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Pedro Castillo Pineda & Asociados
ABOGADOS

SUPERINDUSTRIA Y COMERCIO
Radicacion : 04059671 00000001 Folios: 18
Fecha (AMD): 2005-02-02 17:02:25
Tramite : 002 PATENTES D 1 REGISTRO/ 329 COMPLEMEN
Dependencia: 2020 DIVISION DE NUEVAS CREACIONES

SUPERINTENDENCIA DE INDUSTRIA Y C
División de Nuevas Creaciones
E. S. D.

Ref: Expediente No. 04-059671
Solicitud de patente a nombre
de KRAFT FOODS HOLDINGS, INC

En el asunto de la referencia me permito presentarla copia certificada del documento original de cesión de la invención para los Estados Unidos, que comprende ademásel resto de paises del mundo.

Como el expediente esta completo, pido se ordene su tramite.

Atentamente,

JERONIMO CASTILLO BONILLA
C.C. 79.462.057 Bog tá
T.P. 104167 C.S. Judicatura

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A 1270454

THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

January 12, 2005

THIS IS TO CERTIFY THAT ANNEXED IS A TRUE COPY FROM THE RECORDS OF THIS OFFICE OF A DOCUMENT RECORDED ON June 27, 2003.

By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

L. Edelen

L. EDELEN
Certifying Officer

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19704 U.S. PTO
10/609300

07-14-2003

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FORM PTO-1595 (Rev. 10/02) OMB No. 0651-0027 (exp 6/30/2005) 6-27-03

RECORDATION FORM COVER SHEET

U.S. DEPARTMENT OF COMMERCE
Patent and Trademark Office

Attorney Docket No. 77008

To the Director of the United States Patent and Trademark Office: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies):

Kenneth William Cale — Donna Maria Parker
Patricia Carulli Hauser — Jean-Pierre Barli
Zachary Pollack Caplan — Randolph Myers

Additional name(s) of conveying party(ies) attached? ☐ Yes ■ No

2. Name and address of receiving party(ies)

Name: Kraft Foods Holdings, Inc.
Internal Address:
Street Address: Three Lakes Drive
City: Northfield State: IL ZIP: 60093

Additional name(s) and address(es) attached? ☐ Yes ■ No

3. Nature of conveyance:

■ Assignment ☐ Merger
☐ Security Agreement ☐ Change of Name
☐ Other

Execution Date: 6/19/03, 6/20/03, 6/23/03, 6/25/03, 6/26/03

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: June 27, 2003

A. Patent Application No.(s)
10/609300

B. Patent No.(s)

Additional numbers attached? ☐ Yes ■ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Richard A. Kaba
FITCH, EVEN, TABIN & FLANNERY
Internal Address:
Street Address: Suite 1600
120 South LaSalle Street
City: Chicago State: IL ZIP: 60603-3406

6. Total number of applications and patents involved: 1

7. Total fee (37 CFR 3.41).....$ 40.00
☐ Enclosed
■ Authorized to be charged to deposit account

8. Deposit Account Number:
06-1135
(Attach duplicate copy of this page if paying by deposit account)

07/21/2003 [illegible] 00000080 06-1135 10609300
01 FC:8021 40.00 DA

DO NOT USE THIS SPACE

9. Statement and signature.
To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.

Richard A. Kaba	30,562		6/27/03
Name of Person Signing	Registration No.	Signature	Date

Total number of pages including cover sheet, attachments, and document: 6

Fax documents to be recorded with required cover sheet information to (703) 306-5995
Mail documents to be recorded with required cover sheet information to:
Mail Stop Assignment Recordation Services, Director of the United States Patent and Trademark Office
P.O. Box 1450, Alexandria, VA 22313-1450

Attorney Docket 77008

ASSIGNMENT

We, KENNETH WILLIAM CALE, City of Suffern, State of New York, DONNA MARIA PARKER, City of Nanuet, State of New York, PATRICIA CARULLI HAUSER, City of Highland Mills, State of New York, JEAN-PIERRE BARIL, City of Fishkill, State of New York, ZACHARY POLLACK CAPLAN, City of Tarrytown, State of New York, and RANDOLPH MYERS, City of New Haven, State of Connecticut, of for good and valuable consideration, have assigned and do hereby assign to KRAFT FOODS HOLDINGS, INC., a IL corporation, with its principal place of business at Three Lakes Drive, Northfield, IL 60093, its successors, assigns and legal representatives, the entire right, title and interest in and to all subject matter invented by us and disclosed in the application for Letters Patent of the United States entitled

NUTRITIONAL NON-CULTURED BEVERAGE COMPOSITION

signed by each of us contemporaneously with his execution of this assignment; and in and to all Letters Patent and all Convention and Treaty rights of all kinds, in all countries throughout the world, for all such subject matter. We agree to sign all documents necessary to secure all said Letters Patent and rights, and request issuance of all said Letters Patent to the above assignee in accordance with this assignment.

6/23, 2003 — Kenneth William Cale

6/25, 2003 — Donna Maria Parker

6/24, 2003 — Patricia Carulli Hauser

6/20, 2003 — Jean-Pierre Baril

6/20, 2003 — Zachary Pollack Caplan

6/19, 2003 — Randolph Myers

State of NEW YORK)
County of Westchester) ss

I hereby certify that before me in the County of Westchester, in the State of New York, personally appeared KENNETH WILLIAM CALE, personally known by me, who then and there was duly sworn by me, and under oath acknowledged that the foregoing assignment was duly signed, sealed, and delivered by him on the date appearing at the foot thereof.

June 23, 2003

Thomas A Marcoux
Notary Public
My Commission Expires:

THOMAS A. MARCOUX
Notary Public, State of New York
No. 02MA4809928
Qualified in Nassau County
Commission Expires 4/30/2006

State of NEW YORK)
County of Westchester) ss

I hereby certify that before me in the County of Westchester, in the State of New York, personally appeared DONNA MARIA PARKER, personally known by me, who then and there was duly sworn by me, and under oath acknowledged that the foregoing assignment was duly signed, sealed, and delivered by him on the date appearing at the foot thereof.

June 25, 2003

Thomas A Marcoux
Notary Public
My Commission Expires:

THOMAS A. MARCOUX
Notary Public, State of New York
No. 02MA4809928
Qualified in Nassau County
Commission Expires 4/30/2006

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State of NEW YORK)
) ss
County of Westchester)

I hereby certify that before me in the County of Westchester, in the State of New York, personally appeared PATRICIA CARULLI HAUSER, personally known by me, who then and there was duly sworn by me, and under oath acknowledged that the foregoing assignment was duly signed, sealed, and delivered by him on the date appearing at the foot thereof.

