agent selected from the group consisting of gelatin, agar, carrageenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamnan gum or modified starches.

~~3. The seamless breakable capsule according to claim 1 or 2, wherein the amount of gelling agent present in the shell is 4 to 95%, preferably 5 to 75%, even more preferably 10 to 50% by weight of the total dry weight of the shell.~~

4. The seamless breakable capsule according to claim 3, wherein the gelling agent is gellan gum alone.

5. The seamless breakable capsule according to anyone of claims 1 to 3, wherein, when used in combination with at least another gelling agent, the weight ratio between gellan gum and the other gelling agent(s) is from 80/20 to 20/80, preferably 75/25 to 25/75, and even more preferably from 60/40 to 50/50.

6. The seamless breakable capsule according to anyone of claims 1 to 5, wherein the filler is a starch derivative such as dextrin, maltodextrin, cyclodextrin and/or a cellulose derivative such as hydroxypropylmethylcellulose (HPMC), hydroxypropylcellulose (HPC), methylcellulose (MC), polyvinyl alcohols, polyols or mixtures thereof.

~~7. The seamless breakable capsule according to anyone of claims 1 to 6, wherein the amount of the filler in the shell is at most 98.5%, preferably from 25 to 95% and even more preferably from 50 to 80% by weight on the total dry weight of the shell.~~

~~8. The seamless breakable capsule according to anyone of claims 1 to 7, wherein the sequestering agent is a metal salt, preferably selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.~~

~~9. The seamless breakable capsule according to anyone of claims 1 to 8, wherein the amount of sequestering agent is at most 2%, preferably at most 1% and even more preferably at most 0.5% by weight of the total dry weight of the shell.~~

~~10~~ 7. The seamless breakable capsule according to anyone of claims 1 to ~~6~~ 9, wherein the shell further comprises an acid salt selected from the group comprising such as citrate, glucuronate, adipate, fumarate, gluconate and salt of glucono-delta-lactone, and mixtures thereof.

~~11~~ 8. The seamless breakable capsule according to anyone of claims 1 to ~~10~~ 7, having an crush strength from 0.01 to 5 kp.

~~12~~ 9. The seamless breakable capsule according to anyone of claims 1 to ~~8~~ ~~11~~, wherein the amount of plasticizer ranges from 0.1 to 30% by weight, preferably from 2% to 15% by weight and even more preferably from 3 to 10% by weight of the total dry weight of the shell.

~~13~~ 10. The seamless breakable capsule according to anyone of claims 1 to ~~12~~ 9, having an crush strength from 0.01 to 5 kp.

~~14~~ 11. A process for manufacturing a seamless breakable capsule according to anyone of claims 1 to 10, comprising

20 - co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase, and a shell comprising the external and hydrophilic phase,

25 - immersing into an aqueous solution containing a curing agent comprising calcium ions,

wherein the external liquid phase includes ~~a~~ the gelling agent comprising gellan gum alone or in combination

with another gelling agent, ~~a~~ the filler, and ~~a~~ the divalent metal sequestering agent.

45 12. The process for manufacturing a seamless breakable capsule according to claim 14 11, comprising:

- 5 - co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase and a shell comprising the external and hydrophilic phase,
- 10 - optionally solidifying and/or gelling the surface of the shell by keeping the capsule under cold conditions,
- optionally washing the so-obtained capsule with an organic solvent,
- 15 - immersing into an aqueous solution containing a curing agent comprising calcium ions,
- optionally drying the capsule.

~~16. The process for manufacturing a seamless breakable capsule according to claim 14 or 15, wherein the curing agent comprises divalent ions, preferably calcium ions.~~

17 13. The process for manufacturing a seamless breakable capsule according to anyone of claims 14 11 to 16 12, wherein the aqueous solution containing a curing agent is a calcium chloride solution, which pH is preferably of 3 to 4.

18 14. The process for manufacturing a seamless breakable capsule according to anyone of claims 14 11 to 17 13, wherein the gelling agent is a combination of gellan

and at least one other gelling agent selected from the group consisting of gelatin and hydrocolloids such as agar, carragheenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamnan gum or
5 modified starches, and mixtures thereof.

