

62591

COMMONWEALTH OF AUSTRALIA

Patents Act 1952-1969

CONVENTION APPLICATION FOR A PATENT

(1) Here insert (in full) Name or Names of Applicant or Applicants, followed by Address (es).

~~xx~~ (1) DOW CORNING CORPORATION  
We of Midland, State of Michigan, United States of America

(2) Here insert Title of Invention.

hereby apply for the grant of a Patent for an invention entitled: (2)  
PREVENTION OF ANAL LEAKAGE OF POLYORGANOSILOXANE FLUIDS USED AS FAT  
SUBSTITUTES IN FOODS

(3) Here insert number(s) of basic application(s)

which is described in the accompanying complete specification. This application is a  
Convention application and is based on the application numbered (a)  
267,949

(4) Here insert Name of basic Country or Countries, and basic date or dates

for a patent or similar protection made in (4) United States of America  
on 7th November 1988

~~xx~~ My address for service is ~~Messrs. Edward Waters & Sons, Patent Attorneys~~  
Our Watermark Patent & Trademark Attorneys  
50 Queen Street, Melbourne, Victoria, Australia.

FO12097 06/11/89

DATED this 3rd day of November 1989

(5) Signature (s) of Applicant (s) or Seal of Company and Signatures of its Officers as prescribed by its Articles of Association

(5)

DOW CORNING CORPORATION

by

*Ian A. Scott*

Ian A. Scott

Registered Patent Attorney

## COMMONWEALTH OF AUSTRALIA

Patents Act 1952-1969

DECLARATION IN SUPPORT OF A CONVENTION  
APPLICATION FOR A PATENT OR PATENT OF ADDITION(1) Here  
insert (in  
full) Name of  
Company.In support of the Convention Application made by<sup>(1)</sup>  
DOW CORNING CORPORATION of Midland, State of Michigan,  
United States of America

(hereinafter referred to as the applicant) for a Patent

(2) Here  
insert title  
of Invention.for an invention entitled:<sup>(2)</sup>  
PREVENTION OF ANAL LEAKAGE OF POLYORGANOSILOXANE FLUIDS  
USED AS FAT SUBSTITUTES IN FOODS(3) Here  
insert full Name  
and Address  
of Company  
official  
authorized  
to make  
declaration.I,<sup>(3)</sup> NORMAN EDWARD LEWIS, General Patent Counsel &  
of DOW CORNING CORPORATION of Midland, Assistant Secretary  
State of Michigan, United States of America

do solemnly and sincerely declare as follows:

1. I am authorised by the applicant for the patent  
to make this declaration on its behalf.(4) Here  
insert basic  
Country or  
Countries  
followed by  
date or dates  
and basic  
Applicant or  
Applicants.2. The basic application as defined by Section 141 of the Act was  
made in<sup>(4)</sup> United States of America, Serial No. 267,949  
on the 7th day of November 1988, by  
JOHN WILLIAM RYAN~~on the~~ ~~day of~~ ~~1988~~(5) Here  
insert (in  
full) Name  
and Address  
of Actual  
Inventor or  
Inventors.3.<sup>(5)</sup> JOHN WILLIAM RYAN, 514 Linwood Drive, Midland,  
Michigan, United States of Americais~~are~~ the actual inventor of the invention and the facts upon which the applicant  
is entitled to make the application are as follow:

The applicant is the assignee of

JOHN WILLIAM RYAN

4. The basic application referred to in paragraph 2 of this Declaration  
was the first application made in a Convention country in  
respect of the invention the subject of the application.DECLARED at Midland, Michigan, United States of America  
this 3rd day of October 1989.

(6) Signature.

