

PATENT SPECIFICATION

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(54) EDIBLE FAT COMPOSITION AND FOOD PRODUCTS CONTAINING SAME

(71) We, AMERICAN HOME PRODUCTS CORPORATION, a corporation organised and existing under the laws of the State of Delaware, United States of America, of 685 Third Avenue, New York 10017, New York, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

This invention concerns new edible, highly assimilable, fat compositions. Additionally, this invention concerns food products particularly adapted for human infant nutrition (feeds) incorporating the edible, highly assimilable fat compositions.

More particularly, this invention concerns new edible, highly assimilable, fat compositions with a fatty acid composition resembling that of human milk fat comprising, by weight, from 15% to 45% of oleic oil; from 10% to 45% of oleo oil; from 0% to 25% of a seed oil comprising one or more of the following: soybean oil, corn oil, peanut oil, sunflower seed oil and cottonseed oil; from 10% to 35% of coconut oil and/or babassu oil; and from 0% to 2% of soy lecithin: and infant feeds incorporating said edible oil composition.

The composition is prepared by mixing the ingredients together.

Breast feeding of all infants for at least six months offers the best nutrition and greatest resistance to disease. Unfortunately, only about 10% of infants in the United States are breast-fed at one month of age. The reasons for the superiority of breast-feeding have not been elucidated. However, the view that "humanised" infant feeds, i.e. feeds similar to human milk in chemical composition, supply the best nutrition for artificially-fed infants is well established. Over 80% of all artificially-fed infants in the United States during 1969 were fed "humanised" infant feeds.

Improvement in "humanised" infant feeds

[Price 25p]

in respect to mineral protein and carbohydrate components (U.S. Patents No. 2,604,403; 3,201,245; 3,201,256 and 3,320,072) have resulted in a feed in which these essential nutrients are present in amounts similar to those in human milk and which closely approximate to the nutritional properties of human milk both in respect of absorption from the intestine and in metabolism for growth and maintenance. However, the fat mixtures utilised in "humanised" infant feeds have not been found as satisfactory in infant nutrition as the other nutritional components.

It has been known for many years that the fatty acid composition of dietary fat influences the fatty acid composition of the adipose tissue. Recently, the influence of dietary fat on the composition of lipids present in all cells of the body including nerve and brain cells has been pointed out. The short- or long-term implications of changes in the fatty acid composition of the structural lipids of actively metabolising cells of the young infant resulting from ingestion of fats supplying fatty acids widely divergent from the amounts supplied by human milk are unknown. In the absence of knowledge, teleological reasoning supports the view that the amounts of fatty acids supplied by infant feeds should approach the amounts supplied by human milk.

In addition, specific difficulties with fat mixtures used in infant feeds have been pointed out. Widdowson (Lancet, November 27, 1965, 1099:1965) found that the fat in an artificial feed with approximately the same fatty acid composition as breast milk fat was not well absorbed in young infants. Of greater importance was the finding that the lowered fat absorption resulted in low and in some infants negative absorption of calcium. The low absorption results from binding of calcium by unabsorbed fatty acids, particularly palmitic and stearic acids, forming highly insoluble soaps.

Another variety of fat compositions used in

- humanised infant feeds is characterised by levels of fatty acids greatly different from those present in human milk fat. A syndrome consisting of edema, skin lesions, an elevated platelet count and morphologic changes in erythrocytes has been described in premature infants fed feeds containing fat with a relatively high content of linoleic acid (Hassan, H. et al, *Am. J. Clin. Nutr.* 19, 147:1966).
- 5 Oski F. and L. Barness (*J. Pediat.* 70, 211: 1967) described a hemolytic anemia in premature infants fed feeds with high linoleic acid content. In both studies, the findings were reversed by administration of vitamin E.
- 10 Neurological pathology showed that the death of an infant was attributable to the infant being fed linoleic acid at high levels without added vitamin E (Horwitt, M. and P. Bailey [*Arch. Neurol.* 1, 312:1959]).
- 15 This invention seeks to provide a "humanised" fat mixture suitable for use in infant feeds which is well absorbed from the intestine and at the same time provides a physiological level of linoleic acid using commercially available, reasonably priced fats and oils.
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At the present state of the art, these objectives have not been achieved.