19 15. The process for manufacturing a seamless breakable capsule according to anyone of claims 14 11 to 18 14, wherein the filler is a starch derivative such as dextrin, maltodextrin, cyclodextrin, a cellulose derivative
10 such as HPMC, HPC, MC and mixtures thereof.

20 16. The process for manufacturing a seamless breakable capsule according to anyone of claims 14 11 to 19 15, wherein the sequestering agent is a metal salt, preferably selected from the group comprising sodium
15 carbonate, trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

21 17. The process for manufacturing a seamless breakable capsule according to anyone of claims 14 11 to 20 16, wherein the external hydrophilic liquid phase further comprises a plasticizer, preferably selected from the group consisting of glycerol, sorbitol, maltitol, triacetine or PEG type, or another polyol with plasticizing properties, and mixtures thereof.

25 22 18. Slurry containing breakable capsules according to anyone of claims 1 to 13 10, in suspension in a gel formed with a gel forming agent such CMC, xanthan gum, or Carbopol, and optionally comprising preservatives and stabilizers.

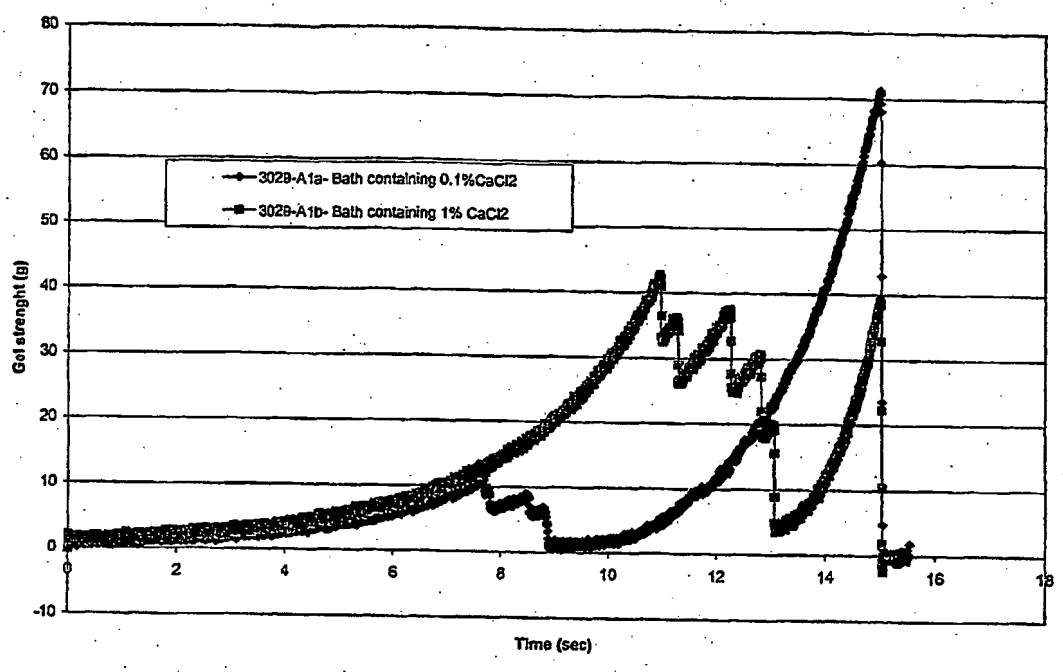
23 19. Food product including breakable capsules according to anyone of claims 1 to ~~13~~ 10.

24 20. Oral care product including breakable capsules according to anyone of claims 1 to ~~13~~ 10.

5 25 21. Pharmaceutical product including breakable capsules according to anyone of claims 1 to ~~13~~ 10.

26 22. Fragrance including breakable capsules according to anyone of claims 1 to ~~13~~ 10.

Fig 1



Claims Currently Pending in Chinese Patent Application No. 200680022457.6

1. A seamless breakable capsule comprising a core and a shell, having a crush strength from 0.01 to 5 kp and being manufactured by a co-extrusion process, comprising:

5 - co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase, and a shell comprising the external and hydrophilic phase,

10 - washing and immersing the capsules into an aqueous solution containing a curing agent,

 wherein the shell includes a gelling agent comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent.