June 26, 2003 Thomas A Marcoux
Notary Public
My Commission Expires:

THOMAS A. MARCOUX
Notary Public, State of New York
No. 02MA4606928
Qualified in Nassau County
Commission Expires 4/20/2006

State of NEW YORK)
) ss
County of Westchester)

I hereby certify that before me in the County of Westchester, in the State of New York, personally appeared JEAN-PIERRE BARIL, personally known by me, who then and there was duly sworn by me, and under oath acknowledged that the foregoing assignment was duly signed, sealed, and delivered by him on the date appearing at the foot thereof.

June 20, 2003 Thomas A Marcoux
Notary Public
My Commission Expires:

THOMAS A. MARCOUX
Notary Public, State of New York
No. 02MA4606928
Qualified in Nassau County
Commission Expires 4/20/2006

State of NEW YORK)
County of Westchester) SS

I hereby certify that before me in the County of Westchester, in the State of New York, personally appeared ZACHARY POLLACK CAPLAN, personally known by me, who then and there was duly sworn by me, and under oath acknowledged that the foregoing assignment was duly signed, sealed, and delivered by him on the date appearing at the foot thereof.

June 20, 2003

Thomas A Marcoux
Notary Public
My Commission Expires:

THOMAS A. MARCOUX
Notary Public, State of New York
No. 02MA4606926
Qualified in Nassau County
Commission Expires 4/20/2006

State of CONNECTICUT)
County of Westchester) SS

I hereby certify that before me in the County of Westchester, in the State of Connecticut, personally appeared RANDOLPH MYERS, personally known by me, who then and there was duly sworn by me, and under oath acknowledged that the foregoing assignment was duly signed, sealed, and delivered by him on the date appearing at the foot thereof.

June 19, 2003

Thomas A Marcoux
Notary Public
My Commission Expires:

THOMAS A. MARCOUX
Notary Public, State of New York
No. 02MA4606926
Qualified in Nassau County
Commission Expires 4/20/2006

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DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. **04- 59671**

EL EXTRACTO DE LA PRESENTE SOLICITUD DE **PATENTE DE INVENCION ,**

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No **553** DE

FECHA **30** DE **JUNIO** DE **2005**, EL TERMINO HABIL SEÑALADO POR LA LEY

EXPIRA EL **27** DE **SEPTIEMBRE** DE **2005**.

NOTA: Dentro del plazo de los seis (6) meses siguientes a partir de la fecha de publicación en la gaceta de Propiedad Industrial, deberá solicitar y cancelar el examen de patentabilidad so pena de que la solicitud caiga en abandono, de acuerdo con lo establecido en el Artículo 44 de la Decisión 486/2000.

SE PRESENTARON OPOSICIONES POR PARTE DE TERCEROS.

SI ____ _____ NO ____ **X** ____

Carrera 13 No. 27-00 Piso 5 y 10
Conmutador: 334 12 21-2-3-4
Fax: 281 31 25 e-mail: info@sic.gov.co
Santa Fe de Bogotá D.C. - Colombia

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SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
CONSULTA DE ACTUACIONES DE NUEVAS CREACIONES
Miercoles 2 de Mayo de 2007

Cerrar Ventana

No.	Radicación	Evento	Actuación	Fecha	Sistema	Folios	Persona
1	4-59671 0 0	REGISTRO/DEPOSITO/CO	PRESENTACION	24/06/2004	TRAMITES	62	CASTILLO BONILLA JERONIMO
2	4-59671 0 0	REGISTRO/DEPOSITO/CO	ORDEN DE PUBLICACION	30/07/2004	PATENTES	0	adpa9
3	4-59671 0 0	REGISTRO/DEPOSITO/CO	PARA PUBLICAR FECHA POSTERIOR	30/07/2004	RUTA	0	adpa9
4	4-59671 0 1	REGISTRO/DEPOSITO/CO	COMPLEMENTO DE INFORMACION	02/02/2005	TRAMITES	10	CASTILLO BONILLA JERONIMO
5	4-59671 0 2	REGISTRO/DEPOSITO/CO	PETICION DE EXAMEN	11/11/2005	TRAMITES	2	CASTILLO BONILLA JERONIMO

SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES

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Bogotà, D.C.

Doctor
Jerònimo Castillo Bonilla
Apoderado

Oficio No. 07147

REFERENCIA: Radicación No. 04-59671
Tràmite 002
Evento 001
Actuación 430
Folios 015

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

1. DOCUMENTOS ESTUDIADOS.

- Capitulo descriptivo: folios 8 al 18
- Capitulo reivindicatorio: folios 19 al 21

Se acepta reivindicación de prioridad US 10/609300 del 27 de Junio de 2003.

2. OBJETO DE LA INVENCION.

Titulo: "Bebida nutritiva sin cultivos"

La invención se refiere a :

- Bebida nutritiva que contiene: 1) un componente de proteìna que comprende proteìna de leche 2) un componente de grasa làctea emulsificada 3) un componente de fortificaciòn que comprende vitaminas y minerales 4) agua. Los contenidos son: 1.5 a 10% de proteìna total y 0.15 a 5% de grasa total en donde la bebida tiene una primera proporción de la proteìna de leche siendo esta mayor que igual o alrededor de 0.45; en donde la bebida tiene una segunda proporción de la grasa diaria siendo esta mayor que o igual a 0.33 y en donde el componente de fortificaciòn aporta como mìnimo 10% del valor diario, por porciòn ùnica de bebida; de por lo menos 6 vitaminas y minerales.
- Bebida nutritiva en donde la proteìna total es alrededor del 1.5 a 6% y la grasa total es alrededor de 0.5 a 3.5%; esta bebida también comprende edulcorante de 0.001 a 15%.
- Bebida nutritiva en donde la proteìna total es alrededor de 2 a 4.5% y el componente edulcorante esta presente entre 0.003 a alrededor de 12%. El componente de fortificaciòn aporta como mìnimo alrededor del 20% del valor diario, por porciòn ùnica de bebida, de por lo menos 10 vitaminas y minerales.
- Bebida nutritiva sin cultivos que comprende: 1) un componente de proteina que comprende proteìna de leche con procesamiento mìnimo, concentrado de proteìna làctea y proteìna no làctea. 2) Un componente de grasa emulsificada que comprende grasa làctea y grasa no làctea 3) Un componente de fortificaciòn que comprende vitaminas y minerales 4) agua.