(6) DOW CORNING CORPORATION

To: THE COMMISSIONER OF PATENTS. By: *Norman Edward Lewis*

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(12) PATENT ABRIDGMENT      (11) Document No. AU-B-44413/89  
(19) AUSTRALIAN PATENT OFFICE      (10) Acceptance No. 629591

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- (54) Title  
ANTI-ANAL LEAKAGE OF POLYORGANOSILOXANE USED AS FAT SUBSTITUTES
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(51)<sup>b</sup> A23D 009/02
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267949      07.11.88      US UNITED STATES OF AMERICA
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- (56) Prior Art Documents  
AU 597886 58000/86 A23D 3/00 A23L 1/308  
US 4005196  
US 4005195
- (57) Claim

1. A low calorie food composition comprising non-fat ingredients and fat ingredients wherein from 0.1% to 100% by weight of the total fat ingredients have been replaced by a substitute comprising:

a. an edible, non-absorbable, non-digestible liquid siloxane polymer of the general formula  $(\text{CH}_3)_3\text{SiO}[(\text{CH}_3)_2\text{SiO}]_b\text{Si}(\text{CH}_3)_3$  wherein b has an average value of 25 to 500; and

b. sufficient particulate silica to prevent leakage of said liquid siloxane through the anal sphincter.

629591

COMMONWEALTH OF AUSTRALIA  
PATENTS ACT 1952-60

Form 10

# COMPLETE SPECIFICATION

(ORIGINAL)

Class

Int. Class

Application Number:  
Lodged:

Complete Specification Lodged:

Accepted:

Published:

Priority:

Related Art:

Name of Applicant: DOW CORNING CORPORATION

Address of Applicant: Midland, State of Michigan, United States of America

Actual Inventor: JOHN WILLIAM RYAN

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50 QUEEN STREET, MELBOURNE, AUSTRALIA, 3000.

Complete Specification for the invention entitled:

PREVENTION OF ANAL LEAKAGE OF POLYORGANOSILOXANE FLUIDS USED AS FAT  
SUBSTITUTES IN FOOD

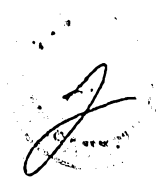
The following statement is a full description of this invention, including the best method of performing it known to : US

PREVENTION OF ANAL LEAKAGE OF POLYORGANOSILOXANE FLUIDS  
USED AS FAT SUBSTITUTES IN FOODS

The present invention relates to a method of controlling the anal leakage of polyorganosiloxane fluids used as fat substitutes in food by adding an anti-anal leakage  
5 agent of the type disclosed hereinafter to the liquid siloxane or to foods containing same.

Non-degradable polyorganosiloxane fluids can be substituted for fats in food compositions. However, rats fed a diet containing about 6.5% by weight of polyorganosiloxane fluid exhibited undesirable anal leakage of the siloxane fluid. It has now been determined that this undesirable affect can be obviated by combining the polyorganosilox-  
10 ane fluid with particulate silica as an anti-anal leakage (AAL) agent.

For purposes of this invention, the silicones can be described as polyorganosiloxanes which have an organic carbon content of at least fifteen (15) weight percent. Included within the scope of this invention are those siloxanes having organic substitutions wherein the organic substitution is linked to the silicon atom through a  
15 carbon/silicon bond. Such a limitation distinguishes the siloxanes useful in this invention from those wherein there is no organic substitution such as partial hydrolyzates and condensates of  $\text{Si}(\text{OR})_4$  wherein R is an alkyl radical. Further, this invention contemplates small amounts of -Si-O-C- bonded materials wherein the hydrolyzable by-products of such materials are not toxic to the human



body, such as for example, ethanol, glycerol, sucrose and other organic sugars.

In order to minimize the possibility of absorption of the siloxanes in the gastrointestinal tract, the siloxanes preferred for this invention should not contain significant amounts of material with molecular weights of less than 500 g/mole. By "significant", it is meant that there should be less than about 10 weight percent of such low molecular weights materials present in the composition, based on the total siloxane present. Preferred for this invention are siloxanes that are essentially free of low molecular weight materials as defined.

Also, preferred for this invention is a polyorganosiloxane fluid of the general formula  $(\text{CH}_3)_3\text{SiO}[(\text{CH}_3)_2\text{SiO}]_b\text{Si}(\text{CH}_3)_3$  wherein b has an average value of 25 to 500.

The siloxanes of this invention need not necessarily be truly soluble or miscible with the other components of the foods in which they are being used. They may be combined with the food either separately or in combination with the anti-anal leakage agent.

