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[54] **INFANT NUTRITIONAL FORMULA WITH RIBO-NUCLEOTIDES**

[75] Inventors: **Marc L. Masor**, Worthington; **James L. Leach**, Columbus; **Bruce E. Molitor**, Westerville; **John D. Benson**, Powell; **Jeffrey H. Baxter**, Galena, all of Ohio

[73] Assignee: **Abbott Laboratories**, Abbott Park, Ill.

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[58] **Field of Search** 514/45, 46, 47, 514/49, 50, 51; 426/69, 72, 73, 541, 658, 801

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,231,385	1/1966	Ziro et al.	426/72
4,544,559	10/1985	Gil	426/72
4,758,553	7/1988	Ogashi	514/47
4,994,442	2/1992	Gil et al.	514/45
5,021,245	6/1991	Borschel et al.	426/2
5,066,500	11/1991	Gil et al.	426/72
5,075,225	12/1991	Wong	435/87
5,221,545	6/1993	Borschel et al.	426/2
5,223,285	6/1993	DeMichele et al.	426/72

FOREIGN PATENT DOCUMENTS

88500521	5/1988	European Pat. Off. .
893133918	12/1989	European Pat. Off. .
2152814	12/1984	United Kingdom .
2216416	7/1989	United Kingdom .

OTHER PUBLICATIONS

L. M. Janas et al, "The Nucleotide Profile of Human Milk" Pediatric Research, vol. 16, pp. 659–662, 1992.

A. Gil et al, "Acid–Soluble Nucleotides of Human Milk at Different Stages of Lactation." J. Dairy Research, vol. 49, pp. 301–307, 1992.

J. Leach et al, "Nucleic Acid Content of Enteral Formulas" Fed. Soc. Exp. Biology, Abstract #2184, p. A378, Mar., 1993.

J. Espinoza et al. "Nucleotide Enriched Milk and Diarrheal Disease in Infants." Mar. 1993 Federation Society Experimental Biology, Abstract #16, p. 739.

L. Zhang et al "Immunomodulatory actions of nucleotides on Ag/Ig production . . . " Fed. Soc. Exp. Biology, Abstract #2389, Mar. 1993.

O'Brunser et al., "Effect of Dietary Nucleotide Supplementation on Diarrhoel Disease in Infants". Acta Pediatrics, vol. 83, pp. 188–191, 1994.

F. B. Rudolph et al; "Role of RNA as a Dietary Source of Pyrimidines & Purines in Immune Function"; Nutrition, vol. 6, pp. 45–52, 1990.

F. B. Rudolph, "Nucleotides: Micronutrient Building Blocks of Nutrition". Nutrition, Sep. 1989, pp. 8–13.

F. Oski, "The Evolution of Infant Formula", Nutrition, pp. 4–7, Sep., 1989.

L. A. Barness, "The Effects of Nucleotides on Aspects of Neonatal Immunity", Nutrition, pp. 20–24, 1989.

R. J. Chandra, "Nutrients and Immune Function" Nutrition, pp. 25–31, Sep., 1989.

J. Carver et al "Dietary Nucleotides May Act as Growth Factors in Liver and Intestine" Fed. Soc. Exp. Biology, Abstract #3726, p. A643, Mar. 1993.

Primary Examiner—Marian C. Knode
Assistant Examiner—Francisco C. Prats
Attorney, Agent, or Firm—Donald O. Nickey; Lonnie R. Drayer

[57] **ABSTRACT**

An improved enteral nutritional formula containing ribonucleotide equivalents (RNA, mono-, di- and triphosphate nucleotides, nucleosides and adjuncts such as activated sugars) at a level of at least 10 mg/100 Kcal (kilocalorie) of formula is disclosed. The formula comprises carbohydrates, lipids, proteins, vitamins and minerals and four (4) ribonucleotide equivalents at specific levels and ratios. The invention also discloses novel methods of production and analytical techniques. An infant formula containing cytidine nucleotide equivalents in the range of 29 to 39 mg/liter of formula, uridine nucleotide equivalents in the range of 15 to 20 mg/liter of formula, adenosine nucleotide equivalents in the range of 10 to 15 mg/liter of formula and guanosine nucleotide equivalents in the range of 14 to 20 mg/liter of formula provides a dietary formula that enhances the immune system and alleviates diarrhea.

9 Claims, No Drawings