- La bebida descrita anteriormente contiene alrededor de 1.5 a alrededor de 10% de proteina total y alrededor de 0.15 a alrededor de 5% de grasa total; en donde la bebida tiene una primera proporción mayor que o igual o alrededor de 0.45 con respecto a proteina. Tambièn tiene una segunda proporción de grasa que es mayor o igual alrededor de 0.33 y donde el componente de fortificaciòn aporta como mìnimo 10% del valor diario , por porciòn ùnica de bebida; de por lo menos 6 vitaminas y minerales.
- La bebida descrita anteriormente contiene edulcorante. La primera proporción es mayor que alrededor de 0.65 y la segunda proporción es mayor que alrededor y la segunda proporción es mayor que alrededor de 0.67. Como forma especifica la primera proporción es mayor que alrededor 0.8 y la segunda proporción es mayor que alrededor de 0.9.
- La bebida tiene un contenido de proteina total 1.5 a alrededor del 6%, la grasa total esta alrededor de 0.5 a alrededor del 3.5% y el componente edulcorante està presente en alrededor de 0.001 a alrededor de 15%.
- El componente de fortificaciòn de la bebida aporta como mìnimo alrededor del 20% del valor diario, por porciòn ùnica de bebida, de por lo menos 10 vitaminas y minerales.

Clasificaciòn Internacional de Patentes: A23 C 23/00

3. **CLARIDAD DE LA SOLICITUD**.

De acuerdo a la Decisión 486 de la Comisión de la Comunidad Andina en su Artículo 30.- "*Las reivindicaciones definirán la materia que se desea proteger mediante la patente. Deben ser claras y concisas y estar enteramente sustentadas por la descripción*"; se hacen las siguientes observaciones al capitulo reivindicatorio:

En la reivindicación 1 se presenta una bebida nutritiva de alta calidad la cual esta constituida por: proteína cuyo origen es proteína de leche; grasa láctea emulsificada; vitaminas y minerales y agua. Los rangos presentados para el contenido de proteína total y grasa total; son muy amplios y se utiliza el término "alrededor de" , el cual produce ambigüedad en la reivindicación ya que de esta forma no es posible establecer el contenido exacto de proteína y grasa; contenidos que se deberían indicar con mucha exactitud ya que en términos de patentes los productos son definidos en términos de los componentes que conforman la composición así como de los contenidos que se encuentren de tales compuestos. De tal manera que esta reivindicación, en la cual se presenta el producto de bebida láctea es necesario que se indiquen todos los componentes que se encuentren en la misma; así como las proporciones o concentraciones de los mismos. Por lo tanto, en esta reivindicación no se contempla el contenido de las vitaminas y minerales que se encuentran en la bebida, por lo que es necesario establecerlos para que la reivindicación 1 reúna las características de claridad y concisión suficientes para continuar con el estudio de patentabilidad.

De igual forma se esta presentando para la reivindicación independiente 10 una bebida nutritiva de alta calidad; la cual contempla un origen de proteína y grasa diferente al lácteo. Al especificar los tipos de proteínas que se pueden encontrar en la composición así como los ácidos grasos que conforman la grasa de la composición Esa reivindicación no sería necesaria si en la reivindicación 1 se especificaran las fuetes de proteína y grasa

La forma de presentar los contenidos de proteína y grasa por medio de una primera y una segunda proporción le resta claridad a la solicitud ya que se presenta de una forma confusa.

En la reivindicación 1 se presenta la proporción de proteína y grasa que la bebida aporta en términos nutricionales, esto es una característica del producto la cual refleja la ventaja que el producto pueda tener con respecto a otras bebidas pero , estas proporciones, no establecen los contenidos de grasa y proteína que puede presentar el producto; por lo tanto esta información no debería ser presentada dentro del capitulo reivindicatorio ya que es un parámetro que no indica proporciones en su composición y por tanto no es relevante la definición del mismo.

En la reivindicación 4 se esta presentando un rango màs estrecho para proteina y grasa ; este rango màs especìfico deberìa ser presentado en la reivindicaciòn 1.

En la reivindicaciòn 5 se esta presentando un edulcorante como uno de los componentes de la composición; este compuesto edulcorante no se habìa mencionado en la reivindicaciòn 1; por lo tanto se podrìa considerar que en la solicitud se contempla otra composición en la cual se tiene el edulcorante como un compuesto adicional. Por lo tanto, se le recuerda al solicitante que en la reivindicación independiente 1 de la solicitud se deben especificar todos los componentes que forman parte de la composición para que en esta reivindicaciòn se encuentre delimitada la materia que se desea proteger y las formas preferidas de la invenciòn se van indicando en las reivindicaciones dependientes que se deriven de la reivindicaciòn independiente; con el fin de delimitar y definir aùn màs la materia objeto de la protecciòn pero en ningún momento ampliar la materia contenida en la reivindicaciòn independiente. De otra parte, el rango de concentración en el cual se encuentra el edulcorante es muy amplio, por lo que deberìa presentarse de una forma màs especìfica.

Las reivindicaciones dependientes 7, 8 y 9 se encuentran referidas al componente de fortificaciòn que se encuentra en la bebida; a este respecto se contempla que dicho componente de fortificaciòn: "aporta como mìnimo alrededor de 20 por ciento del valor diario, por porciòn ùnica de bebida, de por lo menos 10 vitaminas y minerales". Estas reivindicaciones se encuentran formuladas de una forma muy general ya que no especifican las 10 vitaminas a las que están haciendo referencia, y tampoco están indicando las concentraciones en las cuales se encuentran tales vitaminas. El aporte nutricional que realice tal componente de fortificaciòn a la bebida no define composición por lo que este parámetro no debe contemplarse en el capitulo reivindicatorio. De otra parte, la materia que se encuentra contenida en las reivindicaciones mencionadas; es la misma en cada una de ellas ya que las dependencias que se están planteando se encuentran haciendo alusiòn a la misma composición.

En la reivindicación 10 se esta presentando una bebida nutritiva, sin cultivos, lista para tomar; dentro de los componentes de dicha bebida se encuentran contemplando una fuente adicional de proteína como es la proteína no láctea de igual manera se considera como otra fuente de grasa la que no proviene de un producto lácteo; los contenidos para grasa y proteína son los mismos que los contemplados en la bebida nutritiva presentada en la reivindicación 1.

En las reivindicaciones 12 a 15 se están presentando los valores para las proporciones de proteína y grasa que aporta la bebida; éste parámetro no indica la concentración de dichos componentes en la bebida; que finalmente es la característica técnica principal para definir el producto objeto de la solicitud. También se observa que tal como se encuentran presentadas las reivindicaciones, estas se encuentran contemplando la misma materia.

En las reivindicaciones 18 a 20 se encuentra presentada la misma materia ya que en las dependencias que presenta no se evidencia de una forma clara las caracterìsticas tècnicas que diferencian la materia presentada en tales reivindicaciones.

En las reivindicaciones independientes 1 y 10 no es posible definir las características técnicas nuevas e inventivas que pueda presentar la bebida nutritiva ya que, tal como se encuentra presentada, la reivindicación no es fácilmente identificable el preámbulo y la parte característica de la misma. Por lo tanto, es necesario plantear dichas reivindicaciones en dos partes; la primera de ellas que contenga el preámbulo de la reivindicaciòn y donde se presentan las características técnicas del producto que se encuentren descritas en el estado de la tècnica. La otra parte de la reivindicaciòn es la parte caracterìstica; la cual debe presentar las caracterìsticas tècnicas que representen los aspectos nuevos e inventivos del producto.