The reasons for not obtaining both objectives is due to the fatty acid composition of available fats and oils. Fatty acids are absorbed to different extents by the new-born infant. Stearic acid and palmitic acid are poorly absorbed from the infant intestine. All the other fatty acids are absorbed to a considerably greater extent than stearic and palmitic acid. Oleic acid is intermediate in the extent of absorption. Therefore, this invention seeks to provide a fat mixture which approximates the composition of human milk fat and provides absorption characteristics similar to those of milk fat and also to provide a food product particularly adapted for infant nutrition substantially approximating to human milk containing the above-described fat composition.

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Table I lists classes of animal and vegetable fats used in infant feeds together with the ranges of the fatty acids which comprise in each case over 90% of the total present.

TABLE I

% of total fatty acids

	1 Palmitic acid Oils	2 Lauric acid Oils	3 Animal Fats	4 Seed Oils
Palmitic acid	42	7—9	25—29	8—21
Stearic acid	4	1—4	13—30	2—4
Linoleic acid	9	1—2	2—6	22—60
Oleic acid	43	6—14	32—42	27—29
Lauric acid	0	45—48	0	0

The fats which are used in existing infant feeds are grouped into four classes, as follows:

- I. Palmitic acid oils
palm oil
- 55 II. Lauric acid oils
coconut
babassu
- III. Animal fats
oleo oil (beef fat)
- 60 IV. Seed oils
corn
peanut
soybean
cottonseed oil

Among the palmitic acid oils and lauric acid oils, the ones listed above include all members of these classes. The other commercial animal fats (butter, lard, mutton tallow) are not used because of price (butter), religious prejudice (lard) and relative unavailability (mutton tallow). The other available seed oils are not considered suitable for various reasons: linseed because of containing over 50% linolenic acid; olive oil because of uneconomic price, safflower because it contains over 70% linoleic acid; sesame seed oil because of the presence of phenolic compounds and sunflower oil because of unavailability.

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- Some of the fat compositions used in commercially prepared infant feeds together with their fatty acid composition are shown in Table II. Inspection of the table shows that
- 5 none of these commercially prepared feeds has achieved the purposes of this invention. With every composition where the absorption of fat is high, the linoleic acid content or lauric acid content is above the human milk range.
- 10 In formulations where the linoleic acid content is in the range of human milk, the absorption is low.
- 15 In Table II, the fat mixtures denominated 1—6 are presently available in commercial infant feeds. Following each fat mixture ingredient is the percent, by weight, of the fat in the mixture. The fat mixtures are then identified by the type and amount (% by weight) of the fatty acids making up the mixture. Each fatty acid is identified by the length of the carbon chain and number of unsaturated positions, e.g., lauric acid contains 12 carbon atoms and is fully saturated. It is possible to estimate the proportion of fat absorption based on the sum of palmitic and stearic acids in the fat mixtures. A high absorption is expected for mixtures containing less than 15% stearic and palmitic acids. In fat mixtures 2 and 4, the linoleic acid level is high and the absorption is high. In fat mixture 3, the lauric and linoleic acid levels are both high and the absorption is high. In fat mixture 5, the linoleic acid is in the range of human milk fat and the absorption is low. In fat mixture 6, the linoleic acid level is high and the absorption is poor.