15 2. The seamless breakable capsule according to claim 1, wherein the gelling agent is a combination of gellan gum and one gelling agent selected from the group consisting of gelatin, agar, carrageenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamsan gum or modified starches.

20 3. The seamless breakable capsule according to claim 1, wherein the amount of gelling agent present in the shell is 4 to 95% by weight of the total dry weight of the shell.

25 4. The seamless breakable capsule according to claim 3, wherein the amount of gelling agent present in the shell is 10 to 50% by weight of the total dry weight of the shell.

30 5. The seamless breakable capsule according to claim 1, wherein the gelling agent is gellan gum alone.

6. The seamless breakable capsule according to claim 1, wherein, when used in combination with at least another gelling agent, the weight ratio between gellan gum and the other gelling agent(s) is from 80/20 to 20/80.

5 7. The seamless breakable capsule according to claim 6, wherein the weight ratio between gellan gum and the other gelling agent(s) is from 60/40 to 50/50.

10 8. The seamless breakable capsule according to claim 1, wherein the filler is selected from the group consisting of a starch derivative, a cellulose derivative, polyvinyl alcohols, polyols or mixtures thereof.

15 9. The seamless breakable capsule according to claim 8, wherein said starch derivative is selected from the group consisting of dextrin, maltodextrin, cyclodextrin or mixtures thereof.

 10. The seamless breakable capsule according to claim 8, wherein said cellulose derivative is selected from the group of hydroxypropylmethylcellulose, hydroxypropylcellulose, methylcellulose or mixtures thereof.

20 11. The seamless breakable capsule according to claim 8, wherein the amount of the filler in the shell is from 25 to 95% by weight on the total dry weight of the shell.

25 12. The seamless breakable capsule according to claim 11, wherein the amount of the filler in the shell is from 50 to 80% by weight on the total dry weight of the shell.

30 13. The seamless breakable capsule according to claim 1, wherein the divalent metal sequestering agent is selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

14. The seamless breakable capsule according to claim 13, wherein the amount of divalent metal sequestering agent is at most 2% by weight of the total dry weight of the shell.

5

15. The seamless breakable capsule according to claim 14, wherein the amount of divalent metal sequestering agent is at most 0.5% by weight of the total dry weight of the shell.

10

16. The seamless breakable capsule according to claims 1, wherein the shell further comprises an acid salt selected from the group consisting of citrate, glucuronate, adipate, fumarate, gluconate, a salt of glucono-delta-lactone, and mixtures thereof.

15

17. The seamless breakable capsule according to claim 1, wherein the shell further comprises a plasticizer selected from the group consisting of glycerol, sorbitol, maltitol, triacetine or polyethylene glycol type product and mixtures thereof; the amount of plasticizer ranges from 0.1 to 30% by weight of the total dry weight of the shell.

20

18. The seamless breakable capsule according to claim 17, wherein the amount of plasticizer ranges 3 to 10% by weight of the total dry weight of the shell.

25

19. A process for manufacturing a seamless breakable capsule according to any one of claims 1 to 18, comprising:

- co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase, and a shell comprising the external and hydrophilic phase,

- washing and immersing the capsules into an aqueous solution containing a curing agent, wherein the external liquid phase includes a gelling agent comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent.

20. The process for manufacturing a seamless breakable capsule according to claim 19, comprising:

- co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase and a shell comprising the external and hydrophilic phase,
- optionally solidifying and/or gelling the surface of the shell by keeping the capsule under cold conditions, between 2 °C and 18 °C.
- optionally washing the so-obtained capsule with an organic solvent,
- immersing into an aqueous solution containing a curing agent.
- optionally drying the capsule.

21. The process for manufacturing a seamless breakable capsule according to claim 19, wherein the curing agent comprises calcium ions.

22. The process for manufacturing a seamless breakable capsule according to claim 19, wherein the aqueous solution containing a curing agent is a calcium chloride solution which pH is of 3 to 4.

