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Señor
SUPERINTENDENTE DE INDUSTRIA Y COMERCIO
DIVISION DE NUEVAS CREACIONES
E. S. D.

166
169
SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
Folios: 2
Radicación: 01009749 00000003
Fecha (HH): 2003-11-21 15:52:04
Trámite: 002 PATENTES D 1 REGISTRO/ 530 PETICION
Dependencia: 2520 DIVISION DE NUEVAS CREACIONES

REF: Expediente No.:
Patente de Invención:

01-009.749

Titulares:

**"COMPOSICIONES DE RECUBRIMIENTO
ENTÉRICAS ACRILICAS"**
BPSI Holdings, Inc.
Röhm GmbH & Co. KG.

Publicada en la Gaceta de la Propiedad Industrial No. 528 de 30 de Mayo de 2.003

SOLICITUD DE EXAMEN DE PATENTABILIDAD

HUMBERTO RUBIO CAMACHO, mayor de edad, domiciliado en Bogotá, D.C., identificado con la cédula de ciudadanía número 17.192.082 de Bogotá, abogado Titulado con Tarjeta Profesional No. 50.007 del Consejo Superior de la Judicatura, actuando en carácter de APODERADO de las Sociedades BPSI Holdings, Inc. y Röhm GmbH & Co. KG. domiciliadas en Estados Unidos de América y Alemania; respetuosamente solicito a esa Dependencia:

- 1.- De conformidad con lo establecido en el Artículo 44 de la Decisión 486 de la Comisión de la Comunidad Andina y estando dentro del término legal de seis meses contados desde la fecha de publicación en la Gaceta No. 528 de 30 de Mayo de 2.003, de la solicitud de la patente de la referencia, solicito se sirvan proceder a efectuar el examen de patentabilidad de la Invención.
- 2.- Para que la presente petición sea viable, estoy anexando el siguiente documento:
 - 2.1. Recibo de pago No. 05 - \$4,848 de 20 de Noviembre de 2.003 por la suma de \$ 385.000.00, de acuerdo con la Resolución No. 41887 de 24 de Diciembre de 2.002
- 3.- Por lo anterior solicito se continúe con el trámite correspondiente.

Del Señor Superintendente,



HUMBERTO RUBIO CAMACHO
C.C. 17.192.082 de Bogotá
T.P. 50.007 Consejo Superior
de la Judicatura.
COD. 4134

01/1200-01/1200-01/PI
/icar

PARA USO EXCLUSIVO DE
HUMBERTO RUBIO & CIA. LTDA

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EXAMEN DE PATENTABILIDAD
Expediente No.: 01-009.749
Patente de Invención: "COMPOSICIONES DE
RECUBRIMIENTO ENTERICAS ACRILICAS"
SUPERINTENDENCIA Y COMERCIO
Radicación : 01007749 00000003 Folios: 2
Fecha (AMD): 2003-11-21 15:32:04
Trámite : 002 PATENTES D REGISTRO/ 538 PETICION
Dependencia: 2029 DIVISION DE NUEVAS CREACIONES

NIT : 800176089-2

RECIBO OFICIAL DE CAJA : 03 - 84,848
FECHA : NOVIEMBRE 20 DE 2003

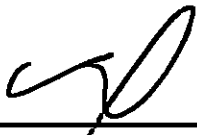
***** CONSIGNACION *****

DEPOSITANTE	TIPO PAGO	BANCO	CUENTA	No. PAGO	FECHA PAGO	Vr. PAGO
HUMBERTO RUBIO ABOGADOS	LCONSIGNACION	BANCO POPULAR	050-00110-6	3121723	20/11/2003	14,000.00
HUMBERTO RUBIO ABOGADOS	LCONSIGNACION	BANCO POPULAR	050-00110-6	16828976	20/11/2003	6,105,000.00

***** CONCEPTO *****

CANT.	RENTISTICO	CONCEPTO	TOTAL CONCEPTO
1	50005-01-01	SOLICITUDES	85 EXAMEN DE PATENTABILIDAD DE INVEN
			TOTAL : \$ 335,000.00

SOM: TRESCIENTOS TREINTA Y CINCO MIL PESOS

RESPONSABLE : 

RECIBO DE CAJA APLICADO AL EXPEDIENTE No. _____

168.



DIVISION DE NUEVAS CREACIONES

RADICACIÓN EXPEDIENTE No. 01-9749

EL EXTRACTO DE LA PRESENTE SOLICITUD DE PATENTE DE INVENCION

FUE PUBLICADO EN LA GACETA DE PROPIEDAD INDUSTRIAL No 528, DE

FECHA 30 DE MAYO DE 2003, EL TERMINO HABIL SEÑALADO POR LA LEY

EXPIRA EL 29 DE AGOSTO DE 2003.

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**

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[Handwritten signature]

**SUPERINTENDENCIA DE INDUSTRIA Y COMERCIO
DIVISIÓN DE NUEVAS CREACIONES**

2020/
Bogotá, D.C.,

Doctor
Humberto Rubio
Apoderado

Oficio Nº U 13438

REFERENCIA	Radicación	01 09749
	Trámite	002
	Evento	001
	Actuación	430
	Folios	019

Como resultado del examen de patentabilidad de la solicitud de patente de invención Nº 00 32520, realizado según el artículo 45 de la decisión 486 de la comisión de la Comunidad Andina, se notifica:

Documentos estudiados:

- . Descripción: folios 5-21
- . Ejemplos: folios 21-37
- . Capítulo reivindicatorio estudiado: folios 38-48
- . Se reivindica prioridad presentada en Estados Unidos, el 10.02.00, bajo el número 09/501866

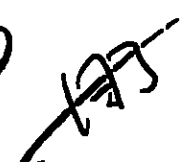
Objeto de la invención

Según las reivindicaciones 1 a 27 de la presente solicitud, se refiere a una composición en polvo seca de recubrimiento de película entérica comestible que comprende: a) una resina acrílica, b) un agente de alcalización, y c) un antiadherente.

Clasificación internacional de patentes A 61 K 9/32

Determinación del estado de la técnica:

Consultadas las fuentes de información con que cuenta este despacho, se encontraron los siguientes documentos, anteriores a la fecha de prioridad de la presente solicitud - 10.02.00-, relacionados con la materia de la presente solicitud:

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Nº	Documento	Título	Fecha de publicación
1	US 4543370	"Composición de cubierta de película comestible seca, métodos y formas de cubrimiento"	24.09.85
2	US 4683256	"Composición de cubierta de película comestible seca, métodos y formas de cubrimiento"	28.07.87

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 de la comisión de la comunidad andina, se procedió a evaluar los requisitos de novedad, nivel inventivo y aplicación industrial con el fin de establecer la patentabilidad de la invención reivindicada en la solicitud en estudio.

Evaluación de la NOVEDAD

El artículo 16 de la decisión 486 establece que *"Una invención se considerará nueva cuando no está comprendida en el estado de la técnica"*

Las patentes US 4543370 y US 4683256 revelan composiciones secas formadoras de película comestibles que son útiles en la fabricación de comestibles y formas farmacéuticas, así como su método de fabricación; tales composiciones contienen:

- Una resina acrílica, N-vinilpirrolidona
- Un agente alcalinizante
- Un antiadherente
- Pigmentos
- Antiaglomerantes
- Plastificador
- Surfactante
- Un ayudante de fluencia
- Un formador secundario de película

Finalmente, en el ejemplo 1 de los dos documentos citados se menciona que la película en polvo se mezcla con agua y se aplica a tabletas farmacéuticas.

Comparando elemento por elemento, las composiciones y el método de las reivindicaciones 1-27 son iguales a los de los documentos citados y pueden afectar la novedad de la presente solicitud.

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

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Nº	Documento	Reivindicaciones afectadas	Requisito que afecta
1	US 4543370	1-27	Novedad
2	US 4683256	1-27	Novedad

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 5 del título primero de la Circular Única Nº 10 de 2001


Álex Carmenza Céspedes de Vergel
Jefe de la División de Nuevas Creaciones

23 NOV. 2006

El anterior requerimiento fue notificado por fijación en lista, de fecha _____

CONCEPTO TÉCNICO Número 1783	EXAMINADOR TÉCNICO Código 202024
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United States Patent [19]
Porter et al.

172 D1 1985
[11] **Patent Number:** 4,543,370
[45] **Date of Patent:** Sep. 24, 1985

[54] **DRY EDIBLE FILM COATING
COMPOSITION, METHOD AND COATING
FORM**

[75] **Inventors:** Stuart C. Porter, Hatfield; Edward J.
Wonnicki, Douglassville, both of Pa.