TABLE II

% of total fatty acids by weight

Fat Mixture	Approximate Composition	shorter than lauric <12:0	% of total fatty acids by weight					% of fatty acids by weight		
			lauric 12:0	myristic 14:0	palmitic 16:0	stearic 18:0	oleic 18:1	linoleic 18:2	linolenic 18:3	
1	Human Milk	1.6 0.9—2.8	7.0 2.8—10.8	8.8 5.9—12.1	21.0 17.6—24.6	7.2 6.4—9.0	35.8 28—41	7.5 4.3—13	0.8 0.5—1.1	
2	Coconut Oil Corn Oil	6.3	20	7.4	11	2.5	19.1	32	0.6	
3	Coconut Oil Corn Oil Soybean Oil	10	35	13.3	10	2.8	12.3	16	0.6	
4	Corn Oil	0	0.1	0.2	11	2.4	27	57	0.8	
5	Coconut Oil Palm Oil Peanut Oil	3.4	12	5.1	27	4.1	32	14	0.3	
6	Coconut Oil Corn Oil Oleo Oil		10	5.1	17	8.8	29	24	0.4	

- 5 Additionally, the palmitic acid in human milk fat (26%) is 32% in the 1,3-position on the glyceride molecule, whereas the palmitic acid derived from vegetable sources is 82% in the 1,3-position. A reasonably good correlation is found between the product of the 1,3-palmitic acid and the stearic acid contents of a fat and the amount of the total fat not absorbed. See U.S. Patent No. 3,542,560.
- 10 Recent research in the area of vegetable oil production has produced a safflower oil which contains a high level of oleic acid (about 80%) and a low level of linoleic acid (about 15%) which is in the reverse ratio found in normally occurring safflower oil. This new oil derived from a genetic mutant of common safflower has been assigned by the National (U.S.A.) Institute of Oil Manufacturers, the generic name of oleic oil (e.g., Oleinate 181, Pacific Vegetable Oil Corporation, Richmond, California).
- 20 Within the range of fat compositions within the scope of this invention, particular interest is directed to compositions consisting essentially of from 25% to 35% of oleic oil; from 30% up to 40% of oleo oil; preferably from 10% to 20% of seed oil, e.g., soybean oil; from 20% to 30% of coconut oil and/or babassu oil; and optionally about 1% of soy lecithin. In other compositions the seed oil may be present in an amount from 10% to 25% and comprise cottonseed oil and corn oil or soybean oil.
- 30 In Table III are listed the fat blends (mixtures) which are incorporated into humanised infant feeds and tested by feeding to seven- to ten-day old infants and measuring total fat and calcium absorption. These fat blends are identified similarly to those listed in Table II. Mixture J is the preferred composition of this invention. This is the only composition which is as well absorbed from the intestine as human milk and from which the calcium present is as well absorbed as from human milk. This result was unexpected as the palmitic and stearic acid contents (poorly absorbed fatty acids) are similar to those of mixture A. The reason why unexpectedly high fat and calcium absorptions were found cannot be predicted from present knowledge of fatty acid and calcium absorption from the intestine. Possibly, the reason lies in the high ratio of oleic to stearic acid. Also unexpected was the finding that infants fed mixture J gained more weight.
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TABLE III
% of total fatty acids by weight (1)

Fat Mixture	shorter than lauric <12:0	lauric 12:0	myristic 14:0	palmitic 16:0	stearic 18:0	oleic 18:1	linoleic 18:2	linolenic 18:3	Fat and Calcium absorption in 7—10 day old infants (2)	
									Fat % Absor.	Ca % Absor.
Human Milk	1.2	4.3	6.4	24.3	9.1	33.0	11.3	0.5	85.0	43.9
A Coconut Oil (23%)	3.7	11.6	5.5	16.4	9.5	26.2	21.2	2.1	84.6	20.1
Corn Oil (12%)										
Soybean Oil (25%)										
Oleo Oil (40%)	2.7	11.3	5.9	25.5	8.0	32.5	10.6	0.3	81.7	21.1
Oleo Oil (25%)										
Coconut Oil (20%)										
Palm Oil (35%)										
Peanut Oil (20%)	3.0	6.4	4.0	18.7	13.4	32.5	18.1	2.6	79.2	5.4
Coconut Oil (17.5%)										
Corn Oil (10%)										
Soybean Oil (16.5%)										
Oleo Oil (55%)	3.3	12.3	6.0	13.5	8.4	39.5	11.9	2.6	89.8	45.7
Oleic Oil (25%)										
Oleo Oil (33%)										
Soybean Oil (15%)										
Coconut Oil (27%)										

(2) The fatty acid compositions listed are for the samples actually tested.