23. The process for manufacturing a seamless breakable capsule according to claim 19, wherein the gelling agent is a combination of gellan gum and at least one other gelling agent selected from the group consisting of gelatine, agar, carragheenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamsan gum or modified starches, and mixtures thereof.

24. The process for manufacturing a seamless breakable capsule according to claim 19, wherein the filler is selected from the group consisting of dextrin, maltodextrin, cyclodextrin, HPMC, HPC, MC and mixtures thereof.

5 25. The process for manufacturing a seamless breakable capsule according to claim 19, wherein the divalent metal sequestering agent is a metal salt, preferably selected from the group comprising sodium carbonate, trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

10 26. The process for manufacturing a seamless breakable capsule according to claim 19, wherein the external hydrophilic liquid phase further comprises a plasticizer selected from the group consisting of glycerol, sorbitol, maltitol, triacetine, a polyethylene glycol type product, and mixtures thereof.

15 27. Slurry containing seamless breakable capsules according to any one of claims 1 to 18, in suspension in a gel formed with a gel forming agent selected from the group consisting of CMC, xanthan gum, or Carbopol, and optionally comprising preservatives and stabilizers.

20 28. Food product including seamless breakable capsules according to any one of claims 1 to 18.

25 29. Oral care product including seamless breakable capsules according to any one of claims 1 to 18.

30. Pharmaceutical product including seamless breakable capsules according to any one of claims 1 to 18.

31. Fragrance including seamless breakable capsules according to any one of claims 1 to 18.

10 January 2011

A J PARK
DX SP20064
Wellington

RECEIVED

11 JAN 2011

AJ PARK
WELLINGTON OFFICE

Patent Application No: 564191
In the Name of: V. MANE FILS
Your ref: 605534 JVA/TVG/kxc

Examination Report and Notice of Acceptance of Complete Specification

Thank you for your letter of 14 December 2010.

Receipt of amended page 26 and page 26 showing amendments is acknowledged.

The applicant is notified under section 20(2) of the Patents Act 1953 that patent application 564191 has been accepted as of **10 January 2011**. Acceptance of 564191 will be advertised in Journal No. 1579 to be published on **28 January 2011**.

Please note a Notice of Opposition to the grant of the Letters Patent may be filed by any interested party up to 3 months from the date of issue of the journal, or 4 months if an extension is obtained.

If no Notice of Opposition is received your application will be sealed and Letters Patent granted as prescribed. The date of sealing shall be entered in the Register of Patents.

For information on this patent please go to our website: www.iponz.govt.nz.

Please contact me if you have any questions.

Yours sincerely



Steve Smith
Principal Patent Examiner
For Commissioner of Patents, Trade Marks and Designs
Phone: +64 4 978 3626
www.iponz.govt.nz/online-services

WHAT WE CLAIM IS:

1. A seamless breakable capsule comprising a core and a shell, wherein the shell includes a gelling agent comprising gellan gum alone or in combination with another
5 gelling agent, wherein the shell further includes a filler and a divalent metal sequestering agent selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof, wherein the amount of the filler in the
10 shell is from 25 to 95% by weight of the total dry weight of the shell, the amount of the divalent metal sequestering agent is at most 2% by weight of the total dry weight of the shell.
2. The seamless breakable capsule according to
15 claim 1, wherein the gelling agent is a combination of gellan gum and one gelling agent selected from the group consisting of gelatin, agar, carrageenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamsan gum or modified starches.
- 20 3. The seamless breakable capsule according to claim 1 or 2, wherein the amount of gelling agent present in the shell is 4 to 95% by weight of the total dry weight of the shell.
4. The seamless breakable capsule according to claim
25 1 or 2, wherein the amount of gelling agent present in the shell is 10 to 50% by weight of the total dry weight of the shell.
5. The seamless breakable capsule according to any one of claims 1, 3 or 4, wherein the gelling agent is
30 gellan gum alone.
6. The seamless breakable capsule according to anyone of claims 1 to 4, wherein, when used in combination

with at least another gelling agent, the weight ratio between gellan gum and the other gelling agent(s) is from 80/20 to 20/80, preferably 75/25 to 25/75, and even more preferably from 60/40 to 50/50.