A lo largo de capitulo reivindicatorio se encuentra el tèrmino "procesamiento mìnimo" el cual no es claro; ya que no se encuentra definiendo el tipo de proteìna que se utiliza en la composición.

Por lo anteriormente expuesto la solicitud no cumple con lo establecido en el artc. 30 de la Decisión, se deben realizar los ajustes correspondientes en dicha solicitud.

4. DETERMINACIÓN DEL ESTADO DE LATÉCNICA

Tomando como base lo anterior y la definición dada en el **art. 16.-** "Una invención se considerará nueva cuando no está comprendida en el estado de la técnica.
El estado de la técnica comprenderá todo lo que haya sido accesible al público por una descripción escrita u oral, utilización, comercialización o cualquier otro medio antes de la fecha de presentación de la solicitud de patente o, en su caso, de la prioridad reconocida.

Sólo para el efecto de la determinación de la novedad, también se considerará dentro del estado de la técnica, el contenido de una solicitud de patente en trámite ante la oficina nacional competente, cuya fecha de presentación o de prioridad fuese anterior a la fecha de presentación o de prioridad de la solicitud de patente que se estuviese examinando, siempre que dicho contenido esté incluido en la solicitud de fecha anterior cuando ella se publique o hubiese transcurrido el plazo previsto en el artículo 40." . *A pesar de la falta de claridad de la solicitud se procediò a hacer una bùsqueda parcial de anterioridades en los archivos con que cuenta esta Oficina y se encontraron los siguientes documentos relacionados con la materia de la presente solicitud*:

N°	DOCUMENTO	TITULO	FECHA DE PUBLICACION
D1	US 4,303,692	Infant milk formula	1981-12-01
D2	EP0705539 A2	A food for pregnante and lactating women.	1996-04-10

Los documentos mencionados se anexan al expediente.

Una vez se realicen los ajustes necesarios a la solicitud; se completarà la bùsqueda de anterioridades.

7. EVALUACIÓN DE LOS REQUISITOS DE PATENTABILIDAD

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

En cumplimiento del artículo 14 de la Decisión 486, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

7.1 Evaluación del NIVEL INVENTIVO

De acuerdo al **art. 18.-** "*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.*", se conceptúa:

La anterioridad D1 presenta una fòrmula làctea que es utilizada en la nutriciòn de niños, esta fòrmula es lìquida y se basa en leche de vaca la fòrmula propuesta en a invenciòn principalmente se caracteriza por contener taurina o mezclas de taurina y colesterol la cual es considerada como nutricionalmente adecuada para promover el crecimiento y desarrollo normal de bebes que se encuentren en una edad aproximadamente de 12 meses. La composición de la fòrmula propuesta se basa en leche de vaca o de otros animales y otros constituyentes que provienen de fuentes variadas incluyendo pescado o fuentes de origen vegetal. La fòrmula contiene vitaminas liposolubles e hidrosolubles asì como minerales. La proteina que se utiliza es caseina y como fuente de grasa contiene àcido linoleico . La composición tambièn presenta agentes espesantes, emulsificantes y ajustadores de pH y antioxidantes.

La anterioridad D2 divulga una composición nutricional para mujeres embarazadas y lactantes; la cual contiene leche descremada, leche entera en polvo y grasa vegetal. Esta composición se suplementa específicamente con àcido docohexanoico y àcido eicosapentanoico. La composición tambièn contiene una serie de vitaminas lipo e hidrosolubles.

Como se observa en las anterioridades presentadas; son varias las composiciones nutricionales que presentan premezclas vitamìnicas y minerales asì como componentes que le proporcionan los niveles requeridos de proteìna y grasa para las necesidades nutricionales que se pretenden suplementar El origen tanto de la proteìna como de la grasa en estas composiciones; tambièn lo contemplan como lacteo y no lacteo. Por lo tanto, tal como se encuentra presentada la solicitud, esta carece de nivel inventivo ya que segùn lo que se encuentra publicado en el estado del arte es posible derivar una bebida nutritiva de las caracterìsticas presentadas en la solicitud.

Por lo anterior la solicitud no cumple con el articulo 18 de la Decisión 486.carece de nivel inventivo.

En conclusión los requisitos de patentabilidad de la presente solicitud se encuentran afectados así:

N°	DOCUMENTO	REIVINDICACIONES AFECTADAS	REQUISITO QUE AFECTA
D1	US 4,303,692	1 a 20	NIVEL INVENTIVO
D2	EP0705539 A2	1 a 20	NIVEL INVENTIVO

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

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

ALIX CARMENZA CÉSPEDES DE VERGEL
Jefe de la División de Nuevas Creaciones.

El anterior requerimiento fue notificado por fijación en lista, de fecha 14 JUN. 2007

CONCEPTO TÉCNICO N° 0820	EXAMINADOR TÉCNICO CÓDIGO 202064

D1 79

United States Patent [19]

Gaull

[11] **4,303,692**

[45] **Dec. 1, 1981**

[54] **INFANT MILK FORMULA**

[76] Inventor: **Gerald E. Gaull, 1107 Fifth Ave., New York, N.Y. 10028**

[21] Appl. No.: **90,639**

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Related U.S. Application Data

[63] Continuation of Ser. No. 963,026, Nov. 22, 1978, abandoned, which is a continuation of Ser. No. 738,080, Nov. 22, 1976, abandoned.

[51] Int. Cl.³ A23C 11/00; A23C 21/00; A23J 1/14; A23J 1/20

[52] U.S. Cl. 426/580; 426/2; 426/583; 426/590; 426/634; 426/656; 426/801

[58] Field of Search 426/2, 590, 71, 580, 426/583, 801, 656, 634; 424/177, 319, 335, 115

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,231,385	1/1966	Ziro et al.	426/71
3,636,195	1/1972	Monson	424/115
3,896,240	7/1975	Gruette et al.	426/801 X

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Armstrong, et al., Free Amino Acids in Milk Chem. Abstr., vol. 60:2135c, 1964.

Sturman et al., Taurine In the Brain and Liver of the Developing Human and Monkey, Journal of Neurochemistry, vol. 25, 1975, (pp. 831–835).

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[57] **ABSTRACT**

Synthetic infant formulas which are essentially free of taurine are improved for nourishing infants by adding taurine to the formula. In addition to taurine, there may also be added cholesterol and/or isethionic acid.

15 Claims, No Drawings

INFANT MILK FORMULA

This is a continuation, of application Ser. No. 963,026 filed Nov. 22, 1978 which, in turn, is a continuation of Application Ser. No. 738,080 filed Nov. 22, 1976, both now abandoned.

This invention relates to synthetic infant milk formulas. In one embodiment, this invention relates to improving infant nutrition. In another embodiment, this invention relates to formulas, especially liquid infant milk formulas based on cow milk, particularly in the ready-to-use form.