(1) Ten infants in each group.

- The edible fat compositions of this invention, because of their surprisingly high absorption and beneficial effect on calcium absorption, are especially suited for incorporation into food products particularly adapted for human infant nutrition (feed). Basically, such an infant feed would be composed of the edible fat composition herein previously described, a protein source and a sugar. A typical useful protein source is electrodialysed whey and/or electrodialysed non-fat milk such as that described in U.S. Patent No. 3,320,072, although other protein sources are available. Sugars would include substances such as glucose; however, edible lactose is preferred. Additionally, such infant feeds would include the following vitamins and minerals: calcium, phosphorus, potassium, sodium, chloride, magnesium, iron, copper, zinc, iodine, vitamins A, D, E and the B vitamins. These substances would be added in the form of commonly accepted nutritional compounds in amounts recommended by the National (U.S.A.) Research Council or other accepted nutritional body. A typical infant feed at ready-to-feed concentration would provide 20 kcal/fl. oz. and provide in each 100 ml., 3.6 g. of fat blend, 1.5 g. of pro-

tein, 7.2 g. lactose and have 0.25 g. of ash.

The fat compositions of this invention also are incorporated into aqueous infant feed compositions comprising the edible fat composition, a sugar, water and a protein source. Exemplary feeds of this type would comprise an aqueous suspension containing in each 100 ml. from 1.00 to 6.00 gm. of the edible fat composition; from 1.0 to 2.5 gm. of a protein source; and from 2.0 to 15 gm. of a sugar, particularly, a food product particularly adapted for infant nutrition substantially approximating to human milk in composition comprising an aqueous suspension containing in each 100 ml. about 3.6 gm. of the edible fat composition, preferably mixture J as hereinbefore described; about 1.5 gm. of a protein source, preferably from electrodialysed whey and non-fat milk; and about 7.2 gm. of sugar, preferably lactose. Preferably, the ash content should be about 0.25 gms/100 mls.

The following examples provide representative embodiments of this invention.

EXAMPLE I.

Compositions of edible fat blend are provided as set forth in Table IV, following:

TABLE IV

Oil	A	B	C	D	E	F	G	H	I	J
Oleic Oil	25	25	45	15	20	43	42	39	30	27
Oleo Oil	33	33	10	26	35	10	10	30	45	17
Soybean Oil	14	15	—	—	10	—	7	—	—	24
Corn Oil	—	—	25	12	—	—	—	—	15	—
Cottonseed Oil	—	—	—	12	—	15	7	—	—	—
Coconut Oil	27	27	—	35	34	15	—	30	10	31
Babassu Oil	—	—	20	—	—	15	34	—	—	—
Soy Lecithin	1	—	—	—	1	2	—	1	—	1

EXAMPLE II.

- Using the fat composition of Table IV, Column A, the following ready-to-feed infant feed is provided, amounts set forth in 100 ml.

- 60 Fat Composition 3.6 g.
Lactose 7.2 g.
Protein (from electrodialysed Whey and Non-Fat Milk) 1.5 g.
65 Vitamin A U.S.P. units 264
Vitamin D U.S.P. units 42.0
Vitamin E I.U. 0.64
Vitamin B₁ (Thiamine HCl) mg. 0.071
70 Pantothenic Acid mg. 0.21
Vitamin B₂ (Riboflavin) mg. 0.11
Vitamin C (Ascorbic Acid) mg. 5.3

- Vitamin B₆ (Pyridoxine HCl) mg. 0.042
75 Vitamin B₁₂ (Cyanocobalamin) mcg. 0.11
Niacinamide mg. 0.53
Folic Acid mcg. 3.2
Calcium mg. 42
80 Phosphorus mg. 33
Sodium mg. 15
Potassium mg. 55
Chloride mg. 41
Magnesium mg. 6.0
Iron mg. 0.85
85 Copper mg. 0.04
Zinc mg. 0.32
Iodine mcg. 6.9
Water q.s. ad 100.0 ml.