The polyorganosiloxane fluid may be substituted in the food in a quantity of about 0.1 to 100 percent of the total food composition. The amount of siloxane used will depend on the amount of fat in the food composition.

Types of food compositions within the scope of this invention include salad oils and salad dressings; dairy products such as cheese, cottage cheese, milk, ice cream, whipped cream and yogurt; baked goods such as cakes, pie crusts, cookies, bread, cereal, doughnuts and crackers; shortening substitutes; margarine; mayonnaise; peanut butter; and other food compositions where the fat component can be substituted with silicone oil.

Preferably the particulate silica should have a surface area of greater than 10 m<sup>2</sup>/g as determined by the BET method. The BET method of measuring surface area is based on the adsorption of nitrogen at its boiling point under 1 atm pressure and measures both the interior as well as the total surface area of the particles. For the present invention, it is believed that the exterior surface area of the particle is the critical area. In cases where particles have considerable surface area interior to the particle, it is anticipated one skilled in the art will appropriately adjust the weight of silica used to provide the requisite exterior surface area.

Preferred is a silica with a surface area of at least 80 m<sup>2</sup>/g and most preferred is a silica with a surface area of about 300 m<sup>2</sup>/g to about 400 m<sup>2</sup>/g.

The silica particles used as the AAL agent may be produced by any process adequate to produce the required surface area including grinding, milling, precipitation and vapor phase deposition.

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The AAL agent may be incorporated into the food composition either separately or by first being combined with the siloxane fluid. The AAL agent and fluid in combination or individually may be added to the food as appropriate during formulation, processing or preparation. It is preferred that the AAL agent be present in the final food composition at a concentration of at least about 10% by weight of the combined siloxane and AAL agent portions of the food composition. It is more preferred that the AAL agent be present in the final food composition at a concentration of at least about 20% by weight of the combined siloxane and AAL agent portions of the food composition. It is most preferred that the AAL agent is present at a concentration of about 20% to about 50% by weight of the combined siloxane and AAL agent portions of the food composition. These concentrations as specified reduce or abolish anal leakage of the siloxane fluid.

Those skilled in the art will recognize that the disclosed AAL agents if found normally in a food may allow adjustment of the actual AAL agent required to be added to the food. In addition, it may be recognized that diets containing the disclosed AAL agents could reduce the amount of AAL agent needed in a food composition to prevent anal leakage. The concentrations presented in the food compositions of this invention are those which reduce or prevent anal-leakage in the absence of other potential sources of AAL agent activity.

The following non-limiting examples illustrate the composition of this invention.

Example 1

As a control food composition a polyorganosiloxane fluid of the general formula  $(\text{CH}_3)_3\text{SiO}[(\text{CH}_3)_2\text{SiO}]_b\text{Si}(\text{CH}_3)_3$  wherein b had an average value of about 35 was blended into

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Purina Rat Chow 5012 Meal (Ralston Purina Company, St. Louis, Missouri) in the proportions of: 1500 g rat chow + 105 g siloxane fluid. A group of five adult rats weighing 275-350 g was allowed ad libitum access to this food composition as their exclusive diet for seven days. Animals were observed daily for evidence of anal leakage.

- 5 Within 48 hours of access to this diet, all animals demonstrated slight to moderate anal leakage of the siloxane fluid.

Example 2 (Comparative)

- Stearic acid, as representative of the group of  $C_{12}$ - $C_{24}$  saturated fatty acids, was incorporated as an AAL agent into the food composition of Example 1 in the following proportions: 1500 g rat chow + 105 g siloxane fluid + 30 g stearic acid. Other experimental details were the same as those specified in Example 1. None of the five animals fed this diet with stearic acid added as an AAL agent demonstrated signs of anal leakage of the siloxane fluid at any time during the seven day observation period.

Example 3 (Comparative)

- 15 Suet is representative of naturally occurring digestible fats which can serve as a source for  $C_{12}$ - $C_{24}$  saturated fatty acids and their esters. In this example, the food composition of Example 1 was blended with suet as an AAL agent in the following proportions: 1500 g rat chow + 105 g siloxane fluid + 30 g suet. Other experimental details were the same as in Example 1. None of the five animals fed this diet with suet added as an AAL agent demonstrated signs of anal leakage of the siloxane fluid at any time during the seven day observation period.