Synthetic infant milk formulas, particularly synthetic infant milk formulas based on cow milk, have been employed for nourishing infants, i.e. infants having an age not greater than about 12±2 months.

Human milk has an average composition in percentages by weight 87.5 water, 12.5 total solids, 1.0–1.5 protein and non-protein nitrogen compounds, 3.0–4.0 lipids, 7.0–7.5 carbohydrates and 0.2 ash. Cow milk has an average composition in percentages by weight 87 water, 13 total solids, 3.0–4.0 protein, 3.5–5.0 lipids, 3.5–4.0 carbohydrates and 0.7 ash. Also, cow milk is low in taurine, about 4 μmoles percent. With respect to carbohydrates, lactose, the disaccharide of galactose and glucose, occurs both in cow and in human milk and the lipids of human and cow milk are chiefly triglycerides dispersed as very small globules. The fat of cow milk contains all the saturated fatty acids with an even number of carbon atoms from butyric to stearic, with about 10% of the total fat composed of glycerides of lower fatty acids. The principal fatty acids are oleic, 32%; palmitic, 15%; myristic, 20%; stearic, 20%; and lauric, 6%, with small amounts of phospho-lipids and cholesterol being present. On the other hand, human milk fat contains no fatty acids with a molecular weight lower than that of decanoic acid and differs from cow milk in this respect, although the quantities of most of the fatty acids are similar to those of cow milk. Cow milk contains substantially all the known vitamins and is rich in vitamin A and riboflavin, but vitamin C, vitamin D, thiamine, pantothenic acid and niacin are present in small amounts. Pasteurization of cow milk, however, destroys most of the vitamin C. Therefore, additional amounts of vitamins C and D are specially supplied or added to an infant milk formula based on cow milk.

The principal proteins of cow milk are caseins, representing about 82% of the protein nitrogen. When cow milk is centrifuged and the cream skimmed off the top and the remaining fluid, skim milk, acidified, casein is precipitated. The resulting supernatant liquid or fluid is whey which contains about 18% of the total protein in cow milk. The whey proteins appear to be as numerous as those of serum and the principal protein of cow whey is β-lacto-globulin which amounts to about 50–60% of whey protein. Alpha-lactabumin is one of the two proteins required for lactose synthesis. Other important constituents of cow milk whey are the immonoglobulins which carry the antibodies; these account for about 10% of the whey protein. Human milk contains not only much less protein than cow milk, but the distribution of proteins is different. Caseins account for only about 40% of the proteins in human milk and the whey proteins about 60%.

Because of certain similarities in chemical properties and composition and overall nutritional value of human milk and cow milk, particularly for infant feeding, and

because of the usual availability of cow milk, synthetic infant milk formulas based on modified cow milk have been widely used for the nourishment of infants. Infant milk formulas based on cow milk, particularly the protein content or components thereof, have been prepared such that the protein content (about 82% casein and 18% whey in cow milk) has been modified such that the protein content of the formula is 60% whey protein and 40% casein protein. However, infant milk formulas for the nourishment of infants and in ready-to-use form have a low taurine content, e.g. less than about 4 μmoles percent.

Infant milk formulas based on cow milk have been further modified or fortified by the incorporation therein of constituents normally not found in cow milk, either per se or in the concentrations found in cow milk in order to prepare a better source of nourishment for infants. The same approach has been taken with respect to animal feeds, not necessarily feed for new-born animals. For example, U.S. Pat. No. 3,959,519 discloses the fortification of feeds and foods by incorporating therein a methionine source selected from glycyl-D,L-methionine, glycyl-L-methionine, D,L-methionylglycine and L-methionylglycine. U.S. Pat. No. 2,542,723 discloses nutrition compositions which contain a chemical composition biologically equivalent to cystine and methionine, such as the inorganic salts of diacetyl-L-cystine. U.S. Pat. No. 3,415,655 discloses cow milk compositions or products containing methionine and/or tryptophan together with monosodium glutamate and at least one amino acid of the group consisting of glycine, alanine, serine and threonine. Animal feeds containing taurine and fermentation and/or distillers' product as growth promoting materials have been proposed, see U.S. Pat. No. 3,636,195. Infant milk formulas of special composition and their preparation have been the subject of many patents; see, for example, U.S. Pat. Nos. 2,694,640, 3,542,560 and 3,798,339.

It is an object of this invention to provide an improved synthetic infant milk formula, particularly synthetic infant milk formulas based on cow milk.

It is another object of this invention to provide an improved method or program for nourishing infants up to an age of about 12±2 months, more or less.

These and other objects of this invention are achieved in the light of the accompanying disclosure.

Synthetic infant milk formulas, particularly synthetic infant milk formulas based on cow milk and containing taurine in accordance with this invention, have been prepared. In addition to taurine which is incorporated in the synthetic infant milk formula in a minor amount, there may also be incorporated or added to the synthetic infant milk formula isethionic acid and/or cholesterol, also in minor amounts. A synthetic infant milk formula in accordance with this invention would contain taurine in an amount such that when the synthetic infant milk formula is in the form ready-to-use, taurine would be present in an amount or concentration in the range from about 15–20 to about 55–60 μmoles percent, preferably about 30 μmoles percent. Isethionic acid, when present along with taurine in accordance with this invention, would be incorporated or added to the synthetic milk formula in an amount in the range from about 4 to about 25 μmoles percent. Cholesterol, when present either with taurine alone or taurine together with isethionic acid, would be present or added to the synthetic milk formula in an amount in the range from about 20% less to about 20% more than the cholesterol

concentration found in human milk. Human milk, in addition to containing cholesterol, is known to contain many free amino acids including taurine, see *Chemical Abstracts*, Vol. 60:2135c.

In the practices of this invention, particularly in the preparation of synthetic milk formulas, especially those based on cow milk, it is preferred that taurine be added or incorporated in the synthetic milk formulas in an amount equivalent to or approximating the taurine content in human milk, about 10–35 μmoles percent.