[73] **Assignee:** Calorecon, Inc., West Point, Pa.

[21] **Appl. No.:** 202,831

[22] **Filed:** Nov. 6, 1980

Related U.S. Application Data

[63] **Continuation-in-part of Ser. No. 98,531, Nov. 29, 1979,
abandoned.**

[51] **Int. Cl.⁴** C08J 3/12

[52] **U.S. Cl.** 523/100; 523/105;
424/33; 424/34; 106/193 J; 106/193 P; 106/149

[58] **Field of Search** 106/154 Z, 193 D, 193 J,
106/193 P; 260/31.8 R, 29.6 H, 33.4 R, 32.8 R,
33.8 UA; 424/33-36; 523/100, 105; 8/524

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,149,040 9/1964 Jeffries 424/35
3,297,535 1/1967 Butler et al. 424/34
3,576,663 4/1971 Signorino et al. 424/34
3,835,221 9/1974 Faltborth et al. 424/33

3,981,984 9/1976 Signorino 260/33.4 R
4,009,131 2/1977 Farone 260/31.8 R
4,015,999 4/1977 Robertson 106/193 D
4,112,215 9/1978 Boemler 523/100
4,293,851 10/1981 Neumann et al. 8/524
4,330,338 5/1982 Banker 424/33

Primary Examiner—Paul R. Michl

Attorney, Agent, or Firm—John F. A. Earley, John F. A.
Earley, III

[57] **ABSTRACT**

A dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture including powdered particles of a film forming non-toxic polymer, powdered edible pigment particles, and an edible polymer plasticizer, said dry mixture being solvent free. A method of making a dry powder edible film coating composition of powdered pigment particles for use in pharmaceuticals, confectionery and food, comprising the steps of mixing a powder of a film forming polymer and powdered pigment particles in a blender to form a polymer-pigment mix, and adding the plasticizer to the blender containing the polymer-pigment mix and mixing until the combined mix is blended to form the dry powder edible film coating composition.

63 Claims, No Drawings

DRY EDIBLE FILM COATING COMPOSITION, METHOD AND COATING FORM

This is a continuation-in-part of our U.S. patent application Ser. No. 98,531, filed on Nov. 29, 1979, now abandoned.

TECHNICAL FIELD

This invention is in the field of coating of pharmaceutical tablets and the like, and provides a dry edible film coating composition for use in pharmaceuticals, confectionery, and food.

CROSS-REFERENCE TO RELATED PATENTS

This patent application is concerned with edible coating systems and is related to U.S. Pat. No. 3,981,984 which issued Sept. 21, 1976 to Charles A. Signorino, owned by Colorcon, Inc., West Point, Pa. 19486, the assignee of this patent application, and is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Signorino U.S. Pat. No. 3,981,984 provides an edible concentrated pigment suspension that is shipped, for example, to a pharmaceutical manufacturer who mixes it with a polymer solution to form a coating suspension which may be used for coating tablets and the like. The pigment suspension, polymer solution, and coating suspension are in a non-aqueous solvent.

It has long been desired to provide a dry edible film coating composition which can be constituted with solvent by the customer, that eliminates the problem of shipping of pigment dispersions containing aqueous or non-aqueous solvents and thereby eliminates the problems caused by solvents, and also makes shipping less expensive by eliminating the weight of the solvents.

It is known in the prior art to mix a dry polymer powder with pigment particles, and to grind the mixture to obtain a dry polymer-pigment mixture which is then ground into a fine powder mixture. However, when this fine polymer-pigment mixture is stirred into water and dispersed, the polymer makes lumps and fish eyes because it agglomerates, and the result is not really a uniform dispersion. Accordingly, when this polymer-pigment dispersion is used as a coating dispersion and is coated onto tablets and the like, unless the dispersion is left to solvate for a considerable period of time like overnight, the coating is lumpy and not uniform and is therefore undesirable.

SUMMARY OF THE INVENTION

A dry edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a mixture including polymer particles, pigment particles, and a polymer plasticizer. Advantageously, a surfactant may be added especially when the plasticizer may be a solid. The composition may also include a flow aid.

A method of making a dry edible film coating composition for use in pharmaceuticals, confectionery and food, comprises the steps of mixing a polymer powder and pigment particles in a blender, adding a plasticizer to the blender containing the polymer-pigment mix, and mixing until the combined mix is thoroughly blended. A surfactant may be mixed with the plasticizer, especially when the plasticizer is a solid. A flow aid may be mixed into the polymer-pigment mix, such as Cabosil (finely divided colloidal silica by Cabot Corp., Boston Mass.),

or Aerosil (finely divided colloidal silica by Degussa, Frankfurt, W. Germany).

The polymer may be methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, xeta, polyvinylacetatephthalate, methacrylic acid-methacrylic acid ester co-polymer, or other film forming polymer used for coating tablets and the like.

Any of the pigments heretofore used in making coating dispersions for coating tablets and the like may be used in the dry coating mixture of this invention. Examples are FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, and insoluble dyes. Also natural pigments such as riboflavin, carmine 40, curcumin, and annatto. Other examples are listed in Jeffries U.S. Pat. No. 3,149,040 and Butler et al. U.S. Pat. No. 3,297,535, as well as in Colorcon U.S. Pat. No. 3,981,984. All these patents and patent applications are incorporated herein by reference.

Exemplary of the polymer plasticizer for use in the dry coating mixture of the invention are polyethylene glycol, for example, polyethylene glycol having a molecular weight of 200 to 8000 (Carbowax by Union Carbide), glycerin, propylene glycol, Triacetin (Pfizer's glycerin triacetate), acetylated monoglyceride, and Citroflex 2 (triethylcitrate), Citroflex 4 (tributylcitrate), Citroflex A2 (acetyltriethylcitrate), Citroflex A4 (acetyltributylcitrate), diethyl phthalate, and mineral oil. Citroflex 2, 4, A2 and A4 are made by Pfizer and are plasticizers adapted for use with organic solvents.

The polymer plasticizer, to soften the polymer and make it less brittle, may be a liquid or a solid plasticizer, and a preferred plasticizer is a liquid such as polyethylene glycol 400.

The surfactant may be, for example, a solid powder surfactant such as Aerosol OT (dioctyl sodium sulfosuccinate by Cyanamid) which is preferably used with the liquid polyethylene glycol 400, or Tween 80 (polyorbate 80 by ICI Americas, Wilmington, Del.) which is a liquid and is preferably used with a solid plasticizer such as the polyethylene glycol 3350 and 8000.

DETAILED DESCRIPTION

We now turn to the examples of the invention, all ingredients being in parts by weight:

EXAMPLE 1

1500 grams of a polymer, powdered hydroxypropyl methylcellulose, are mixed with 750 grams of a powdered pigment, titanium dioxide in a V blender, a P-K blender with an intensifier bar. Then 150 grams of a plasticizer, polyethylene glycol 400, are thoroughly mixed with 5 grams of a surfactant, dioctyl sodium sulfosuccinate. The polyethylene glycol 400 - dioctyl sodium sulfosuccinate mix is then added to the blender and thoroughly mixed with the mixture of hydroxypropyl methylcellulose and titanium dioxide to form a coating mixture. The resulting mixture is then passed through a grinder in order to reduce it to a fine powder which is adapted for shipping in dry form to a pharmaceutical manufacturer where it is dispersed in water to form a coating dispersion that is applied to tablets and dried to form a uniform film coating on the tablets.

The coating dispersion obtained when the coating mixture is mixed with the solvent is surprisingly fluid and uniform, and easy to apply to the tablets.

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EXAMPLE 2

The method of Example 1 is followed except that the 750 grams of titanium dioxide powder are replaced by 375 grams of titanium dioxide and 375 grams of red iron oxide which are mixed into the hydroxypropyl methylcellulose in the blender before the plasticizer-surfactant mix of polyethylene glycol 400 and dioctyl sodium sulfosuccinate is added.

EXAMPLE 3

The method of Example 1 is followed except that the 750 grams of titanium dioxide powder are replaced by 499 grams of titanium dioxide, 75 grams of FD&C Yellow No. 6 aluminum lake, 25 grams of FD&C Red No. 3 aluminum lake, and 25 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 4

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 5

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 83 grams of titanium dioxide, 199 grams of FD&C Yellow No. 6 aluminum lake, 67 grams of FD&C Red No. 3 aluminum lake, and 67 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 6

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake. Also, the 5 grams of dioctyl sodium sulfosuccinate are replaced by 5 grams of polysorbate 80 (Tween 80 by ICI Americas), another surfactant.

