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MEDICAL FOODS HAVING SOLUBLE FIBER

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(57) Claim

1. A nutritionally complete, liquid enteral feeding composition, essentially neutral in nature and having a viscosity of less than 50 cp, comprising hydrolysed soluble fiber selected from the group consisting of hydrolysed guar gum, hydrolysed pectin, hydrolysed gum arabic, hydrolysed locust bean gum and hydrolysed xanthan gum, in an amount such that the daily dosage of the feeding composition provides from 10 to 60 grams of hydrolysed soluble fiber per day.

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COMPLETE SPECIFICATION

NAME OF APPLICANT(S):

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INVENTION TITLE:

~~Improvements in or relating to organic compounds~~
Medical Foods having Soluble Fiber

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

This application relates to low-viscosity enteral and medical foods which contain hydrolysed soluble fiber, and to the use of these foods to maintain healthy colon cells and to prevent bacterial sepsis.

Nutritionally complete liquid diets are often administered to patients either orally or through feeding tubes (enterally). It has been noted that a frequent side-effect of this type of feeding is diarrhea. Diarrhea can lead to fluid and/or electrolyte imbalance and malnutrition. Further, it can cause discomfort and sanitation problems, require considerable staff time, thus resulting in increase patient care costs.

It has also been noted that many critically ill patients develop bacterial sepsis, a leading cause of death in intensive care units.

Feeding compositions are currently known which contain soy polysaccharide fiber. Soy polysaccharide fiber is considered to be an insoluble fiber. A recent study questioned the effectiveness of such a formulation in preventing diarrhea. See, e.g. Frankenfield et al., 1989. "Soy-Polysaccharide Fiber: Effect on Diarrhea in Tube-fed, Head Injured Patients" Am. J. Clin. Nutr. 50:533-538. Whilst certain soluble fibers, in particular pectin, have been proposed for treatment or prevention of diarrhea, these products have not been successfully applied in enteral formulation for technological reasons, i.e. the occurrence of extreme product thickening after the required heat treatment of enteral formulations comprising soluble fibres.

Description of the Invention

It has been found that adding a hydrolysed soluble fiber supplement to an otherwise nutritionally complete liquid food composition can control diarrhoea and prevent bacterial sepsis and gut atrophy while retaining the low viscosity character of the food composition. The invention, therefore relates to food compositions comprising such hydrolysed soluble fiber, and to the use of such food compositions to prevent diarrhoea, bacterial sepsis and gut atrophy.

According to one aspect of the present invention there is provided a nutritionally complete, liquid enteral feeding composition, essentially neutral in nature and having a viscosity of less than 50 cp, comprising hydrolysed soluble fiber selected from the group consisting of hydrolysed guar gum, hydrolysed pectin, hydrolysed gum arabic, hydrolysed locust bean gum and hydrolysed xanthan gum, in an amount such that the daily dosage of the feeding composition provides from 10 to 60 grams of hydrolysed soluble fiber per day.

According to another aspect of the present invention there is provided a method of preventing bacterial sepsis in a patient, comprising administering to the patient a feeding composition as defined above.

As used throughout the specification and claims, the term "nutritionally complete" refers to a feeding composition which contains carbohydrates, proteins. essential fatty acids, vitamins, and minerals in such amounts that a person can ingest only that composition for a prolonged period of time and not suffer any malnutrition. The composition may have water added to it such that the composition is in liquid form and suitable for drinking or for use with a tube-feeding apparatus. Alternatively, the composition may be in dry form.

Numerous feeding compositions are known and commercially available, including those commercially available from Sandoz Nutrition Corp. under the trademarks RESOURCE® and ISOSOURCE® (both liquid formulations), STRESSTEIN® (dry product), NUTRODRIP® and IMPACT®. These compositions typically provide approximately 20-70 % of calories in the form of carbohydrates, 13-30 % of calories in the form of protein, 20-50 % of calories as lipid (which includes essential fatty acids) as well as vitamins, minerals, and optionally water, flavoring agents, fillers, binders, coloring agents, coating materials, or other nutritional supplements.

As used throughout the specification and claims, the term "soluble fiber" refers to fibers which are able to undergo fermentation in the colon to produce short chain fatty acids (SCFA). Examples of soluble fibres are: pectin, guar, and gum arabic.