The fat-soluble vitamins are dissolved in the fat composition and the remaining ingredients are dissolved in the water. The fat composition and water solution are then mixed and homogenised. Adequate amounts of other trace minerals are present in the electro-dialysed whey and non-fat milk. The process is repeated using the other fat compositions of Example I.

10 WHAT WE CLAIM IS:—

1. An edible fat composition comprising, by weight, from 15% to 45% of oleic oil; from 10% to 45% of oleo oil; from 0% to 25% of a seed oil comprising one or more of the following: soybean oil, corn oil, peanut oil, sunflower seed oil and cottonseed oil; from 10% to 35% of coconut oil and/or babassu oil; and from 0% to 2% of soy lecithin.

2. A composition as claimed in Claim 1, wherein the amount of oleic oil is from 25% to 35% by weight.

3. A composition as claimed in Claim 2, wherein the amount of oleic oil is about 25% by weight.

4. A composition as claimed in any one of the preceding claims wherein the amount of oleo oil is from 30% to 40% by weight.

5. A composition as claimed in Claim 4, wherein the amount of oleo oil is about 33% by weight.

6. A composition as claimed in any one of the preceding claims, wherein the seed oil is present in an amount from 10% to 20% by weight.

7. A composition as claimed in Claim 6, wherein the seed oil is soybean oil.

8. A composition as claimed in any one of Claims 1 to 5, wherein the seed oil is present in an amount from 10% to 25% by weight and comprises soybean oil and cottonseed oil.

9. A composition as claimed in any one of Claims 1 to 5, wherein the seed oil is present in an amount from 10% to 25% by weight and is corn oil and cottonseed oil.

10. A composition as claimed in any one of the preceding claims, wherein the coconut oil and/or babassu oil is present in an amount from 20% to 30% by weight.

11. A composition as claimed in Claim 1, consisting essentially of from 25% to 35% of oleic oil; from 30% to 40% of oleo oil; from 10% to 20% of soybean oil; and from 20% to 30% of coconut oil.

12. A composition as claimed in Claim 11, consisting essentially of about 25% oleic oil; about 33% of oleo oil; about 15% of soybean oil; and about 27% of coconut oil.

13. An edible fat composition substantially as hereinbefore described in Example I.

14. A food product particularly adapted for human infant nutrition comprising: the edible fat composition of any one of the preceding claims, a protein source; and a sugar.

15. An aqueous food product particularly adapted for human infant nutrition comprising: the edible fat composition of any one of the preceding claims 1 to 13, a protein source; a sugar; and water.

16. An aqueous food product particularly adapted for infant nutrition comprising an aqueous suspension containing in each 100 ml. from 1.00 to 6.00 gm. of the edible fat composition of any one of Claims 1 to 13; from 1.0 to 2.5 gm. of a protein source; and from 2.0 to 15 gm. of a sugar.

17. A food product particularly adapted for infant nutrition comprising: an aqueous suspension containing in each 100 ml. about 3.6 gm. of the edible fat composition of any one of Claims 1 to 13; about 1.5 gm. of a protein source; and about 7.2 gm. of sugar.

18. A food product as claimed in any one of Claims 14 to 17 wherein said protein source is electro-dialysed whey and non-fat milk.

19. A food product as claimed in any one of Claims 14 to 18 wherein the sugar is lactose.

20. A food product particularly adapted for infant nutrition comprising: an aqueous suspension containing in each 100 ml. about 3.6 gm. of the edible fat composition of Claim 12; about 1.5 gm. of protein from electro-dialysed whey and non-fat milk; and about 7.2 gm. of lactose, said food product having an ash content of about 0.25 gm./100 ml.

21. An aqueous food product adapted for human infant nutrition comprising: the edible fat composition of any one of Claims 1 to 13; an electro-dialysed whey protein source; a sugar; and water.

22. An aqueous food product adapted for human infant nutrition comprising: the edible fat composition of any one of Claims 1 to 13; a sugar; a non-fat milk protein source; and water.