Although taurine has been known to be present in human milk (about 30 μmoles percent) and in cow milk (about 4 μmoles percent) and is exceeded in concentration only by glutamate, heretofore it has not been incorporated in synthetic infant milk formulas. Cow milk base formulas, particularly casein-predominant synthetic infant milk formulas also contain little cystine, a taurine precursor. It has been observed that infants fed cow milk excrete smaller amounts of taurine than infants fed human milk. It has been observed also that when pre-term infants are fed pooled human milk, lower concentrations of all amino acids in plasma are present than in infants fed casein-predominant formulas, except taurine which is higher. It has also been observed that urinary taurine is highest in infants fed human milk and lowest in infants fed casein-predominant synthetic milk formulas. The activity of cysteine-sulfinic acid decarboxylase (which synthesizes taurine) is very low in fetal and mature human liver. It has also been demonstrated in the rat model that there is a large and rapid transfer of taurine from the mother to the liver and brain of the infant via the milk of the mother. It appears, therefore, that taurine may be essential for the well-being and nourishment of the infant. Purified casein diets fed kittens result in depletion of brain taurine, reduced synthesis of taurocholic acid and retinal disease. Accordingly, it may be that human infants nourished on casein-predominant formulas, particularly pre-term infants, potentially may suffer some of the same effects, at least in part. Accordingly, synthetic infant milk formulas incorporating taurine, or taurine and isethionic acid, or taurine and cholesterol, or taurine and isethionic acid and cholesterol in accordance with the practices of this invention would appear to provide an improved or superior nourishment to human infants, particularly pre-term infants. Instead of taurine, metabolizable derivatives thereof which yield taurine when fed to the infant may replace at least a portion of taurine per se. It is presently preferred, however, to employ taurine and not a derivative thereof.

Many synthetic infant milk formulas based on cow milk are known and all such infant milk formulas in addition to non-cow milk base synthetic milk formulas (with the exception of meat-based synthetic formulas) are improved by incorporating therein taurine, or taurine and isethionic acid, or taurine, isethionic acid and cholesterol, or taurine and cholesterol, all in minor amounts, particularly in the amounts set forth hereinabove.

One infant milk formula sold under the trade name ENFAMIL manufactured by Mead Johnson Laboratories of Mead Johnson & Company, Evansville, Ind., U.S.A., and hereinafter referred to as Formula A, which is improved by the incorporation therein of taurine, or taurine and isethionic acid, or taurine and cholesterol, or taurine, isethionic acid and cholesterol in accordance with this invention, contains the following homogenized and ready-to-use ingredients: Water, nonfat milk, lactose, soy and coconut oils, soy lecithin, carrageenan, vitamins (vitamin A palmitate, ergocalciferol, D-alpha-tocopheryl acetate, sodium ascorbate, folic acid, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, and calcium pantothenate), and minerals (ferrous sulfate, cupric sulfate, zinc sulfate, and manganese sulfate).

Proximate Analysis (% W/V)	20 Kcal./fl. oz.
Protein	1.5
Fat	3.7
Carbohydrate	7
Minerals (ash)	0.36
Water	87.5

Each quart of ENFAMIL formula (20 Kcal./fl. oz) supplies 640 kilocalories and the following vitamins and minerals:

	Per 100 Kcal. (3 fl. oz.)	Per Quart
Vitamin A, I.U.	250	1600
Vitamin D, I.U.	62.5	400
Vitamin E, I.U.	1.9	12
Vitamin C (Ascorbic Acid), mg	7.8	50
Folic Acid (Folacin), mg	0.016	0.1
Thiamine (Vitamin B_1), mg	0.08	0.5
Riboflavin (Vitamin B_2), mg	0.09	0.6
Niacin, mg	1.25	8
Vitamin B_6, mg	0.06	0.4
Vitamin B_{12}, mcg	0.31	2
Pantothenic Acid, mg	0.47	3
Choline, mg	7	45
Calcium, mg	81	520
Phosphorus, mg	69	440
Iodine, mcg	10	65
Iron, mg	0.2	1.4
Magnesium, mg	7	45
Copper, mg	0.09	0.6
Zinc, mg	0.63	4
Manganese, mg	0.16	1

Another infant milk formula sold under the trade name SIMILAC manufactured by Ross Laboratories, Columbus, Ohio, U.S.A., and hereinafter referred to as Formula B, which is improved by the incorporation therein of taurine, or taurine and isethionic acid, or taurine and cholesterol, or taurine, isethionic acid and cholesterol in accordance with this invention, contains the following homogenized and ready-to-use ingredients: Water, nonfat milk, lactose, soy, coconut and corn oils, mono- and diglycerides, soy lecithin, carrageenan, ascorbic acid, zinc sulfate, niacinamide, alpha-tocopheryl acetate, cupric sulfate, calcium pantothenate, vitamin A palmitate, thiamine chloride hydrochloride, pyridoxine hydrochloride, riboflavin, folic acid, manganous chloride, vitamin D_3 concentrate and cyanocobalamin.

Approximate Analysis (wt/liter)	
Fat	36.1 g
Carbohydrate	72.3 g
Protein	15.5 g
Minerals	3.6 g
Calcium	0.58 g
Phosphorus	0.43 g
Magnesium	41 mg
Iron	trace

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Zinc	5.0 mg
Copper	0.41 mg
Iodine	0.10 mg
Water	902.0 g
*Calories per fl. oz.	20
Calories per 100 ml	68

Vitamins Per Liter

Vitamin A	2500 Int. Units
Vitamin D	400 Int. Units
Vitamin E	15 Int. Units
Vitamin C	55 mg
Vitamin B_1	0.65 mg
Vitamin B_2	1 mg
Niacin (mg equiv)	7
Vitamin B_6	0.40 mg
Folic Acid	50 mcg
Pantothenic Acid	3 mg
Vitamin B_{12}	1.5 mcg

*Special formulas substantially as described hereinabove may have a higher calorie content, e.g. 27-28 calories/oz. for premature infants.

Yet another infant milk formula sold under the trademark SMA manufactured by Wyeth Laboratories, Inc., Philadelphia, Pa., U.S.A., and available in concentrated liquid form or powder form, each of which provides 20 calories per ounce of normal dilution, and hereinafter referred to as Formula C, which is improved by the incorporation therein of taurine, or taurine and isethionic acid, or taurine and cholesterol, or taurine, isethionic acid and cholesterol in accordance with this invention, contains the following ingredients in homogenized and ready-to-use form: Water; nonfat milk; demineralized (electrodialyzed) whey; lactose; oleo, coconut, oleic (safflower), and soybean oils; soy lecithin; calcium carrageenan. Minerals: Potassium bicarbonate; calcium chloride and citrate; potassium chloride; sodium citrate; ferrous sulfate; sodium bicarbonate; zinc, cupric and manganese sulfates. Vitamins: Ascorbic acid, d-alpha tocopheryl acetate, niacinamide, vitamin A palmitate, calcium pantothenate, thiamine hydrochloride, riboflavin, pyridoxine hydrochloride, beta-carotene, folic acid, phytonadione, activated 7-dehydrocholesterol, cyanocobalamin.