EXAMPLE 7

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake. Also, 10 grams of fumed silica (Cabosil by Cabot Corp., Boston, Mass.) are added to the polymer-pigment mix to improve the flow in the grinder, and to improve the flow when the dry coating mixture is shipped in containers such as drums.

EXAMPLE 8

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 9

The method of Example 1 is followed except that the 1500 grams of hydroxypropyl methylcellulose are re-

placed by 1500 grams of methyl cellulose (Methocel A15 by Dow Chemical Co.).

EXAMPLE 10

The method of Example 1 is followed except that 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of hydroxypropyl cellulose (Klucel, by Hercules, Inc., Wilmington, Del.).

EXAMPLE 11

The method of Example 1 is followed except the 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of sodium ethyl cellulose sulphate.

EXAMPLE 12

The method of Example 1 is followed except the 150 grams of polyethylene glycol 400 liquid plasticizer are replaced by 150 grams of glycerin.

EXAMPLE 13

The method of Example 1 is followed except the 150 grams of the liquid plasticizer, polyethylene glycol 400 are replaced by 150 grams of propylene glycol.

EXAMPLE 14

The method of Example 1 is followed except the 150 grams of polyethylene glycol 400 are replaced by 150 grams of powdered polyethylene glycol 6000, and the 5 grams of Aerosol OT are replaced by 5 grams of Tween 80.

EXAMPLE 15

The method of Example 1 is followed except the 150 grams of polyethylene glycol 400 are replaced by 150 grams of powdered polyethylene glycol 8000, and the 5 grams of Aerosol OT are replaced by 5 grams of Tween 80.

EXAMPLE 16

1500 grams of a polymer, powdered hydroxypropyl methylcellulose are mixed with 750 grams of a powdered pigment, titanium dioxide in a V blender, a P-K blender with an intensifier bar. Then 150 grams of a plasticizer, polyethylene glycol 400, are added to the blender and thoroughly mixed with the mixture of hydroxypropyl methylcellulose and titanium dioxide to form a coating mixture. The resulting mixture is then passed through a grinder in order to reduce it to a fine powder which is adapted for shipping in dry form to a pharmaceutical manufacturer where it is dispersed in water to form a coating dispersion that is applied to tablets and dried to form a uniform film coating on the tablets.

EXAMPLE 17

The method of Example 16 is followed except that the 750 grams of titanium dioxide powder are replaced by 375 grams of titanium dioxide and 375 grams of red iron oxide which are mixed into the hydroxypropyl methylcellulose in the blender before the plasticizer polyethylene glycol 400 is added.

EXAMPLE 18

The method of Example 16 is followed except that the 750 grams of titanium dioxide powder are replaced by 499 grams of titanium dioxide, 75 grams of FD&C Yellow No. 6 aluminum lake, 25 grams of FD&C Red

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No. 3 aluminum lake, and 25 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 19

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 20

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 83 grams of titanium dioxide, 199 grams of FD&C Yellow No. 6 aluminum lake, 67 grams of FD&C Red No. 3 aluminum lake, and 67 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 21

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 22

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake. Also, 10 grams of fumed silica (Cabosil by Cabot Corp., Boston, Mass.) are added to the polymer-pigment mix to improve the flow in the grinder, and to improve the flow when the dry coating mixture is shipped in containers such as drums.

EXAMPLE 23

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 24

The method of Example 16 is followed except that the 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of methyl cellulose (Methocel A15 by Dow Chemical Co.).

EXAMPLE 25

The method of Example 16 is followed except that 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of hydroxypropyl cellulose (Klucel, by Hercules, Inc., Wilmington, Del.).

EXAMPLE 26

The method of Example 16 is followed except the 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of sodium ethyl cellulose sulphate.

EXAMPLE 27

The method of Example 16 is followed except the 150 grams of polyethylene glycol 400 liquid plasticizer are replaced by 150 grams of glycerin.

EXAMPLE 28

The method of Example 16 is followed except the 150 grams of the liquid plasticizer, polyethylene glycol 400, are replaced by 150 grams of propylene glycol.

EXAMPLE 29

The method of Example 16 is followed except the 750 grams of titanium dioxide are replaced by 120 grams of titanium dioxide, 83 grams of FD&C Blue No. 1 aluminum lake, and 132 grams of riboflavin.

The optimum amount of plasticizer is about 10% of the polymer, as illustrated in Examples 1 and 16, for example. The preferred range is about 5% to 20% by weight of plasticizer to polymer, and a workable range is about 1% to 30% of plasticizer to polymer.

EXAMPLE 30

The method of Example 16 except the 150 grams of plasticizer are replaced by 75 grams.

EXAMPLE 31

The method of Example 16 except 15 grams of plasticizer are used instead of 150 grams.

EXAMPLE 32

The method of Example 16 except 300 grams of plasticizer are used instead of 150 grams.

EXAMPLE 33

The method of Example 16 except 450 grams of plasticizer replace the 150 grams of plasticizer.

The preferred polymer to pigment volume ratio is about 6.5 to 1 as is illustrated by Examples such as Examples 1 and 16. The ratio of polymer to pigment on a volume basis may vary between about 4 to 1 to 10 to 1.

EXAMPLE 34

The method of Example 16 except 923 grams of the polymer are used to give a volume ratio of polymer to pigment of 4 to 1.

EXAMPLE 35

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 166 grams of titanium dioxide, 398 grams of Yellow No. 6 aluminum lake, 134 grams of FD&C Red No. 3 aluminum lake, and 134 grams of FD&C Blue No. 2 aluminum lake. The volume ratio of polymer to pigment is 4 to 1. Also, instead of 150 grams of the plasticizer, 300 grams are used. The plasticizer is 20% by weight of the polymer.

EXAMPLE 36

The method of Example 16 except 490 grams of red iron oxide are used instead of the 750 grams of titanium dioxide to give a volume ratio of polymer to pigment of 10 to 1, and 75 grams of the plasticizer are used instead of the 150 grams.

The preferred polymer to pigment ratio on a weight to weight basis is 3 to 1 as is illustrated by Example 4, but may vary between 2 to 1 as illustrated by Examples 1, 2, 16 and 17, and 5 to 1 as illustrated by Example 37.

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EXAMPLE 37

The method of Example 16 except the 750 grams of titanium dioxide are replaced by 180 grams of FD&C Yellow No. 6 aluminum lake, 60 grams of FD&C Red No. 3 aluminum lake, and 60 grams of FD&C Blue No. 2 aluminum lake.

In regard to the surfactant, it may or may not be needed, depending on the plasticizer used. For example, when using plasticizers which are normally solids under processing conditions, the use of a surfactant can facilitate processing and subsequent constitution of the dry coating system with the solvent. Under these circumstances, from 0.2 to 2% of a non-toxic FDA approved surfactant was found to be advantageous.

As to particle size, the pigment particle size range may be between about 0.1 to 40 microns. The optimum mean particle size range for iron oxides is about 0.5 to 1 micron, for lakes and insoluble dyes is from about 1 to 5 microns, for titanium dioxide is about 0.5 to 2 microns, and for channel black is about 0.2 to 1 micron.

The methyl cellulose of Example 9 is Methocel A15 by Dow Chemical Co. Methocel E15 or E5 (also by Dow) may be used in place of Methocel A15.

The liquid plasticizers when used in making up the inventive dry coating mixture seem to have surfactant properties. The liquid plasticizers seem to act as a solvent for the surfactants, when used, and seem to disperse the surfactants throughout the system.

It is to be noted that the polymer to pigment ratio is a fixed ratio on a volume basis, not on a weight basis. The ratio of polymer to pigment on a volume basis is from about 4 to 1 to 10 to 1 with the preferred ratio being about 6.5 to 1. The volume ratio is used because of the different densities of the various lakes compared to the very dense titanium dioxide. The specific gravity of titanium dioxide to aluminum lakes is roughly about 4 to 2. If a lake of lesser density than titanium dioxide were substituted for an equal weight of titanium dioxide, you would get a greater volume of lake particles and you could get a situation where there would not be enough polymer to bind all the lake particles, which is undesirable. So for loading pigment particles into a polymer, a volume ratio is more satisfactory than a weight ratio.