23. A food product substantially as hereinbefore described with reference to Example II.

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The fat-soluble vitamins are dissolved in the fat composition and the remaining ingredients are dissolved in the water. The fat composition and water solution are then mixed and homogenised. Adequate amounts of other trace minerals are present in the electro-dialysed whey and non-fat milk. The process is repeated using the other fat compositions of Example I.

10 WHAT WE CLAIM IS:—

1. An edible fat composition comprising, by weight, from 15% to 45% of oleic oil; from 10% to 45% of oleo oil; from 0% to 25% of a seed oil comprising one or more of the following: soybean oil, corn oil, peanut oil, sunflower seed oil and cottonseed oil; from 10% to 35% of coconut oil and/or babassu oil; and from 0% to 2% of soy lecithin.

2. A composition as claimed in Claim 1, wherein the amount of oleic oil is from 25% to 35% by weight.

3. A composition as claimed in Claim 2, wherein the amount of oleic oil is about 25% by weight.

4. A composition as claimed in any one of the preceding claims wherein the amount of oleo oil is from 30% to 40% by weight.

5. A composition as claimed in Claim 4, wherein the amount of oleo oil is about 33% by weight.

6. A composition as claimed in any one of the preceding claims, wherein the seed oil is present in an amount from 10% to 20% by weight.

7. A composition as claimed in Claim 6, wherein the seed oil is soybean oil.

8. A composition as claimed in any one of Claims 1 to 5, wherein the seed oil is present in an amount from 10% to 25% by weight and comprises soybean oil and cottonseed oil.

9. A composition as claimed in any one of Claims 1 to 5, wherein the seed oil is present in an amount from 10% to 25% by weight and is corn oil and cottonseed oil.

10. A composition as claimed in any one of the preceding claims, wherein the coconut oil and/or babassu oil is present in an amount from 20% to 30% by weight.

11. A composition as claimed in Claim 1, consisting essentially of from 25% to 35% of oleic oil; from 30% to 40% of oleo oil; from 10% to 20% of soybean oil; and from 20% to 30% of coconut oil.

12. A composition as claimed in Claim 11, consisting essentially of about 25% oleic oil; about 33% of oleo oil; about 15% of soybean oil; and about 27% of coconut oil.

13. An edible fat composition substantially as hereinbefore described in Example I.

14. A food product particularly adapted for human infant nutrition comprising: the edible fat composition of any one of the preceding claims, a protein source; and a sugar.

15. An aqueous food product particularly adapted for human infant nutrition comprising: the edible fat composition of any one of the preceding claims 1 to 13, a protein source; a sugar; and water.

16. An aqueous food product particularly adapted for infant nutrition comprising an aqueous suspension containing in each 100 ml. from 1.00 to 6.00 gm. of the edible fat composition of any one of Claims 1 to 13; from 1.0 to 2.5 gm. of a protein source; and from 2.0 to 15 gm. of a sugar.

17. A food product particularly adapted for infant nutrition comprising: an aqueous suspension containing in each 100 ml. about 3.6 gm. of the edible fat composition of any one of Claims 1 to 13; about 1.5 gm. of a protein source; and about 7.2 gm. of sugar.

18. A food product as claimed in any one of Claims 14 to 17 wherein said protein source is electro-dialysed whey and non-fat milk.

19. A food product as claimed in any one of Claims 14 to 18 wherein the sugar is lactose.

20. A food product particularly adapted for infant nutrition comprising: an aqueous suspension containing in each 100 ml. about 3.6 gm. of the edible fat composition of Claim 12; about 1.5 gm. of protein from electro-dialysed whey and non-fat milk; and about 7.2 gm. of lactose, said food product having an ash content of about 0.25 gm./100 ml.

21. An aqueous food product adapted for human infant nutrition comprising: the edible fat composition of any one of Claims 1 to 13; an electro-dialysed whey protein source; a sugar; and water.

22. An aqueous food product adapted for human infant nutrition comprising: the edible fat composition of any one of Claims 1 to 13; a sugar; a non-fat milk protein source; and water.

23. A food product substantially as hereinbefore described with reference to Example II.

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