Proximate Analysis	(W/V)
Fat	3.6%
Carbohydrate	7.2%
Protein	1.5%
60% Lactalbumin (whey protein)	0.9%
40% Casein	0.6%

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Ash	0.25%
Crude fiber	none
Total solids	12.6%
*Calories/fl. oz.	20

Vitamins and Minerals (each quart contains):

A	2,500 I.U.
D_3	400 I.U.
E	9 I.U.
K_1	55 mcg
B_1 (thiamine)	0.67 mg
B_2 (riboflavin)	1 mg
C (ascorbic acid)	55 mg
B_6	0.4 mg
B_{12}	1 mcg
Niacin mg equivalents	9.5
Pantothenic acid	3 mg
Folic acid	50 mcg
Choline	130 mg
Calcium	420 mg
Phosphorus	312 mg
Magnesium	50 mg
Sodium	142 mg
Potassium	530 mg
Chloride	350 mg
Iron	12 mg
Copper	0.45 mg
Zinc	3.5 mg
Manganese	150 mcg
Iodine	65 mcg

*Special formulas substantially as described hereinabove may have a higher calorie content, e.g. 27-28 calories/oz. for premature infants.

Specifications have been proposed for a standard infant milk formula which in the liquid form may be used either directly or diluted with water before feeding, as appropriate, or which in powdered form requires water for preparation. The proposed formula hereinafter referred to as Formula D, which is improved by the incorporation therein of taurine, or taurine and isethionic acid, or taurine and cholesterol, or taurine, isethionic acid and cholesterol in accordance with this invention, is considered to be nutritionally adequate to promote normal growth and development when properly used. Essentially, the composition of the proposed standard infant formula is a product based on cow's milk or other animals and/or on other edible constituents of animals, including fish, or plant origin, which have been proved to be suitable for infant feeding. The proposed infant formula contains, per 100 available calories or 100 kilojoules of intake, the following minimum and maximum levels of vitamins, minerals in an available form, choline, protein, fat and linoleate:

	Amounts per 100 Available Calories		Amounts per 100 Available Kilojoules	
	Minimum	Maximum	Minimum	Maximum
(a) Vitamins Other Than Vitamin E				
Vitamin A	250 I.U. or 75 μg expressed as retinol	500 I.U. or 150 μg expressed as retinol	60 I.U. or 18 μg expressed as retinol	120 I.U. or 37 μg expressed as retinol
Vitamin D	40 I.U.	80 I.U.	10 I.U.	19 I.U.
Ascorbic Acid (Vitamin C)	8 mg	none specified	1.9 mg	none specified
Thiamine (Vitamin B_1)	40 μg	"	10 μg	"
Riboflavin (Vitamin B_2)	60 μg	"	14 μg	"
Nicotinamide	250 μg	"	60 μg	"
Vitamin B_6[1]	35 μg	"	9 μg	"
Folic Acid	4 μg	"	1 μg	"

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	Amounts per 100 Available Calories		Amounts per 100 Available Kilojoules	
	Minimum	Maximum	Minimum	Maximum
Pantothenic Acid	320 μg	"	70 μg	"
Vitamin B_{12}	0.1 μg	"	0.04 μg	"
Vitamin K_1	4 μg	"	1 μg	"
Biotin (Vitamin H)	1.5 μg	"	0.4 μg	"
(b) Vitamin E (α-tocopherol compounds)	0.7 I.U./g linoleic acid[2], but in no case less than 0.7 I.U./100 available calories	"	0.7 I.U./g linoleic acid[2], but in no case less than 0.7 I.U./100 available kilojoules	"
(c) Minerals				
Sodium (Na)	20 mg	60 mg	5 mg	15 mg
Potassium (K)	80 mg	200 mg	20 mg	50 mg
Chloride (Cl)	55 mg	150 mg	14 mg	32 mg
Calcium (Ca)[3]	50 mg	none specified	12 mg	none specified
Phosphorus (P)[3]	25 mg	"	6 mg	"
Magnesium (Mg)	6 mg	none specified	1.4 mg	none specified
Iron (Fe)	1 mg[1]	"	0.25 mg[1]	"
Iron (Fe)	0.15 mg	"	0.04 mg	"
Iodine (I)	5 μg	"	1.2 μg	"
Copper (Cu)	60 μg	"	14 μg	"
Zinc (Zn)	0.5 mg	"	0.12 mg	"
Manganese (Mn)	5 μg	"	1.2 μg	"
(d) Choline	7 mg	"	1.7 mg	"

[1]Formulas with a higher protein content than 1.8 g protein/100 calories should contain a minimum of 15 μg vitamin B_6 per gramme of protein.
[2]Or per g polyunsaturated fatty acids, expressed as linoleic acid.
[3]The Ca:P ratio shall be not less than 1.2 and not more than 2.0.

[1]Products containing not less than 1 mg iron (Fe)/100 available calories shall be labelled "Infant Formula with Iron".

(e) Protein

(i) Shall not be less than 1.8 g per 100 available calories (or 0.43 g per 100 available kilojoules) of protein of nutritional quality equivalent to that of casein or a greater quantity of other protein in proportion to its biological value. The quality of the protein shall not be less than 85% of that of casein. The total quantity of protein shall not be more than 4 g per 100 available calories (or 0.96 g per 100 available kilojoules). The minimum value set for quality and the maximum for quantity of the protein may be modified by national authorities according to their own regulations and/or local conditions.

(ii) Isolated amino acids may be added to infant formula only to improve its nutritional value for infants. Essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only natural L forms of amino acids shall be used.

(f) Fat and Linoleate

The formula shall contain linoleic acid (in the form of glycerides) at a level not less than 300 mg per 100 available calories (or 70 mg per 100 available kilojoules) and fat at a level not less than 3.3 g and not more than 6 g per 100 available calories (or not less than 0.8 g and not more than 1.5 g per 100 available kilojoules).

In addition to the vitamins and minerals listed hereinabove, food additives can be included, such as the following thickening agents, emulsifiers, pH adjusting agents and antioxidants, at the levels indicated:

	Maximum Level in 100 ml of the Ready-To-Drink Formula
Thickening Agents	
Guar Gum	0.1 g in all types of infant formula
Locust Bean Gum	0.1 g in all types of infant formula
Distarch phosphate, singly or in combination	0.5 g in soy-based infant formula only, in hydrolyzed protein and/or amino acid-based infant formula only
Acetylated distarch phosphate, singly or in combination Phosphated distarch phosphate, singly or in combination Hydroxypropyl starch, singly or in combination	2.5 g in soy-based infant formula only, in hydrolyzed protein and/or amino acid-based infant formula only
Carrageenan	0.03 g in regular, milk- and soy-based liquid infant formula only 0.1 g in hydrolyzed protein and/or amino acid-based liquid infant formula only
Emulsifiers	
Lecithin	0.5 g in all types of infant formula
Mono- and Di-glycerides	0.4 g in all types of infant formula
pH-Adjusting Agents	
Sodium Hydrogen Carbonate Sodium Carbonate Potassium Hydrogen Carbonate Potassium Carbonate Sodium Citrate Potassium Citrate	Limited by GMP (within the limits for Na and K above) in all types of infant formula
L(+) Lactic Acid	Limited by GMP in all types of

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	Maximum Level in 100 ml of the Ready-To-Drink Formula
	infant formula
L(+) Lactic Acid Producing Cultures	Limited by GMP in all types of infant formula
Citric Acid	Limited by GMP in all types of infant formula
Antioxidants	
Mixed Tocopherols Concentrate	1 mg in all types of infant formula
L-Ascorbyl Palmitate	1 mg in all types of infant formula

The above-described proposed standard milk formula is a proposed formula of the Codex Committee of Foods for Special Dietary Uses.