We want the highest pigment loading possible. A preferred loading of 3 parts dry polymer to 1 part of pigment mixture of titanium dioxide and aluminum lake, by weight, gives a 50-50 ratio by weight of titanium dioxide to aluminum lake. This mixture is about 6.5 to 1 of polymer to pigment on a volume basis. We calculate the volume of that pigment mixture, and use that volume of pigment mixture no matter what pigments are used in the dry pigment mixture and the dry coating mixture. This provides about the same surface area of pigment to be bound by the polymer, no matter what pigments are dispersed in the polymer.

If you put too much pigment into the polymer, you do not have enough polymer to bind the pigment particles. If you put in too little pigment into the polymer, when you put the polymer-pigment mix into water you get a weak color which when applied to a tablet would produce a non-uniform color coating unless many layers of coating were applied.

Referring to the Examples, in Example 2, 375 grams of titanium dioxide were replaced by an equal volume of 375 grams of red iron oxide. In Example 3, 251 grams of titanium dioxide were replaced by an equal volume of 125 grams of aluminum lakes. In Examples 4, 6, 7 and

8, 500 grams of titanium dioxide were replaced by 250 grams of aluminum lakes. In Example 5, 667 grams of titanium dioxide were replaced by 333 grams of aluminum lakes.

ADVANTAGES

One advantage of the dry edible film coating system of the invention is that it breaks down and disperses out the polymer so that when you add the dry coating mixture to a solvent, the polymer does not agglomerate and form fish eyes or lumps. The pigments in this dry system are more efficiently dispersed throughout the polymer that even the non-aqueous OPASPRAY system described in Colorcon U.S. Pat. No. 3,981,984. The colors produced by the dry system are much darker, which shows that the dry system can be brought to the desired shade easily by using less pigment.

Also, the plasticizer seems to have surfactant properties which aid in the thorough dispersion of the dry coating mixture into the liquid coating dispersion.

The dry system of the invention has another advantage in that it eliminates warehousing problems caused by storing liquid pigment dispersions, such as susceptibility to changes because of heat, cold and bacteria, and also eliminates shelf-life problems caused by the solvent in liquid pigment dispersions.

The dry system when constituted in water has a viscosity lower than that of a conventional polymer coating system colored with an OPASPRAY pigment dispersion and having the same total solids and same polymer-pigment ratios so that for equivalent final dispersion viscosities a coating dispersion can be produced from the dry system which has a higher solids loading and consequently a lower solvent content.

The dry coating mixture of the invention is designed primarily for use in an aqueous system but it may also be used in a non-aqueous system with an appropriate polymer plasticizer, and with an organic solvent such as a mixture of methylene chloride and alcohol.

The superior fluidity and dispersion of the coating dispersion made from the dry coating mixture is new and surprising. Why this result is obtained is not presently clearly understood. This art is highly unpredictable. For example, if we mix Cabosil into Klucel (hydroxypropyl cellulose by Hercules, Inc.), the mixture gums up the grinder. However, if we mix Cabosil into Methocel (hydroxypropyl methyl cellulose by Dow Chemical), the mix works just fine and does not gum up the grinder.

Another advantage of the dry system is that it reduces the amount of dust that usually is connected with the use of lakes because the plasticizer acts as a non-dusting coat on the pigment particles.

The method of this dry system provides a really superior dispersion of the ingredients of the dry coating mixture which is much better dispersed into a solvent to form a coating dispersion simply by adding the coating mixture to a solvent, such as water.

As to the commercial aspects of the invention, the dry coating mix eliminates selling a liquid solvent such as water, shipping water, and preserving water, which is required by the prior art wet systems. The water in this dry system is added to the dry coating mixture at its destination by the customer.

The coating mixture of this dry system may be used within an hour of its being made up; it does not require a waiting period such as overnight, as was required by the prior art aqueous and non-aqueous systems. Also,

the dry system does not require high shear mixers, nor non-dusting equipment. The coating dispersions made from the dry coating mixture may be sprayed within an hour of its being made up.

The final coating dispersion prepared from the dry system has a noticeably lower viscosity than a conventionally prepared system having the same ratios and levels of ingredients. There is about a 30% reduction of viscosity over the prior systems, so that the inventive dry coating system can be incorporated into the solvent at a higher solids level for spraying onto tablets, thus resulting in a lower quantity of water having to be sprayed and dried. This substantial lowering of viscosity of the coating dispersion made from the dry system is totally unexpected.

Although the polymer and pigment are completely mixed in the dry state and in the final applied coating, in the wet state the pigment is wetted to a lesser degree by the water than in a conventionally prepared system and thus is less viscous than would normally be expected.

In some areas, the shipping of alcohol-containing products by air is prohibited, so such products must be shipped by boat which takes much longer. Accordingly, the dry coating mixture of the present invention has the advantage of being shipped by air, whereas the pigment dispersions made with an alcohol solvent could not be so shipped. Also, the decreased weight of the dry coating mixture makes shipping it less expensive than shipping the pigment dispersion which contained an alcohol solvent.

We claim:

1. A dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture obtained by dry blending ingredients, including

powdered particles of a film forming non-toxic edible polymer,

powdered edible pigment particles, an edible polymer plasticizer, and a surfactant,

said dry mixture being capable of dispersion in a liquid without agglomeration to form a liquid coating dispersion.

2. A dry powder edible film coating composition for use in making a coating dispersion, including a solvent useful in pharmaceuticals, confectionery and food, comprising a dry mixture including

powdered particles of a film forming non-toxic edible polymer,

powdered edible pigment particles, an edible polymer plasticizer, and a surfactant for dispersing the plasticizer throughout

said solvent of the coating dispersion, said dry mixture being solvent free, the polymer being methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate.

3. The dry edible film coating composition of claim 1, said pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, riboflavin, carmine 40, curcumin, annatto, or insoluble dyes.

4. The dry edible film coating composition of claim 1, said polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerintriacetate,

tate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.

5. The dry edible film coating composition of claim 1, said polymer plasticizer being polyethylene glycol 400.

6. The dry edible film coating composition of claim 1, the polymer plasticizer being a liquid plasticizer.

7. The dry edible film coating composition of claim 1, said surfactant being dioctyl sodium sulfosuccinate, or polysorbate 80.

8. A dry powder edible film coating composition for use in making a coating dispersion, including a solvent useful in pharmaceuticals, confectionery and food, comprising a dry mixture including powdered particles of a film forming non-toxic edible polymer,

powdered edible pigment particles,

an edible polymer plasticizer, and a surfactant for dispersing the plasticizer throughout said solvent of the coating dispersion,

said dry mixture being solvent free, the polymer being methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate,

the pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, riboflavin, carmine 40, curcumin, annatto, or insoluble dyes,

said polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerintriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate, said surfactant being dioctyl sodium sulfosuccinate, or polysorbate 80.

9. A method of making a dry powder edible film coating composition of powdered pigment particles for use in pharmaceuticals, confectionery and food, comprising the steps of

dry mixing a powder of a film forming polymer and powdered pigment particles in a blender,

mixing a surfactant into a plasticizer, adding the surfactant-plasticizer mix to the blender containing the polymer-pigment mix and dry mixing until the combined mix is blended to form the dry edible film coating composition.

10. The method of making a dry powder edible film coating composition of claim 9,

the polymer being methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate.

11. The method of making a dry edible film coating composition of claim 9,

the pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, or insoluble dyes.

12. The method of making a dry edible film coating composition of claim 9,

the polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerintriacetate,

acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.

13. The method of making a dry edible film coating composition of claim 9, the polymer plasticizer being polyethylene glycol 400.

14. The method of making a dry edible film coating composition of claim 9, the polymer plasticizer being a liquid plasticizer.

15. The method of making a dry edible film coating composition of claim 9, the surfactant being dioctyl sodium sulfosuccinate, or polysorbate 80.

16. The method of making a dry edible film coating in accordance with claim 9,

said polymer being methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate,

said pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, or insoluble dyes,

said polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerinetriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate,

said surfactant being dioctyl sodium sulfosuccinate, or polysorbate 80.

17. A dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture including

Powdered particles of a film forming non-toxic edible polymer,

powdered edible pigment particles, and

An edible polymer plasticizer,

said dry mixture being solvent free.

18. The dry edible film coating composition of claim 17, the polymer being methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate.

19. The dry edible film coating composition of claim 17

said pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, riboflavin, carmine 40, curcumin, annatto, or insoluble dyes.