It has been found in accordance with this invention that hydrolysed soluble fibers can be added to feeding compositions, and result in a composition which prevents diarrhea, bacterial sepsis and gut atrophy. The hydrolysed soluble fiber may be the only fiber in the feeding composition, i.e. it may be added to a feeding composition which previously did not contain any fiber, or it may replace fiber which previously was present in the feeding composition. Alternatively, the hydrolysed soluble fiber may be an addition to a non-hydrolysed soluble fiber and/or an insoluble fiber such as soy polysaccharide present in the feeding composition.

The hydrolysed soluble fiber may be derived from numerous known soluble fibers, including from locust bean gum, xanthan gum, guar gum, and pectin. The preferred fibers, for numerous reasons set forth below are hydrolysed guar gum and hydrolysed pectin; hydrolysed guar gum being the most preferred. The term hydrolysed soluble fibers as used herein refers to soluble fibers hydrolysed in conventional manner, e.g. chemically or enzymatically to soluble fibers having a reduced molecular weight, which hydrolysed products are tube compatible when administered at the desired daily amount.

One primary requirement for tube compatibility of enteral compositions, is that the hydrolysed soluble fiber should not substantially increase the viscosity of the product above approximately 50 cp, and it is preferred that the viscosity remains under 25 cp, more preferably 10-25 cp. As used throughout the specification and claims, the term "low viscosity" means a viscosity of less than 50 cp, preferably less of 25 cp.

For use as enteral formulation (tube feeding) the formulations are essentially neutral in nature, i.e. have a pH of about 7.

A particularly preferred hydrolysed guar gum is commercially available from Taiyo Kagaku Co, Ltd. (Japan) under the trade name SUN FIBER[R]. SUNFIBER[R] is a purified hydrolysed guar gum prepared by hydrolysing guar gum with β-mannase from Aspergillus niger comprising ca. 75 % by weight of soluble fiber. Prior to hydrolysis, the molecular weight of guar gum is approximately 200,000; after hydrolysis it is 20,000-30,000. For use in accordance with this invention, the molecular weight range of the hydrolysed guar gum may vary, as long as the viscosity of the finished product does not exceed 50 cp.

The amount of hydrolysed soluble fiber added to a feeding composition may vary depending on the needs of the patient and whether the composition is to be taken orally or enterally. Thus the fiber content of the composition may vary according to the amount of composition intended to be ingested per day. It is generally preferred that the hydrolysed soluble fiber content of the composition be adjusted so that the patient receives approximately 10-60 g/day soluble fiber, more preferably approximately 10-45 g/day soluble fiber e.g. from 10-30 g/day, particularly from 20-30 g/day soluble fiber.

Such liquid formulations provide conveniently up to 3000 kcal, e.g. 1500 to 2500 kcal per day. They have, in general, a hydrolysed soluble fiber content which lies in the range of from 0.3 to 10 gram, preferably from 0.5 to 7.5 gram, more preferably of from 0.6 to 3.0 gram soluble fiber per 100 ml formulation.

It is well known that colon cells nourished by exclusively liquid diets may atrophy. This atrophy manifests itself in a breaking down of the gut mucosal barrier, allowing gram negative bacterial and/or bacterial endotoxin produced by these bacteria to invade the patient's circulatory system, causing shock. It has been found in accordance with this invention, that providing colon cells with a source of hydrolysed fiber which can be fermented into butyric acid, maintains health of the colon cells and the intactness of the gut mucosal barrier, reducing the incidence of septic shock. In addition, the healthy colon cells can retain minerals better, and are able to reabsorb water. Hydrolysed pectin and hydrolysed guar gum are particularly good sources of butyric acid, as detailed in Example 1 below.

Another benefit which can be realised by the addition of hydrolysed soluble fiber such as hydrolysed guar gum or hydrolysed pectin is that diarrhea can be controlled (treated or prevented).

This invention is further illustrated in the following non-limiting examples.