5 7. The seamless breakable capsule according to anyone of claims 1 to 6, wherein, when used in combination with at least another gelling agent, the weight ratio between gellan gum and the other gelling agent(s) is from 60/40 to 50/50.

10 8. The seamless breakable capsule according to anyone of claims 1 to 7, wherein the filler is a starch derivative such as dextrin, maltodextrin, cyclodextrin and/or a cellulose derivative such as hydroxypropylmethylcellulose (HPMC), hydroxypropylcellulose
15 (HPC), methylcellulose (MC), polyvinyl alcohols, polyols or mixtures thereof.

 9. The seamless breakable capsule according to anyone of claims 1 to 8, wherein the amount of the filler in the shell is from 50 to 80% by weight of the total dry
20 weight of the shell.

 10. The seamless breakable capsule according to anyone of claims 1 to 9, wherein the amount of sequestering agent is at most 0.5% by weight of the total dry weight of the shell.

25 11. The seamless breakable capsule according to anyone of claims 1 to 10, wherein the shell further comprises an acid salt selected from the group comprising such as citrate, glucuronate, adipate, fumarate, gluconate and salt of glucono-delta-lactone, and mixtures thereof.

12. The seamless breakable capsule according to anyone of claims 1 to 11, having a crush strength from 0.01 to 5 kp.

5 13. The seamless breakable capsule according to anyone of claims 1 to 12, wherein the amount of plasticizer is from 0.1 to 30% by weight of the total dry weight of the shell.

10 14. The seamless breakable capsule according to anyone of claims 1 to 13, wherein the amount of plasticizer is from 3 to 10% by weight of the total dry weight of the shell.

15 15. The seamless breakable capsule according to anyone of claims 1 to 14, having an crush strength from 0.01 to 5 kp.

16. A process for manufacturing a seamless breakable capsule, comprising

20 - co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase, and a shell comprising the external and hydrophilic phase,

- immersing into an aqueous solution containing a curing agent comprising calcium ions, wherein the external liquid phase includes a gelling agent
25 comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

30 17. The process for manufacturing a seamless breakable capsule according to claim 16, comprising:

- co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase and a shell comprising
5 the external and hydrophilic phase,

- solidifying and/or gelling the surface of the shell by keeping the capsule under cold conditions,

- washing the so-obtained capsule with an organic solvent,

10 - immersing into an aqueous solution containing a curing agent.

18. The process for manufacturing a seamless breakable capsule according to anyone of claims 16 to 17, wherein the aqueous solution containing a curing agent is a
15 calcium chloride solution, which pH is of 3 to 4.

19. The process for manufacturing a seamless breakable capsule according to anyone of claims 16 to 18, wherein the gelling agent is a combination of gellan and at least one other gelling agent selected from the group
20 consisting of gelatin and hydrocolloids such as agar, carragheenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamsan gum or modified starches, and mixtures thereof.

20. The process for manufacturing a seamless
25 breakable capsule according to anyone of claims 16 to 19, wherein the filler is a starch derivative such as dextrin, maltodextrin, cyclodextrin, a cellulose derivative such as HPMC, HPC, MC and mixtures thereof.

21. The process for manufacturing a seamless
30 breakable capsule according to anyone of claims 16 to 20, wherein the external hydrophilic liquid phase further comprises a plasticizer selected from the group consisting

of glycerol, sorbitol, maltitol, triacetine or PEG type, or another polyol with plasticizing properties, and mixtures thereof.

22. Slurry containing breakable capsules according to anyone of claims 1 to 15, in suspension in a gel formed with a gel forming agent such CMC, xanthan gum, or Carbopol.

23. Food product including breakable capsules according to anyone of claims 1 to 15

10 24. Oral care product including breakable capsules according to anyone of claims 1 to 15.

25. Pharmaceutical product including breakable capsules according to anyone of claims 1 to 15.

15 26. Fragrance including breakable capsules according to anyone of claims 1 to 15.