20. The dry edible film coating composition of claim 17,

said polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerinetriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.

21. The dry edible film coating composition of claim 17,

said polymer plasticizer being polyethylene glycol 400.

22. The dry edible film coating composition of claim 17,

the polymer plasticizer being a liquid plasticizer.

23. The dry edible film coating composition of claim 17,

the polymer being methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, polyvinylacetatephthalate, or methacrylic acid methacrylic acid ester co-polymer,

the pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, riboflavin, carmine 40, curcumin, annatto, or insoluble dyes, and

said polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerinetriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, diethyl phthalate, or mineral oil.

24. The dry edible film coating composition of claim 17,

the plasticizer being in the range of 1% to 30% by weight of the polymer,

the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.

25. The dry edible film coating composition of claim 17,

the plasticizer being in the range of about 5% to 20% by weight of the polymer,

the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.

26. The dry edible film coating composition of claim 17,

the plasticizer being about 10% by weight of the polymer,

the volume ratio of the polymer to pigment being about 6.5 to 1.

27. The dry edible film coating composition of claim 23,

the plasticizer being about 10% by weight of the polymer,

the volume ratio of the polymer to pigment being about 6.5 to 1.

28. A method of making a dry powder edible film coating composition of powdered pigment particles for use in pharmaceuticals, confectionery and food, comprising the steps of

dry mixing a powder of a film forming polymer and powdered pigment particles in a blender to form a polymer-pigment mix, and

adding a plasticizer to the blender containing the polymer-pigment mix and dry mixing until the combined mix is blended to form the dry edible film coating composition.

29. The method of making dry powder edible film coating composition of claim 28,

the polymer being methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate.

30. The method of making a dry edible film coating composition of claim 28,

the pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, or insoluble dyes.

31. The method of making a dry edible film coating composition of claim 28, the polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerintriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.
32. The method of making a dry edible film coating composition of claim 28, the polymer plasticizer being polyethylene glycol 400.
33. The method of making a dry edible film coating composition of claim 28, the polymer plasticizer being a liquid plasticizer.
34. The method of making a dry edible film coating in accordance with claim 28, said polymer being methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate, said pigment particles being FD&C and D&C lakes, titanium dioxide magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, or insoluble dyes, and said polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerintriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.
35. The method of making a dry edible film coating composition of claim 28, the plasticizer being in the range of 1% to 30% by weight of the polymer, the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.
36. The method of claim 28, the plasticizer being in the range of about 5% to 20% by weight of the polymer, the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.
37. The method of claim 28, the plasticizer being about 10% by weight of the polymer, the volume ratio of the polymer to pigment being about 6.5 to 1.
38. The method of claim 34, the plasticizer being about 10% by weight of the polymer, the volume ratio of the polymer to pigment being about 6.5 to 1.
39. A dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture including 500 grams of powdered hydroxypropyl methylcellulose, 750 grams of powdered titanium dioxide, and 150 grams of polyethylene glycol 400, said polyethylene glycol 400 being thoroughly mixed with the hydroxypropyl methylcellulose and the titanium dioxide to form a coating mixture.
40. A dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture including 1500 grams of powdered hydroxypropyl methylcellulose,

- 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, 50 grams of FD&C Blue No. 2 aluminum lake, and 150 grams of polyethylene glycol 400, said polyethylene glycol 400 being thoroughly mixed with the other ingredients to form a coating mixture.
41. A method of making a coating dispersion for use in pharmaceuticals, confectionery and food, comprising the steps of dry mixing 1500 grams of powdered hydroxypropyl methylcellulose and 750 grams of powdered titanium dioxide in a blender to form a polymer-pigment mix, adding 150 grams of polyethylene glycol 400 to the blender containing the polymer-pigment mix, and dry mixing until the combined mix is blended to form a dry edible film coating composition.
42. A method of making a coating dispersion for use in pharmaceuticals, confectionery and food, comprising the steps of dry mixing 1500 grams of hydroxypropyl cellulose in a blender with 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake, to form a polymer-pigment mix, adding 150 grams of polyethylene glycol 400 to the blender containing the polymer-pigment mix, adding 10 grams of fumed silica to the mix, and dry mixing until the combined mix is blended to form a dry edible film coating composition.
43. A dry powder edible film coating composition produced by the method of claim 9.
44. A dry powder edible film coating composition produced by the method of claim 10.
45. A dry powder edible film coating composition produced by the method of claim 11.
46. A dry powder edible film coating composition produced by the method of claim 12.
47. A dry powder edible film coating composition produced by the method of claim 13.
48. A dry powder edible film coating composition produced by the method of claim 14.
49. A dry powder edible film coating composition produced by the method of claim 15.
50. A dry powder edible film coating composition produced by the method of claim 16.
51. A dry powder edible film coating composition produced by the method of claim 28.
52. A dry powder edible film coating composition produced by the method of claim 29.
53. A dry powder edible film coating composition produced by the method of claim 30.
54. A dry powder edible film coating composition produced by the method of claim 31.
55. A dry powder edible film coating composition produced by the method of claim 32.
56. A dry powder edible film coating composition produced by the method of claim 33.
57. A dry powder edible film coating composition produced by the method of claim 34.
58. A dry powder edible film coating composition produced by the method of claim 35.
59. A dry powder edible film coating composition Produced by the method of claim 36.

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60. A dry powder edible film coating composition
produced by the method of claim 37.
61. A dry powder edible film coating composition
produced by the method of claim 38.

62. A dry powder edible film coating composition
produced by the method of claim 41.
63. A dry powder edible film coating composition
produced by the method of claim 42.
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[34] DRY EDIBLE FILM COATING
COMPOSITION, METHOD AND COATING
FORM
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[73] Assignee: Colares, Inc., West Point, Pa.
[21] Appl. No.: 759,673
[22] Filed: Jul. 29, 1985

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4,543,370, which is a continuation-in-part of Ser. No.
98,531, Nov. 29, 1979, abandoned.
[51] Int. Cl.⁴ C08J 3/12
[52] U.S. Cl. 524/285; 424/439;
424/494
[58] Field of Search 424/33, 34; 524/285

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[57] ABSTRACT

A dry powder edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a dry mixture including powdered particles of a film forming non-toxic polymer, powdered edible pigment particles, and an edible polymer plasticizer, said dry mixture being solvent free. A method of making a dry powder edible film coating composition of powdered pigment particles for use in pharmaceuticals, confectionery and food, comprising the steps of mixing a powder of a film forming polymer and powdered pigment particles in a blender to form a polymer-pigment mix, and adding the plasticizer to the blender containing the polymer-pigment mix and mixing until the combined mix is blended to form the dry powder edible film coating composition.

33 Claims, No Drawings

DRY EDIBLE FILM COATING COMPOSITION, METHOD AND COATING FORM

This is a divisional of co-pending application Ser. No. 202,831 filed on Nov. 6, 1980, now U.S. Pat. No. 4,543,370, which is a continuation-in-part of our U.S. patent application Ser. No. 98,531, filed on Nov. 29, 1979, now abandoned.

TECHNICAL FIELD

This invention is in the field of coating of pharmaceutical tablets and the like, and provides a dry edible film coating composition for use in pharmaceuticals, confectionery, and food.

CROSS-REFERENCE TO RELATED PATENTS

This patent application is concerned with edible coating systems and is related to U.S. Pat. No. 3,981,984 which issued Sept. 21, 1976 to Charles A. Signorino, owned by Colorcon, Inc., West Point, Pa. 19486, the assignee of this patent application, and is incorporated herein by reference.

BACKGROUND OF THE INVENTION

Signorino U.S. Pat. No. 3,981,984 provides an edible concentrated pigment suspension that is shipped, for example, to a pharmaceutical manufacturer who mixes it with a polymer solution to form a coating suspension which may be used for coating tablets and the like. The pigment suspension, polymer solution, and coating suspension are in a non-aqueous solvent.

It has long been desired to provide a dry edible film coating composition which can be constituted with solvent by the customer, that eliminates the problem of shipping of pigment dispersions containing aqueous or non-aqueous solvents and thereby eliminates the problems caused by solvents, and also makes shipping less expensive by eliminating the weight of the solvents.

It is known in the prior art to mix a dry polymer powder with pigment particles, and to grind the mixture to obtain a dry polymer-pigment mixture which is then ground into a fine powder mixture. However, when this fine polymer-pigment mixture is stirred into water and dispersed, the polymer makes lumps and fish eyes because it agglomerates, and the result is not really a uniform dispersion. Accordingly, when this polymer-pigment dispersion is used as a coating dispersion and is coated onto tablets and the like, unless the dispersion is left to solvate for a considerable period of time like overnight, the coating is lumpy and not uniform and is therefore undesirable.