EXAMPLE 1

Fermentability of Fibers

Various fibers are suspended in water and buffered to neutrality. A sample of micro-organisms normally found in the colon is added and fermentation is allowed to occur for 24 hours at 37°C in a manometer. The resulting ferment is analysed for the amount of butyric acid per gram of fiber. Results are presented below:

Fiber	Millimoles of Butyric Acid per Gram of Fiber
Hydrolyzed Pectin	0.38
Pectin	0.28
Sun Fiber (hydrolyzed guar)	1.45
Guar	0.86
Gum Arabic	0.22
Polydextrose	0.16

As can be seen from the above, the hydrolysis of both pectin and guar improves the fermentability of these fibers into butyric acid.

EXAMPLE 2

Oral Supplement Containing Soluble Fiber

An oral supplement is made using the following ingredients.

INGREDIENT	FORMULA PERCENTAGE
Deionized Water	75.51
Maltrin 200 (maltodextrin)	10.47
Sugar--Canners grade	3.66
Corn Oil	3.40
Sodium Caseinate	2.97
*Mineral premix	0.38
Calcium Caseinate	0.48
**Gum premix (emulsifier/stabiliser)	0.02
Soy Protein isolate	0.48
***Vitamin premix	0.07
Artificial Vanilla Flavor	0.18
Magnesium Chloride	0.18
Lecithin	0.17
Potassium Citrate	0.26
Choline Chloride	0.07
Potassium Hydroxide	0.05
Natural & Artificial Vanilla Flavor	0.01
Vitamin E Oil	0.12
Potassium Chloride	0.10
Antifoam	0.02
Soluble Fiber	1.4
	100.00

*Mineral premix contains:

Tricalcium phosphate	0.20765%
Sodium citrate	0.16730
Zinc sulfate	0.00538
Ferrous sulfate	0.00330
Copper gluconate	0.00100
Manganese sulfate	0.00076
Potassium iodide	0.00036

**Gum premix contains:

Caragennan	0.01440%
Carrageenan	0.00960%

***Vitamin premix contains:

Ascorbic acid	0.05616%
Niacinamide	0.00230
Biotin	0.00197
Vitamin A	0.00178
Calcium pantothenate	0.00119
Cyanocobalamin B12	0.00098
Vitamin K	0.00070
Thiamin hydrochloride	0.00035
Pyridoxine hydrochloride	0.00035
Folic acid	0.00029
Vitamin D	0.00028
Riboflavin B2	0.00022

Oil is heated to 155-165°F. Wet salts and gum premix is added to the deionized water which is heated to 140°F. Next, the maltrin, sugar, caseinates, and soy protein is added. The soluble fiber source is then added. The soluble fiber may be either hydrolyzed guar gum or pre-treated pectin (at least 0.85%, which equals at least 15 g per 2,000 calories). pH is adjusted to 6.8. Next, the potassium citrate and the mineral premix are added and temperature is increased to 150°F. The hot oil is then added and heated to 165°F. The mixture is then homogenized. Vitamin premix and flavor is added and mixed thoroughly. The mixture is then heat processed and packaged aseptically.

EXAMPLE 3

Replacing Insoluble Fiber with Soluble Fiber

A currently available product, FIBERSOURCE®, contains soy polysaccharide which is insoluble fiber. Hydrolyzed guar gum may be used to replace the soy polysaccharide or may be added in addition to the soy polysaccharide. Below is an example where the hydrolyzed guar gum replaces soy polysaccharide on a one-to-one basis, but other ratios may be used. If one wished to replace soy polysaccharide with hydrolyzed pectin, a different emulsifier system is needed.

INGREDIENT	% FORMULA
Deionized water	73.29
Maltrin 100 (maltodextrin)	11.33
Maltrin 200 (maltodextrin)	4.500
Sodium Caseinate	3.227
Medium Chain Triglyceride Oil	1.994
Canola Oil	1.779
SUNFIBER®	1.319
Calcium Caseinate	1.209
Potassium Citrate	0.4050
Vanilla Flavor	0.1000
Sodium Citrate	0.2025
Magnesium Chloride	0.1829
Tricalcium Phosphate	0.1411
*H_2O Vitamin premix	0.06329
Potassium Chloride	0.08406
Polyglycerol esters of fatty acids	0.06136
**Multimineral premix	0.02859
Choline Chloride	0.04522
***Fat/Vitamin premix	0.00288
Vitamin E Oil	0.003600
Dipotassium Phosphate	0.03283
	100.0