Example 4

- To the food composition of Example 1 was added silica with an average surface area of about 300  $m^2/g$  to about 400  $m^2/g$  in the proportions of 1500 g rat chow + 105 g siloxane fluid + "n" g silica wherein n was 1, 3, 7, 15 or 30 g. Other experimental details were the same as in Example 1. A separate group of five animals each was used for each food composition tested. All test groups displayed a reduction in the incidence and severity of anal leakage in relation to the control group of Example 1. In general, as more silica was added to the diet the time to appearance of anal leakage increased and the number of animals displaying anal leakage decreased. Only the test group receiving the diet containing 30 g of silica was free of all signs of anal leakage of siloxane fluid.

Example 5

- To the food composition of Example 1 was added silica with a particle size of 32-63 micrometer in the proportions of: 1500 g rat chow + 105 g siloxane fluid + 30 g

silica. Other experimental details were the same as given in Example 1. Silica of this particle size at the concentration tested affected a reduction in the severity and incidence of anal leakage of siloxane fluid in relation to the control group of Example 1. However, complete abatement of the anal leakage in all animals of the test group was not achieved.

5 Example 6 (Comparative)


Solka Floc 200 (James River Corporation, Hackensack, NJ) a mechanically ground cellulose of 30-35 micrometer average particle size was added to the food composition of Example 1 in the following proportion: 1500 g rat chow + 105 g siloxane fluid + 30 g of Solka Floc 200. Other experimental details were the same as  
10 given in Example 1. Solka Floc 200 at the concentration tested reduced the severity and incidence of anal leakage of siloxane in relation to the control group of Example 1. However, complete abatement of anal leakage in all animals of the test group was not achieved.

Example 7 (Comparative)

15 Solka Floc 300 (James River Corporation, Hackensack, NJ) a mechanically ground cellulose of 22-24 micrometer average particle size was added to the food composition of Example 1 in the following proportions: 1500 g rat chow + 105 g siloxane fluid + 30 g of Solka Floc 300. Other experimental details were the same as those of Example 1. One of five test animals had signs of slight anal leakage of the  
20 siloxane fluid at 24 and 48 hours after being placed on the test diet containing Solka Floc 300. At 72 hours after being placed on the test diet and thereafter, none of the test animals had signs of anal leakage.

Example 8 (Comparative)

Barley bran, a natural source of plant fibers, was added to the food composition  
25 of Example 1 in the following proportion: 1500 g rat chow + 105 g siloxane fluid + 30 g barley bran. The barley bran was purchased from National Grain Products Co., Inc., Minnetonka, MN. The bran was produced from barley after malting and removal of sugar and starch by hot water extraction. The extracted barley was dried by indirect steam, milled and sifted to obtain flour which 100% passed through a USS 40 mesh screen and  
30 90% was retained by a USS 120 mesh screen. Other experimental details were the same as those of Example 1. None of the test animals exhibited signs of anal leakage of the siloxane fluid at any time during the test period.



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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A low calorie food composition comprising non-fat ingredients and fat ingredients wherein from 0.1% to 100% by weight of the total fat ingredients have been replaced by a substitute comprising:

a. an edible, non-absorbable, non-digestible liquid siloxane polymer of the general formula  $(\text{CH}_3)_3\text{SiO}[(\text{CH}_3)_2\text{SiO}]_b\text{Si}(\text{CH}_3)_3$  wherein b has an average value of 25 to 500; and

b. sufficient particulate silica to prevent leakage of said liquid siloxane through the anal sphincter.

2. A composition according to claim 1 wherein the substitute comprises at least 10% to 50% by weight of particulate silica, the balance being liquid siloxane.

3. A composition according to claim 2 wherein the particulate silica has a surface area of about 10 to <sup>400</sup>~~500~~ m<sup>2</sup>/gm.

DATED THIS 23RD DAY OF DECEMBER, 1991.

DOW CORNING CORPORATION

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