SUMMARY OF THE INVENTION

A dry edible film coating composition for use in pharmaceuticals, confectionery and food, comprising a mixture including polymer particles, pigment particles, and a polymer plasticizer. Advantageously, a surfactant may be added especially when the plasticizer may be a solid. The composition may also include a flow aid.

A method of making a dry edible film coating composition for use in pharmaceuticals, confectionery and food, comprises the steps of mixing a polymer powder and pigment particles in a blender, adding a plasticizer to the blender containing the polymer-pigment mix, and mixing until the combined mix is thoroughly blended. A surfactant may be mixed with the plasticizer, especially when the plasticizer is a solid. A flow aid may be mixed

into the polymer-pigment mix, such as Cabosil (finely divided colloidal silica by Cabot Corp., Boston Mass.), or Aerosil (finely divided colloidal silica by Degussa, Frankfurt, W. Germany).

The polymer may be methylcellulose, hydroxypropyl methylcellulose, hydroxypropyl cellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, polyvinylacetate-phthalate, methacrylic acid-methacrylic acid ester co-polymer, or other film forming polymer used for coating tablets and the like.

Any of the pigments heretofore used in making coating dispersions for coating tablets and the like may be used in the dry coating mixture of this invention. Examples are FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, charcoal black, and insoluble dyes. Also natural pigments such as riboflavin, carmine 40, curcumin, and annatto. Other examples are listed in Jeffries U.S. Pat. No. 3,149,040 and Butler et al. U.S. Pat. No. 3,297,535, as well as in Colorcon U.S. Pat. No. 3,981,984. All these patents and patent applications are incorporated herein by reference.

Exemplary of the polymer plasticizer for use in the dry coating mixture of the invention are polyethylene glycol, for example, polyethylene glycol having a molecular weight of 200 to 8000 (Carbowax by Union Carbide), glycerin, propylene glycol, Triacetin (Pfizer's glycerin triacetate), acetylated monoglyceride, and Citroflex 2 (triethylcitrate), Citroflex 4 (tributylcitrate citrate), Citroflex A2 (acetyltriethylcitrate), Citroflex A4 (acetyltributylcitrate), diethyl phthalate, and mineral oil. Citroflex 2, 4, A2 and A4 are made by Pfizer and are plasticizers adapted for use with organic solvents.

The polymer plasticizer, to soften the polymer and make it less brittle, may be a liquid or a solid plasticizer, and a preferred plasticizer is a liquid such as polyethylene glycol 400.

The surfactant may be, for example, a solid powder surfactant such as Aerosol OT (dioctyl sodium sulfosuccinate by Cyanamid) which is preferably used with the liquid polyethylene glycol 400, or Tween 80 (polysorbate 80 by ICI Americas, Wilmington, Del.) which is a liquid and is preferably used with a solid plasticizer such as the polyethylene glycol 3350 and 8000.

DETAILED DESCRIPTION

We now turn to the examples of the invention, all ingredients being in parts by weight:

EXAMPLE 1

1500 grams of a polymer, powdered hydroxypropyl methylcellulose, are mixed with 750 grams of a powdered pigment, titanium dioxide in a V blender, a P-K blender with an intensifier bar. Then 150 grams of a plasticizer, polyethylene glycol 400, are thoroughly mixed with 5 grams of a surfactant, dioctyl sodium sulfosuccinate. The polyethylene glycol 400—dioctyl sodium sulfosuccinate mix is then added to the blender and thoroughly mixed with the mixture of hydroxypropyl methylcellulose and titanium dioxide to form a coating mixture. The resulting mixture is then passed through a grinder in order to reduce it to a fine powder which is adapted for shipping in dry form to a pharmaceutical manufacturer where it is dispersed in water to form a coating dispersion that is applied to tablets and dried to form a uniform film coating on the tablets.

The coating dispersion obtained when the coating mixture is mixed with the solvent is surprisingly fluid and uniform, and easy to apply to the tablets.

EXAMPLE 2

The method of Example 1 is followed except that the 750 grams of titanium dioxide powder are replaced by 375 grams of titanium dioxide and 375 grams of red iron oxide which are mixed into the hydroxypropyl methylcellulose in the blender before the plasticizer-surfactant mix of polyethylene glycol 400 and dioctyl sodium sulfosuccinate is added.

EXAMPLE 3

The method of Example 1 is followed except that the 750 grams of titanium dioxide powder are replaced by 499 grams of titanium dioxide, 75 grams of FD&C Yellow No. 6 aluminum lake, 25 grams of FD&C Red No. 3 aluminum lake, and 25 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 4

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 5

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 83 grams of titanium dioxide, 199 grams of FD&C Yellow No. 6 aluminum lake, 67 grams of FD&C Red No. 3 aluminum lake, and 67 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 6

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake. Also, the 5 grams of dioctyl sodium sulfosuccinate are replaced by 5 grams of polyacrylate 80 (Tween 80 by ICI Americas), another surfactant.

EXAMPLE 7

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake. Also, 10 grams of fumed silica (Cabosil by Cabot Corp., Boston, Mass.) are added to the polymer-pigment mix to improve the flow in the grinder, and to improve the flow when the dry coating mixture is shipped in containers such as drums.

EXAMPLE 8

The method of Example 1 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 9

The method of Example 1 is followed except that the 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of methyl cellulose (Methocel A15 by Dow Chemical Co.).

EXAMPLE 10

The method of Example 1 is followed except that 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of hydroxypropyl cellulose (Klucel, by Hercules, Inc., Wilmington, Del.).

EXAMPLE 11

The method of Example 1 is followed except the 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of sodium ethyl cellulose sulphate.

EXAMPLE 12

The method of Example 1 is followed except the 150 grams of polyethylene glycol 400 liquid plasticizer are replaced by 150 grams of glycerin.

EXAMPLE 13

The method of Example 1 is followed except the 150 grams of the liquid plasticizer, polyethylene glycol 400 are replaced by 150 grams of propylene glycol.

EXAMPLE 14

The method of Example 1 is followed except the 150 grams of polyethylene glycol 400 are replaced by 150 grams of powdered polyethylene glycol 6000, and the 5 grams of Aerosol OT are replaced by 5 grams of Tween 80.

EXAMPLE 15

The method of Example 1 is followed except the 150 grams of polyethylene glycol 400 are replaced by 150 grams of powdered polyethylene glycol 8000, and the 5 grams of Aerosol OT are replaced by 5 grams of Tween 80.

EXAMPLE 16

1500 grams of a polymer, powdered hydroxypropyl methylcellulose are mixed with 750 grams of a powdered pigment, titanium dioxide in a V blender, a P-K blender with an intensifier bar. Then 150 grams of a plasticizer, polyethylene glycol 400, are added to the blender and thoroughly mixed with the mixture of hydroxypropyl methylcellulose and titanium dioxide to form a coating mixture. The resulting mixture is then passed through a grinder in order to reduce it to a fine powder which is adapted for shipping in dry form to a pharmaceutical manufacturer where it is dispersed in water to form a coating dispersion that is applied to tablets and dried to form a uniform film coating on the tablets.

EXAMPLE 17

The method of Example 16 is followed except that the 750 grams of titanium dioxide powder are replaced by 375 grams of titanium dioxide and 375 grams of red iron oxide which are mixed into the hydroxypropyl methylcellulose in the blender before the plasticizer polyethylene glycol 400 is added.

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EXAMPLE 18

The method of Example 16 is followed except that the 750 grams of titanium dioxide powder are replaced by 499 grams of titanium dioxide, 75 grams of FD&C Yellow No. 6 aluminum lake, 25 grams of FD&C Red No. 3 aluminum lake, and 25 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 19

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 20

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 83 grams of titanium dioxide, 199 grams of FD&C Yellow No. 6 aluminum lake, 67 grams of FD&C Red No. 3 aluminum lake, and 67 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 21

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 22

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake. Also, 10 grams of fumed silica (Cabosil by Cabot Corp., Boston, Mass.) are added to the polymer-pigment mix to improve the flow in the grinder, and to improve the flow when the dry coating mixture is shipped in containers such as drums.