*H_2O Vitamin Premix contains

Sodium ascorbate	0.05522 %
Niacinamide (B_3)	0.003280
Calcium pantothenate	0.002100
Cyanocobalamin (B_{12})	0.001440
Thiamin hydrochloride	0.000450
Pyridoxine hydrochloride	0.000420
Riboflavin (B_2)	0.000300
Biotin	0.000050
Folic acid	0.000030

**Multimineral premix contains:

Selenium yeast	0.01019
Chromium yeast	0.005150
Zinc sulfate	0.004910
Ferrous sulfate	0.004910
Manganese sulfate	0.001210
Sodium molybdate	0.001100
Copper gluconate	0.001100
Potassium iodide	0.000020

***Fat/vitamin premix contains:

Vitamin A palmitate	0.001720
Vitamin K	0.000780
Vitamin D_3	0.000380

EXAMPLE 4

Effects of Dietary Soluble and Insoluble Fiber on the Intestinal Flora, Intestinal Histology and Bacterial Transaction in Mice.

1. Effect on Bacteria

Four groups of mice are fed either normal mouse chow, a commercially available liquid food composition (abbreviated Liq), the liquid composition supplemented with 2.5 % soy fiber (Liq+S), or the liquid composition supplemented with 2.5 % SUNFIBER® (Liq+G). After 14 days, the type and amount of cecal bacteria are measured. Results are presented in Table 4A below. "Wt" is average (n=24) weight gain in grams in 14 days. Numbers given under the bacterial columns represent the average and standard error ($\log_{10}$) of cecal bacteria per gram (n=8)

TABLE 4A

Diet	Wt	Aerobic + facultative gram-neg. bacilli	Aerobic + facultative gram-pos. bacteria	Strict Anaerobes
Chow	3.5	4.3 ± 0.9	8.0 ± 0.2	9.5 ± 0.1
Liq.	4.5	7.6 ± 0.2[a]	7.8 ± 0.2	9.7 ± 0.2
Liq+S	4.1	6.6 ± 0.2[b]	8.0 ± 0.2	9.9 ± 0.2
Liq+G	4.7	6.2 ± 0.4	8.4 ± 0.1	10.2 ± 0.1[b]

[a]Significantly increased compared to chow-fed mice, $P<0.01$ by ANOVA
[b]Significantly increased compared to chow-fed mice, $P<0.05$ by ANOVA

The table shows that the liquid diet and the liquid diet supplemented with soy fiber both significantly increased the amount of aerobic and facultative gram-negative bacteria. Gram-negative bacteria are those which can cause bacterial sepsis if they or the endotoxins produced by them translocate into the bloodstream. No statistically significant increase was observed in the liquid food supplemented with the hydrolysed guar. The strict anaerobe count was increased with the liquid + hydrolysed guar but these bacteria are considered more "benign" than the aerobic gram-negative bacteria.

2. Translocation of bacteria

Septic shock occurs after bacteria or their endotoxins enter the bloodstream. One of the first steps in this process is the translocation of cecal bacteria to the mesenteric lymph nodes (MLN). As liquid feeding tends to increase the amount of gram-negative bacteria, it is important to maintain the blood-mucosal barrier to eliminate translocation. The effect to diet on this translocation was investigated, and results are presented below in Table 4B. Each group of mice was fed chow, Liq. Liq+S, or Liq+G as described above for 14 days.

TABLE 4 B

Diet	No. of mice with viable bacteria in MLN(%) / Total No. mice[a]	No. and identity of bacteria in the MLN of individual mice
Chow	3/24 (13%)	10 *E. coli* 20 *E. coli* 450 *Lactobacillus* sp.
Liq	1/24 (4%)	20 coagulase-negative staphylococci
Liq+S	2/24 (8%)	10 *Lactobacillus* sp. 40 *Enterobacter* sp.
Liq+G	1/24 (4%)	20 *E. coli*

[a]Chi-Square analysis indicates no significant differences between how-fed mice and mice fed Liq, Liq+S, or Liq+G.

Thus, as shown in he table above, addition of the hydrolysed guar fiber did not have any adverse effects on the translocation of bacteria into the MNL.