27. Any invention as described or claimed herein.

CLAIMSwith apparent amendments

1. A co-extruded seamless breakable capsule comprising a core and a shell, wherein the shell includes a gelling agent comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent.

2. The co-extruded seamless breakable capsule of claim 1, wherein the shell comprises :

10 (i) an underneath layer of gelling agent comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent, and

(ii) an outer layer comprising traces amount of curing agent.

15 3. The co-extruded seamless breakable capsule according to claim 2, wherein the curing agent is selected from the group of divalent metal salt and organic acid and mixtures thereof.

20 4. The co-extruded seamless breakable capsule according to any claims 1 to 3, wherein the larger diameter of the capsule is 0.5 mm to 8 mm.

5. The co-extruded seamless breakable capsule according to claims 1 and 2 wherein the sequestering agent selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

25 26. The co-extruded seamless breakable capsule according to any claims 1 to 5, wherein the gelling agent is a combination of gellan gum and one gelling agent selected from the group consisting of gelatin, agar, carrageenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamsan gum or modified starches.

30 37. The co-extruded seamless breakable capsule according to claim 1 or 2, wherein the amount of gelling agent

present in the shell is 4 to 95%, ~~preferably 5 to 75%, even more preferably is 10 to 50%~~ by weight of the total dry weight of the shell.

48. The co-extruded seamless breakable capsule according to claim ~~31~~, wherein the gelling agent is gellan gum alone.

59. The co-extruded seamless breakable capsule according to ~~any one of claims 1 to 3~~, wherein, when used in combination with at least another gelling agent, the weight ratio between gellan gum and the other gelling agent(s) is from 80/20 to 20/80, ~~preferably 75/25 to 25/75, and even more preferably from 60/40 to 50/50.~~

6 10. The co-extruded seamless breakable capsule according to ~~any one of claims 1 to 5~~, wherein the filler is selected from the group consisting of a starch derivative selected from the group consisting of such as dextrin, maltodextrin, cyclodextrin, and/or a cellulose derivative such as ~~hydroxypropylmethylecellulose (HPMC), hydroxypropylcellulose (HPC), methylcellulose (MC)~~, polyvinyl alcohols, polyols or mixtures thereof.

7 11. The co-extruded seamless breakable capsule according to ~~any one of claims 1 to 6~~ 10, wherein the amount of the filler in the shell is ~~at most 98.5%, preferably from 25 to 95% and even more preferably from 50 to 80%~~ by weight on the total dry weight of the shell.

8 12. The co-extruded seamless breakable capsule according to ~~any one of claims 1 to 7~~, wherein the divalent metal sequestering agent is a ~~metal salt~~, preferably selected from the group consisting of trisodium citrate, trisodium phosphate, tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

9 13. The co-extruded seamless breakable capsule according to ~~any one of claims 1 to 8~~ 13, wherein the amount of sequestering agent is at most 2%, ~~preferably at most 1% and even more preferably at most 0.5%~~ by weight of the total dry weight of the shell.

1014. The co-extruded seamless breakable capsule according to ~~any one of~~ claims 1 ~~to~~ 9, wherein the shell further comprises an acid salt selected from the group consisting of ~~comprising such as~~ citrate, glucuronate, adipate, fumarate, gluconate, ~~and a~~ salt of glucono-delta-lactone, and mixtures thereof.

~~11~~ 15. The co-extruded seamless breakable capsule according to any one of claims 1 to 14 ~~10~~, having a crush strength from 0.01 to 5 kp.

