

TABLE XIX-continued

AVERAGE TOTAL HOURS CRYING AND FUSSING PER DAY				
	Baseline	Formula A	Formula B	Formula C
Minimum	3.0	1.6	1.2	0.4
Maximum	10.6	9.6	8.0	6.7

TABLE XX

AVERAGE TOTAL HOURS SLEEP PER DAY				
	Baseline	Formula A	Formula B	Formula C
Mean	12.4	13.4	13.7	14.4
Median	12.9	13.8	13.1	14.4
Minimum	7.3	9.6	12.0	12.1
Maximum	15.0	16.5	16.5	17.8

Stool characteristics were compared in view of the findings in Study 1. Predominant stool consistencies are shown in Table XXI which is set forth below.

TABLE XXI

AVERAGE DAILY RANKED STOOL CONSISTENCY				
	Baseline	Formula A	Formula B	Formula C
Mean	1.9	2.3	2.9	3.1
Median	1.9	2.3	2.9	3.1
Minimum	1.0	1.0	2.0	2.1
Maximum	2.7	3.6	4.0	3.8

1 = Watery  
 2 = Soft  
 3 = Formed  
 4 = Hard

Watery and soft stools comprised the majority of stools during the baseline period. The predominant stool consistency was soft for infants when they were on Formula A, whereas it was formed for infants when they were on Formulas B and C. One infant had hard stools while on all three study formulas. Additionally one other infant had hard stools while on Formula C. Thus, the percentage of hard stools while on the high-fiber containing formulas in this study was lower than that observed with the higher fiber containing formula in Study 1.

The results from these experiments demonstrate that the infant formula of this invention is effective in treating colicky infants. The fiber level of the formulas in the second study, 7.4-10.5 g/L, are more optimal from the point of view of stool characteristics. Additionally, the formula is nutritionally complete as an infant formula. The manufacture of the formula utilizes conventional equipment and may be readily accomplished.

While the infant formula and method of making said formula herein described constitute a preferred embodiment of this invention, it is to be understood that the invention is not limited to this precise form of apparatus or method and that changes may be made therein without departing from the scope of the invention which is defined in the appended claims.

What is claimed is:

1. An infant formula, said formula comprising:
  - 1) protein, said protein being of a concentration of between 10 and 25 grams per liter of formula;
  - 2) fat, said fat being of a concentration of between 20 and 45 grams per liter of formula;
  - 3) carbohydrates, said carbohydrates including those from total dietary fiber being of a concentration of between 60 and 110 grams per liter of formula; and
  - 4) total dietary fiber, said fiber being of a concentration of above 3.1 and below 14.1 grams per liter of

formula and wherein the source of said fiber is soy polysaccharide derived from soy beans.

2. The formula as claimed in claim 1 wherein said protein is of a concentration of between 15 and 21 grams per liter of formula, said fat is of a concentration of between 23 and 40 grams per liter of formula, and said carbohydrates including total dietary fiber are of a concentration of between 70 and 110 grams per liter of formula.

3. The formula as claimed in claim 2 wherein said protein has as its source soy protein isolate, or sodium and calcium caseinates or a blend thereof, said fat has as its source soy, coconut or corn oil or another vegetable oil or a blend thereof, and said carbohydrates other than total dietary fiber have as their source sucrose, corn syrup, glucose polymers, other carbohydrates or a blend thereof.

4. The formula as claimed in claim 1 wherein said protein is of a concentration of between 15 and 20 grams per liter of formula, said fat is of a concentration of between 24 and 38 grams per liter of formula, said carbohydrates including total dietary fiber are of a concentration of between 75 and 110 grams per liter of formula, and said total dietary fiber is of a concentration of between 3.5 and 14.0 grams per liter of formula.

5. The formula as claimed in claim 1 wherein said protein is of a concentration of approximately 19.6 grams per liter of formula and has as its source soy protein isolate, said fat is of a concentration of approximately 37.4 grams per liter of formula and has as its source a blend of soy and coconut oils, and said carbohydrates including total dietary fiber are of a concentration of approximately 75.9 grams per liter of formula and except for those from dietary fiber have as their source sucrose or corn syrup or a blend thereof.

6. The formula as claimed in claim 1 wherein said protein is of a concentration of approximately 20.3 grams per liter of formula and has as its source a blend of sodium and calcium caseinates and soy protein isolate, said fat is of a concentration of approximately 24.7 grams per liter of formula and has as its source corn oil, and said carbohydrates including total dietary fiber are of a concentration of approximately 106.6 grams per liter of formula and with the exception of those from the fiber have as their source a blend of sucrose and glucose polymers.

7. The formula as claimed in claim 1 wherein said fat provides 50% of the calories and said carbohydrates minus those from total dietary fiber provide 40% of the calories in said formula.

8. The formula as claimed in claim 1 wherein said fat provides 32% of the calories and said carbohydrates minus those from total dietary fiber provide 57% of the calories in said formula.

9. A method of treating infants with colic, said method consists of feeding an infant in need of treatment a formula, the improvement comprising a formula consisting essentially of:

- 1) protein, said protein being of a concentration of between 10 and 25 grams per liter of formula;
- 2) fat, said fat being of a concentration of between 20 and 45 grams per liter of formula;
- 3) carbohydrates, said carbohydrates including total dietary fiber being of a concentration of between 60 and 110 grams per liter of formula; and
- 4) total dietary fiber, said fiber being of a concentration of above 3.1 and below 14.1 grams per liter of