3. **Effect of Diet on Bacteria in Endotoxin Lipopolysaccharide-treated (LPS) mice**

Each group of mice was fed as previously described and was given 200 μg i.p. injection of endotoxin lipopolysaccharide, the toxin which is involved in septic shock. Results are presented in Table 4C below. Abbreviations and units are the same as those used in Table 4A.

TABLE 4C

Diet	Wt.	Aerobic + facultative gram-neg. bacilli	Aerobic + facultative gram-pos. bacteria	Strict Anaerobes
Chow	0.3	9.0 ± 0.1	8.4 ± 0.2	9.7 ± 0.2
Liq	1.8	9.7 ± 0.3	9.4 ± 0.3[a]	10.2 ± 0.2
Liq+S	2.3	9.2 ± 0.2	8.7 ± 0.2	9.7 ± 0.2
Liq+G	1.2	9.1 ± 0.2	8.9 ± 0.2	10.2 ± 0.1

[a]Significantly increased compared to chow-fed mice $P<0.1$ by ANOVA

None of the liquid diets were seen to have an adverse effect on the intestinal flora of LPS-treated mice. AS expected, number of enteric gram-negative bacteria (primarily E. coli) increased with the intraperitoneal LPS treatment for all treatment groups.

4. Translocation of bacteria to MLN in LPS-treted mice

Mice were fed as described supra and treated with LPS as described supra. The number and identity of bacteria found in the MLN was determined. Results are presented in Table 4D, below.

TABLE 4D

Diet	No. mice with viable bacteria in MLN(%) / Total No. of mice	No. and identitiy of viable bacteria in MLN of individual mice
Chow	14/23 (61%)[a]	60 E. coli
		10 E. coli
		60 E. coli
		10 P. mirabilis + 150 Lactobacillus sp.
		10 E. coli
		10 E. coli
		30 E. coli
		100 E. coli
		10 E. coli
		80 E. coli
		60 Enterobacter sp.
		10 E. coli
		10 Enterobacter sp.
		20 E. coli
Liq	21/24 (88%)	10 E. coli
		20 Enterococcus sp.
		70 Enterococcus sp.
		50 Enterococcus sp.
		10 Enterobacter + 650 Enterococcus sp.
		10 Enterococcus sp.
		10 E. coli + 10 Enterobacter sp.
		20 Enterococcus sp.
		120 Enterococcus sp.
		90 E. coli
		110 E. coli
		20 Enterococcus sp.
		10 Lactobacillus sp.
		20 Enterococcus sp.
		30 Enterococcus sp.
		30 E. coli
		10 E. coli + 10 Enterococcus sp.

Diet	No. mice with viable bacteria in MLN(%) / Total No. of mice	No. and identitiy of viable bacteria in MLN of individual mice
		150 *Enterococcus* sp.
		10 *E. coli*
		90 *Enterococcus* sp.
Liq+S	12/24(50%)[b]	20 *E. coli*
		10 coagulase-negative staphylococci
		40 *E. coli*
		40 *E. coli*
		110 *Enterococcus* sp.
		10 *Lactobaccilus* sp.
		10 *E. coli*
		10 *E. coli* + 70 *S.aureus*
		40 *E. coli*
		20 *Enterobacter* sp.
		10 *E. coli*
		10 *Enterococcus* sp.
Liq+G	9/24(42%)[c]	10 *E. coli*
		40 *E. coli* + 30 *Enterococcus* sp.
		10 *Enterobacter* sp.
		70 *E. coli* + 20 *Enterococcus* sp.
		30 *E. coli*
		60 *Enterobacter* sp. + 130 *Enterococcus* sp.
		40 *Enterobacter* sp. + 10 *Enterococcus* sp.
		20 *Enterobacter* sp. + 60 *Enterococcus* sp.
		30 *Enterococcus* sp.

[a] One mouse died out of 24 mice

[b] Significantly decreased compared to mice fed Liq, $P<0.05$ by Chi-square with continuity correction.

[c] Significantly decreased compared to mice fed Liq, $P<0.01$ by Chi-square with continuity correction.