Synthetic infant milk formulas based on Formula C described hereinabove and containing taurine in various concentrations were prepared. More particularly, taurine was incorporated in SMA infant milk formula (Formula C) at concentrations of 25 μmoles taurine/100 ml (3.13 mg/100 ml), 35 μmoles taurine/100 ml (4.38 mg/100 ml) and 45 μmoles taurine/100 ml (5.63 mg/100 ml). A control containing no added taurine was also employed. The taurine-containing SMA formulas and the control were then held at room temperature for an extended period of time. After 4½ and 6 months, the formulas were examined from the point of view of shelf life stability. No difference among the formulas tested was observed and all compositions or formulas were in good condition and unchanged. Similar formulas, including a control having no added taurine, were subjected to a regular shelf life study. In this study, the formulas were maintained at 80° F. The formulas were examined at 1½, 3 and 4 month intervals. Aside from the usual gravitation of a thin layer of fatty material (not free fat), there was no observable difference among the formulas relative to odor, color, pH or physical appearance and all formulas tested looked good. Based on the above results, it appears to be evident that no unusual effects should result from the addition of taurine at the levels tested to an infant milk formula having the composition of Formula C hereinabove, particularly SMA infant milk formula. It is mentioned that infant milk formulas having the composition set forth in Formulas A, B, C and D hereinabove showed no taurine content when tested for taurine.

As will be apparent to those skilled in the art in the light of the foregoing disclosure, many modifications, alterations and substitutions are possible without departing from the spirit or scope thereof.

I claim:

1. A synthetic infant milk formula containing as an additive thereto taurine at a concentration in the range from about 15 to about 60 μmoles percent, said formula being essentially free of taurine prior to addition of taurine thereto.

2. A synthetic infant milk formula in accordance with claim 1, wherein said infant milk formula contains cow milk protein.

3. A synthetic infant milk formula in accordance with claim 1 containing cow milk protein, the cow milk protein content of said formula being such that about 80% is derivable from casein and about 20% is derivable from whey.

4. A synthetic infant milk formula in accordance with claim 1 containing cow milk protein, the cow milk protein content of said formula being such that about 60% is derivable from whey and about 40% is derivable from casein.

5. A synthetic infant milk formula in accordance with claim 1 in ready-to-use liquid form.

6. A synthetic infant milk formula in accordance with claim 1 in ready-to-use liquid form containing taurine at a concentration of about 30 μmoles percent.

7. A synthetic infant milk formula in accordance with claim 1, wherein said infant milk formula contains soy protein.

8. A synthetic infant milk formula in accordance with claim 1 in dry or powder form for reconstitution with water for consumption such that when reconstituted the taurine content thereof is at a concentration in the range from about 15 to about 60 μmoles percent.

9. A synthetic infant milk formula in accordance with claim 1 in dry or powder form for reconstitution with water for consumption such that when reconstituted the taurine content thereof is about 30 μmoles percent.

10. A synthetic infant milk formula in accordance with claim 1 in concentrated liquid form for dilution with water prior to consumption such that when diluted with water for consumption the taurine content thereof is at a concentration in the range from about 15 to about 60 μmoles percent.

11. In the nourishment of an infant wherein the infant is nourished by a synthetic infant milk formula essentially free of taurine, the improvement which comprises adding taurine to said formula in an amount to provide taurine therein at a concentration in the range from about 15 to about 60 μmoles percent.

12. A method in accordance with claim 11 wherein said synthetic infant milk formula contains cow milk protein.

13. A method in accordance with claim 11 wherein said synthetic infant milk formula contains cow milk protein and wherein the cow milk protein present in said formula is such that about 80–82% by weight is derived from casein protein and about 18–20% by weight is derived from whey protein.

14. A method in accordance with claim 11 wherein said synthetic infant milk formula contains cow milk protein and wherein the cow milk protein present in said formula is such that about 40% by weight is derived from casein protein and about 60% by weight is derived from whey protein.

15. A method in accordance with claim 11 wherein said infant milk formula contains soy protein.

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NL-2587 BN 's-Gravenhage (NL)

(54) A food for pregnant and lactating women

(57) A food based on milk products, intended for pregnant and lactating women, which food is specifically supplemented with docosahexaenoic acid and eicosapentaenoic acid and nutrient fibres in an amount accounting for more than 10% of the total mono- and disaccharide fraction.

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EXAMPLE I

A powdery product was prepared, consisting of :

Water	2.6%
Skimmed milk dry matter	49.0%
Desalted whey dry matter	20.2%
Whole milk powder	5.8%
Vegetable fat (palm olein/rapeseed oil/LCP oil)	9.5%
Lecithin	0.2%
Soluble fibres (Fibruline®; containing inulin)	7.5%
Citric acid	1.1%
Calcium hydroxide	0.6%
Minerals, trace elements, vitamins	3.5%

A composition was obtained as specified in Table I. The ratio of linoleic acid/α-linolenic acid is less than 4:1. The product contains 2.5 wt.% EPA and 1.5 wt.% DHA in the fatty fraction.

Table I

		Analysis per 100 g
Protein	g	22.6
Fat	g	12.5
Linoleic acid	mg	1560
α-Linolenic acid	mg	400
Carbohydrates	g	55.7
- Lactose	g	48.2
- Dietary fibres	g	7.5
Moisture	g	3.0
Minerals	g	6.0
Calcium	mg	1000
Phosphorus	mg	620
Ca/P ratio		1.6
Iron	mg	50
Copper	µg	970
Sodium	mg	265
Potassium	mg	940
Chloride	mg	570
Magnesium	mg	265
Zinc	mg	12.7
Iodide	µg	145
Manganese	µg	415
Vitamins		
A	µg RE (IU)	667 (2220)
β-carotene	µg	280
D_3	µg (IU)	8.3 (332)
E	(IU)	8.3
K_1	µg	63.0
B_1	µg	1250
B_2	µg	1335
Niacin NE	mg	14.3
B_6	µg	1835
Folic acid	µg	335
Pantothenic acid	µg	3300
B_{12}	µg	2.4
Biotin	µg	42.0
C	mg	58.0
Energy value	kcal	400
	kJ	1670

The mixture was prepared by mixing whole milk, skimmed milk, and desalted whey in liquid form with the vegetable fat and a suspension of calcium hydroxide and citric acid. After pasteurisation and homogenisation, this mixture was dried to a powdery half-finished product. The last-mentioned product was then finally mixed with the other minerals and