10 ~~12~~ 16. The co-extruded seamless breakable capsule according to ~~any one of~~ claims 1 ~~to~~ 11, wherein the shell further comprises a plasticizer, ~~preferably~~ selected from the group consisting of glycerol, sorbitol, maltitol, triacetine or polyethylene glycol type product, ~~or another polyol with~~ plasticizing properties, and mixtures thereof; the amount of plasticizer ranges from 0.1 to 30% by weight, ~~preferably from 2% to 15% by weight and even more preferably from 3 to 10% by weight of the total dry weight of the shell.~~

20 ~~13. The seamless breakable capsule according to any one of claims 1 to 12, having an crush strength from 0.01 to 5 kp.~~

~~14~~ 17. A process for manufacturing a co-extruded seamless breakable capsule according to any one of claims 1 to 16, comprising:

25 - co-extruding an external and hydrophilic liquid phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase, and a shell comprising the external and hydrophilic phase,

30 - washing and immersing the capsules into an aqueous solution containing a curing agent, wherein the external liquid phase includes a gelling agent comprising gellan gum alone or in combination with another gelling agent, a filler, and a divalent metal sequestering agent.

35

~~15~~18. The process for manufacturing a co-extruded seamless breakable capsule according to claim ~~14~~17, comprising:

- co-extruding an external and hydrophilic liquid
5 phase, and an internal and lipophilic liquid phase, in order to form a capsule constituted of a core comprising the internal and lipophilic phase and a shell comprising the external and hydrophilic phase,
- optionally solidifying and/or gelling the surface
10 of the shell by keeping the capsule under cold conditions, between 2 °C and 18 °C,
- optionally washing the so-obtained capsule with an organic solvent,
- immersing into an aqueous solution containing a
15 curing agent.
- optionally drying the capsule.

~~16~~19. The process for manufacturing a co-extruded seamless breakable capsule according to claim ~~14 or 15~~17, wherein the curing agent comprises ~~divalent ions, preferably~~
20 calcium ions.

~~17~~20. The process for manufacturing a co-extruded seamless breakable capsule according to ~~any one of claims 14 to 16~~21, wherein the aqueous solution containing a curing agent is a calcium chloride solution, which pH is ~~preferably~~
25 of 3 to 4.

~~18~~21. The process for manufacturing a co-extruded seamless breakable capsule according to ~~any one of claims 14 to 17~~17, wherein the gelling agent is a combination of gellan gum and at least one other gelling-agent selected from the
30 group consisting of gelatine, ~~and hydrocolloids such as agar, carragheenan, pectins, xanthan gum, cellulose gum, alginate, dextran, curdlan, welan gum, rhamsan gum or modified starches, and mixtures thereof.~~

~~19~~22. The process for manufacturing a co-extruded seamless breakable capsule according to ~~any one of claims 14~~
35

21

~~to 1817~~, wherein the filler is a ~~starch derivative~~ selected from the group consisting of ~~such as~~ dextrin, maltodextrin, cyclodextrin, a cellulose derivative such as HPMC, HPC, MC and mixtures thereof.

5 2023. The process for manufacturing a co-extruded seamless breakable capsule according to ~~any one of claims 14 to 17~~, wherein the divalent metal sequestering agent is a metal salt, preferably selected from the group comprising sodium carbonate, trisodium citrate, trisodium phosphate, 10 tetrasodium pyrophosphate, sodium hexametaphosphate and mixtures thereof.

15 2124. The process for manufacturing a co-extruded seamless breakable capsule according to ~~any one of claims 14 to 20~~17, wherein the external hydrophilic liquid phase further comprises a plasticizer, ~~preferably~~ selected from the group consisting of glycerol, sorbitol, maltitol, triacetine, ~~or PEG type~~ a polyethylene glycol type product, or another polyol with plasticizing properties, and mixtures thereof.

20 2225. Slurry containing co-extruded seamless breakable capsules according to any one of claims 1 to ~~13~~16, in suspension in a gel formed with a gel forming agent ~~such~~ selected from the group consisting of CMC, xanthan gum, or Carbopol, and optionally comprising preservatives and stabilizers.

25 2326. Food product including co-extruded seamless breakable capsules according to any one of claims 1 to ~~13~~16.

 2427. Oral care product including co-extruded seamless breakable capsules according to any one of claims 1 to ~~13~~16.

30 2528. Pharmaceutical product including co-extruded seamless breakable capsules according to any one of claims 1 to ~~13~~16.

 2629. Fragrance including co-extruded seamless breakable capsules according to any one of claims 1 to ~~13~~16.