Compared to chow fed mice, Liq+S and Liq+G have an improvement in preventing the translocation of intestinal bacteria to the mesenteric lymph nodes of mice. Compared to chow-fed mice, Liq appeared to increase the incidence of bacterial translocation somewhat (P=0.08). However, the supplementation with soy or hydrolysed guar fiber had the beneficial effect of significantly decreasing the incidence of translocation of bacteria. The Liquid composition supplemented with the soy fiber is however not suitable for tube feeding.

EXAMPLE 5

In a randomised, double blind, cross-over study the effect of supplementation of a tube-feeding formula with hydrolysed soluble fiber on gut transit time was investigated in 12 healthy volunteers.

The test diets were a self selected diet (SDS) the standard formula diet NUTRODRIP[R] (SANDOZ Nutrition) and an identical formulation supplemented with 2 % by weight of SUNFIBER[R] (21 g/l) The diets are administered, bolus-wise, in an iso-caloric amount covering the required energy supply (between 2000 and 2500 Kcal per day). The oral-coecum transit time (OCT) was assessed by lactulose H2 breath test, the colonic transit time (CTT) by a radioopaque marker technique. The stool frequency (SF) was recorded as well. The results shown in Table 5 indicate that hydrolysed soluble fibers are beneficial for enterally fed patients with diarrhea due to a prolongation of CTT without significantly affecting OCT. Daily SF was not different, but a trend towards increased SF was observed with NUTRODRIP[R] whereas SUNFIBER[R] reversed this effect.

The results are as follows:

TABLE 5

Diet	SF/d	OCT(min)	CTT(hrs.)
Nutrodrip^{R}	1.15 ± 0.16	127 ± 16	39 ± 5
Nutrodrip^{R} plus 2 % Sunfiber^{R}	0.95 ± 0.08	110 ± 11	55 ± 7
SSD	1.00 + 0.03	117 ± 17	30 ± 5

Throughout this specification and the claims which follow, unless the context requires otherwise, the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated integer or group of integers but not the exclusion of any other integer or group of integers.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A nutritionally complete, liquid enteral feeding composition, essentially neutral in nature and having a viscosity of less than 50 cp, comprising hydrolysed soluble fiber selected from the group consisting of hydrolysed guar gum, hydrolysed pectin, hydrolysed gum arabic, hydrolysed locust bean gum and hydrolysed xanthan gum, in an amount such that the daily dosage of the feeding composition provides from 10 to 60 grams of hydrolysed soluble fiber per day.

2. The composition according to Claim 1, providing from 10 to 45 grams of hydrolysed soluble fiber in a formulation volume providing up to 3000 kcal energy.

3. The composition according to Claim 2 providing from 10 to 45 grams of hydrolysed soluble fiber in a formulation volume providing from 1500 to 2500 kcal energy.

4. A composition according to any one of Claims 1 to 3, wherein the soluble fiber is selected from the group consisting of hydrolysed guar gum and hydrolysed pectin.

5. A composition according to any one of Claims 1 to 4, comprising hydrolysed guar gum.

6. The composition according to any one of Claims 1 to 5, comprising:

carbohydrates providing approximately 20-70% of the total calories;

protein providing approximately 10-30% of the total calories;

lipid containing essential fatty acids providing approximately 20-50% of the total calories;

vitamins;

mineral;

water; and
hydrolysed soluble fiber.

7. A method of preventing bacterial sepsis in a patient, comprising administering to the patient a feeding composition according to any one of Claims 1 to 6.

8. A method of preventing gut atrophy in a patient which comprises administering to the patient a feeding composition according to any one of Claims 1 to 6.

9. A method of treating or preventing diarrhoea in a patient which comprises administering to the patient a feeding composition according to any one of Claims 1 to 6.

10. Nutritionally complete, liquid enteral feeding compositions or methods involving them, substantially as hereinbefore described with reference to the Examples.

DATED this 26th day of May, 1994
Sandoz Nutrition Ltd.
By Its Patent Attorneys
DAVIES COLLISON CAVE

T OFFICE

Medical Foods having Soluble Fiber

~~IMPROVEMENTS IN OR RELATING TO ORGANIC COMPOUNDS~~

Abstract of the Disclosure

A nutritionally complete feeding composition containing hydrolysed soluble fiber, especially hydrolysed guar gum or hydrolysed pectin providing nourishment to colon cells, preventing bacterial sepsis and also preventing diarrhea.