EXAMPLE 23

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 250 grams of titanium dioxide, 150 grams of FD&C Yellow No. 6 aluminum lake, 50 grams of FD&C Red No. 3 aluminum lake, and 50 grams of FD&C Blue No. 2 aluminum lake.

EXAMPLE 24

The method of Example 16 is followed except that the 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of methyl cellulose (Methocel A15 by Dow Chemical Co.).

EXAMPLE 25

The method of Example 16 is followed except that 1500 grams of hydroxypropyl methylcellulose are replaced by 1500 grams of hydroxypropyl cellulose (Klucel, by Hercules, Inc., Wilmington, Del.).

EXAMPLE 26

The method of Example 16 is followed except the 1500 grams of hydroxypropyl methylcellulose are re-

placed by 1500 grams of sodium ethyl cellulose sulphate.

EXAMPLE 27

The method of Example 16 is followed except the 150 grams of polyethylene glycol 400 liquid plasticizer are replaced by 150 grams of glycerin.

EXAMPLE 28

The method of Example 16 is followed except the 150 grams of the liquid plasticizer, polyethylene glycol 400, are replaced by 150 grams of propylene glycol.

EXAMPLE 29

The method of Example 16 is followed except the 750 grams of titanium dioxide are replaced by 120 grams of titanium dioxide, 183 grams of FD&C Blue No. 1 aluminum lake, and 132 grams of riboflavin.

The optimum amount of plasticizer is about 10% of the polymer, as illustrated in Examples 1 and 16, for example. The preferred range is about 5% to 20% by weight of plasticizer to polymer, and a workable range is about 1% to 30% of plasticizer to polymer.

EXAMPLE 30

The method of Example 16 except the 150 grams of plasticizer are replaced by 75 grams.

EXAMPLE 31

The method of Example 16 except 15 grams of plasticizer are used instead of 150 grams.

EXAMPLE 32

The method of Example 16 except 300 grams of plasticizer are used instead of 150 grams.

EXAMPLE 33

The method of Example 16 except 450 grams of plasticizer replace the 150 grams of plasticizer.

The preferred polymer to pigment volume ratio is about 6.5 to 1 as is illustrated by examples such as Examples 1 and 16. The ratio of polymer to pigment on a volume basis may vary between about 4 to 1 to 10 to 1.

EXAMPLE 34

The method of Example 16 except 923 grams of the polymer are used to give a volume ratio of polymer to pigment of 4 to 1.

EXAMPLE 35

The method of Example 16 is followed except that the 750 grams of titanium dioxide are replaced by 166 grams of titanium dioxide, 398 grams of Yellow No. 6 aluminum lake, 134 grams of FD&C Red No. 3 aluminum lake, and 134 grams of FD&C Blue No. 2 aluminum lake. The volume ratio of polymer to pigment is 4 to 1. Also, instead of 150 grams of the plasticizer, 300 grams are used. The plasticizer is 20% by weight of the polymer.

EXAMPLE 36

The method of Example 16 except 490 grams of red iron oxide are used instead of the 750 grams of titanium dioxide to give a volume ratio of polymer to pigment of 10 to 1, and 75 grams of the plasticizer are used instead of the 150 grams.

The preferred polymer to pigment ratio on a weight to weight basis is 3 to 1 as is illustrated by Example 4,

but may vary between 2 to 1 as illustrated by Examples 1, 2, 16 and 17, and 5 to 1 as illustrated by Example 37.

EXAMPLE 37

The method of Example 16 except the 750 grams of titanium dioxide are replaced by 180 grams of FD&C Yellow No. 6 aluminum lake, 60 grams of FD&C Red No. 3 aluminum lake, and 60 grams of FD&C Blue No. 2 aluminum lake.

In regard to the surfactant, it may or may not be needed, depending on the plasticizer used. For example, when using plasticizers which are normally solids under processing conditions, the use of a surfactant can facilitate processing and subsequent constitution of the dry coating system with the solvent. Under these circumstances, from 0.2 to 2% of a nontoxic FDA approved surfactant was found to be advantageous.

As to particle size, the pigment particle size range may be between about 0.1 to 40 microns. The optimum mean particle size range for iron oxides is about 0.5 to 1 micron, for lakes and insoluble dyes is from about 1 to 5 microns, for titanium dioxide is about 0.5 to 2 microns, and for channel black is about 0.2 to 1 micron.

The methyl cellulose of Example 9 is Methocel A15 by Dow Chemical Co. Methocel E15 or E5 (also by Dow) may be used in place of Methocel A15.

The liquid plasticizers when used in making up the inventive dry coating mixture seem to have surfactant properties. The liquid plasticizers seem to act as a solvent for the surfactants, when used, and seem to disperse the surfactants throughout the system.

It is to be noted that the polymer to pigment ratio is a fixed ratio on a volume basis, not on a weight basis. The ratio of polymer to pigment on a volume basis is from about 4 to 1 to 10 to 1 with the preferred ratio being about 6.5 to 1. The volume ratio is used because of the different densities of the various lakes compared to the very dense titanium dioxide. The specific gravity of titanium dioxide to aluminum lakes is roughly about 4 to 2. If a lake of lesser density than titanium dioxide were substituted for an equal weight of titanium dioxide, you would get a greater volume of lake particles and you could get a situation where there would not be enough polymer to bind all the lake particles, which is undesirable. So for loading pigment particles into a polymer, a volume ratio is more satisfactory than a weight ratio.

We want the highest pigment loading possible. A preferred loading of 3 parts dry polymer to 1 part of pigment mixture of titanium dioxide and aluminum lake, by weight, gives a 50-50 ratio by weight of titanium dioxide to aluminum lake. This mixture is about 6.5 to 1 of polymer to pigment on a volume basis. We calculate the volume of that pigment mixture, and use that volume of pigment mixture no matter what pigments are used in the dry pigment mixture and the dry coating mixture. This provides about the same surface area of pigment to be bound by the polymer, no matter what pigments are dispersed in the polymer.

If you put too much pigment into the polymer, you do not have enough polymer to bind the pigment particles. If you put in too little pigment into the polymer, when you put the polymer-pigment mix into water you get a weak color which when applied to a tablet would produce a non-uniform color coating unless many layers of coating were applied.

Referring to the Examples, in Example 2, 375 grams of titanium dioxide were replaced by an equal volume of 375 grams of red iron oxide. In Example 3, 251 grams

of titanium dioxide were replaced by an equal volume of 125 grams of aluminum lakes. In Examples 4, 6, 7 and 8, 500 grams of titanium dioxide were replaced by 250 grams of aluminum lakes. In Example 5, 667 grams of titanium dioxide were replaced by 333 grams of aluminum lakes.

Advantages

One advantage of the dry edible film coating system of the invention is that it breaks down and disperses out the polymer so that when you add the dry coating mixture to a solvent, the polymer does not agglomerate and form fish eyes or lumps. The pigments in this dry system are more efficiently dispersed throughout the polymer that even the non-aqueous OPASPRAY system described in Colorecon U.S. Pat. No. 3,981,984. The colors produced by the dry system are much darker, which shows that the dry system can be brought to the desired shade easily by using less pigment.

Also, the plasticizer seems to have surfactant properties which aid in the thorough dispersion of the dry coating mixture into the liquid coating dispersion.

The dry system of the invention has another advantage in that it eliminates warehousing problems caused by storing liquid pigment dispersions, such as susceptibility to changes because of heat, cold and bacteria, and also eliminates shelf-life problems caused by the solvent in liquid pigment dispersions.

The dry system when constituted in water has a viscosity lower than that of a conventional polymer coating system colored with an OPASPRAY pigment dispersion and having the same total solids and same polymer-pigment ratios so that for equivalent final dispersion viscosities a coating dispersion can be produced from the dry system which has a higher solids loading and consequently a lower solvent content.

The dry coating mixture of the invention is designed primarily for use in an aqueous system but it may also be used in a non-aqueous system with an appropriate polymer plasticizer, and with an organic solvent such as a mixture of methylene chloride and alcohol.

The superior fluidity and dispersion of the coating dispersion made from the dry coating mixture is new and surprising. Why this result is obtained is not presently clearly understood. This art is highly unpredictable. For example, if we mix Cabosil into Klucel (hydroxypropyl cellulose by Hercules, Inc.), the mixture gums up the grinder. However, if we mix Cabosil into Methocel (hydroxypropyl methyl cellulose by Dow Chemical), the mix works just fine and does not gum up the grinder.

Another advantage of the dry system is that it reduces the amount of dust that usually is connected with the use of lakes because the plasticizer acts as a non-dusting coat on the pigment particles.

The method of this dry system provides a really superior dispersion of the ingredients of the dry coating mixture which is much better dispersed into a solvent to form a coating dispersion simply by adding the coating mixture to a solvent, such as water.

As to the commercial aspects of the invention, the dry coating mix eliminates selling a liquid solvent such as water, shipping water, and preserving water, which is required by the prior art wet systems. The water in this dry system is added to the dry coating mixture at its destination by the customer.

The coating mixture of this dry system may be used within an hour of its being made up; it does not require

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a waiting period such as overnight, as was required by the prior art aqueous and non-aqueous systems. Also, the dry system does not require high shear mixers, nor non-dusting equipment. The coating dispersions made from the dry coating mixture may be sprayed within an hour of its being made up.

The final coating dispersion prepared from the dry system has a noticeably lower viscosity than a conventionally prepared system having the same ratios and levels of ingredients. There is about a 30% reduction of viscosity over the prior systems, so that the inventive dry coating system can be incorporated into the solvent at a higher solids level for spraying onto tablets, thus resulting in a lower quantity of water having to be sprayed and dried. This substantial lowering of viscosity of the coating dispersion made from the dry system is totally unexpected.

Although the polymer and pigment are completely mixed in the dry state and in the final applied coating, in the wet state the pigment is wetted to a lesser degree by the water than in a conventionally prepared system and thus is less viscous than would normally be expected.

In some areas, the shipping of alcohol-containing products by air is prohibited, so such products must be shipped by boat which takes much longer. Accordingly, the dry coating mixture of the present invention has the advantage of being shipped by air, whereas the pigment dispersions made with an alcohol solvent could not be so shipped. Also, the decreased weight of the dry coating mixture makes shipping it less expensive than shipping the pigment dispersion which contained an alcohol solvent.

We claim:

1. A method of making a coating dispersion for use in pharmaceuticals, confectionery and food, comprising the steps of

dry mixing a powder of film forming polymer and powdered pigment particles in a blender,

mixing a surfactant into a plasticizer,

adding the surfactant-plasticizer mix to the blender containing the polymer-pigment mix and dry mixing until the combined mix is blended to form a dry edible film coating composition,

and dispersing the dry edible film coating composition into a solvent to form a coating dispersion adapted for use as a film coating for tablets and the like.

2. The method of claim 1, said solvent being an aqueous solvent.

3. The method of claim 1, said solvent being alcohol, methanol, methylene chloride, or acetone.

4. A method of making an edible coated tablet and the like, comprising

dry mixing a powder of film forming polymer and powdered pigment particles in a blender,

mixing a surfactant into a plasticizer,

adding the surfactant-plasticizer mix to the blender containing the polymer-pigment mix and dry mixing until the combined mix is blended to form a dry edible film coating composition,

and dispersing the dry edible film coating composition into a solvent, without agglomeration, to form a coating dispersion adapted for use as a film coating for tablets and the like,

coating a tablet with said coating dispersion, and drying the coating dispersion on the tablet.

5. A method of making a coating dispersion for use in pharmaceuticals, confectionery and food, comprising the steps of

dry mixing a powder of film forming polymer and powdered pigment particles in a blender, adding a plasticizer to the blender containing the polymer-pigment mix and dry mixing until the combined mix is blended to form a dry edible film coating composition,

and dispersing the dry edible film coating composition into a solvent, without agglomeration, to form a coating dispersion adapted for use as a film coating for tablets and the like.

6. The method of claim 5,

said solvent being an aqueous solvent.

7. The method of claim 5,

said solvent being alcohol, methanol, methylene chloride, or acetone.

8. A method of making an edible coated tablet and the like, comprising

dry mixing a powder of film forming polymer and powdered pigment particles in a blender, adding a plasticizer to the blender containing the polymer-pigment mix and dry mixing until the combined mix is blended to form a dry edible film coating composition,

and dispersing the dry edible film coating composition into a solvent, without agglomeration, to form a coating dispersion adapted for use as a film coating for tablets and the like,

coating a tablet with said coating dispersion, and drying the coating dispersion on the tablet.

9. A method of making a coating dispersion for use in pharmaceuticals, confectionery and food, comprising the steps of

mixing a powder of film forming polymer and powdered pigment particles in a blender,

adding a plasticizer to the blender containing the polymer-pigment mix and mixing until the combined mix is blended to form a dry edible film coating composition,

and dispersing the dry edible film coating composition into a solvent to form a coating dispersion adapted for use as a film coating for tablets and the like,

the plasticizer being in the range of 1% to 30% by weight of the polymer, the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.

10. The method of claim 9, the plasticizer being in the range of about 5% to 20% by weight of the polymer, the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.

11. The method of claim 9, the plasticizer being about 10% by weight of the polymer, the volume ratio of the polymer to pigment being about 6.5 to 1.

12. The method of claim 9, the polymer being methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellulose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, xan, or polyvinylacetatephthalate.

13. The method of claim 9, the pigment particles being FD&C and D&C lakes, titanium dioxide, magnesium carbonate, talc, pyrogenic silica, iron oxides, channel black, or insoluble dyes.

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14. The method of making a dry edible film coating composition of claim 9, the polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerinetriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.

15. The method of claim 9, the polymer plasticizer being polyethylene glycol 400.

16. The method of claim 9, the polymer plasticizer being a liquid plasticizer.

17. The method of claim 9, including mixing a surfactant into the plasticizer.

18. A method of making an edible coated tablet and the like, comprising

mixing a powder of film forming polymer and powdered pigment particles in a blender,

adding a plasticizer to the blender containing the polymer-pigment mix and mixing until the combined mix is blended to form a dry edible film coating composition,

and dispersing the dry edible film coating composition into a solvent to form a coating dispersion adapted for use as a film coating for tablets and the like,

coating a tablet with said coating dispersion, and drying the coating dispersion on the tablet, the plasticizer being in the range of 1% to 30% by weight of the polymer,

the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.

19. The method of claim 18, the plasticizer being in the range of about 5% to 20% by weight of the polymer,

the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1.

20. The method of claim 18, the plasticizer being about 10% by weight of the polymer,

the volume ratio of the polymer to pigment being about 6.5 to 1.

21. The method of claim 18, the polymer being methylcellulose, hydroxypropyl cellulose, hydroxypropyl methylcellulose, cellalose acetate phthalate, ethylcellulose, polyvinylpyrrolidone, sodium ethylcellulose sulphate, zein, or polyvinylacetatephthalate.

22. The method of claim 18, the pigment particles being FD&C and D&C lakes, titanium dioxide, magne-

sium carbonate, talc, pyrogenic silica, iron oxides, channel black, or insoluble dyes.

23. The method of making a dry edible film coating composition of claim 18, the polymer plasticizer being polyethylene glycol having a molecular weight in the range of 200 to 8000, glycerin, propyleneglycol, glycerinetriacetate, acetylated monoglyceride, triethylcitrate, tributylcitrate, acetyltriethylcitrate, acetyltributylcitrate, or diethyl phthalate.

24. The method of claim 18, the polymer plasticizer being polyethylene glycol 400.

25. The method of claim 18, the polymer plasticizer being a liquid plasticizer.

26. The method of claim 18, including mixing a surfactant into the plasticizer.

27. A method of coating edible coated tablets and the like, comprising

making a coating dispersion of a cellulosic film forming polymer, pigment particles and plasticizer, the plasticizer being in the range of 1% to 30% by weight of the polymer, and the volume ratio of the polymer to pigment being about 4 to 1 to 10 to 1, and spraying said dispersion on the tablets.

28. The method of claim 27, wherein said dispersion is in water.

29. The method of claim 27, wherein said cellulosic film forming polymer is selected from the group consisting of methylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose, cellulose acetate phthalate, ethylcellulose, and sodium ethylcellulose sulphate.

30. The method of claim 27, wherein said plasticizer being polyethyleneglycol.

31. A method of making a coating dispersion for use in coating pharmaceuticals, confectionery and food, comprising the steps of

making a dry edible film coating composition of a film forming polymer, plasticizer, and powdered pigment particles,

and dispersing the elements of said dry edible film coating composition simultaneously into a solvent by dispersing said composition into the solvent to form a coating dispersion adapted for use as a film coating for tablets and the like.

32. The method of claim 31, including the step of coating tablets with the coating dispersion.

33. The method of claim 32, including coating the tablets by spraying the coating dispersion onto the tablets, and drying the coating on the tablets.

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