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[54] **ENTERAL FORMULATION DESIGNED FOR OPTIMIZED WOUND HEALING**

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[58] **Field of Search** 514/21.2, 23, 54, 514/558, 560, 565, 943; 426/72, 607, 656, 658; 424/439

[56] **References Cited**

U.S. PATENT DOCUMENTS

Re. 28,093	7/1974	Balassal .
Re. 29,909	2/1979	Kurtz .
2,912,359	11/1959	Anigstein et al. .
3,003,917	10/1961	Beiler et al. .
3,400,199	9/1968	Balassa .
3,476,855	11/1969	Balassa .
3,478,146	11/1969	Balassa .
3,558,771	1/1971	Balassa .
3,624,201	11/1971	Balassa .
3,632,754	1/1972	Balassa .
3,804,949	4/1974	Balassa .
3,903,268	9/1975	Balassa .
3,904,753	9/1975	Yamasaki et al. .
3,911,116	10/1975	Balassa .
3,914,413	10/1975	Balassa .
4,001,396	1/1977	Feuer .
4,049,802	9/1977	Fox .
4,056,520	11/1977	Sonenberg et al. .
4,094,973	6/1978	Robertson .
4,177,261	12/1979	Dietze et al. .
4,265,233	5/1981	Sugitachi et al. .
4,287,184	9/1981	Young .
4,318,906	3/1982	Llopart .
4,330,527	5/1982	Arima et al. .
4,399,123	8/1983	Grant et al. .
4,401,651	8/1983	Knutson .
4,414,202	11/1983	Silvetti .
4,414,976	11/1983	Linnau et al. .
4,423,036	12/1983	Schneider .
4,426,378	1/1984	Holaday .
4,427,654	1/1984	Austin .
4,431,582	2/1984	Stenn .
4,442,655	4/1984	Stroetmann .
4,443,437	4/1984	Marshall et al. .
4,444,760	4/1984	Thomas .
4,447,418	5/1984	Maddoux .
4,485,098	11/1984	Ishikawa et al. .
4,503,037	3/1985	Raskai .
4,507,285	3/1985	Kuhne .
4,532,134	7/1985	Malette et al. .
4,575,457	3/1986	Maxarin .
4,604,283	8/1986	Gresham .
4,617,326	10/1986	Bjornberg et al. .
4,657,758	4/1987	Berger et al. .
4,666,708	5/1987	Berger et al. .
4,698,301	10/1987	Hill et al. .
4,699,788	10/1987	Catsimpoolas et al. .

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

8289452	4/1983	Australia .
48473	3/1982	European Pat. Off. .
61917	10/1982	European Pat. Off. .
78191	5/1983	European Pat. Off. .
90997	10/1983	European Pat. Off. .
150053	7/1985	European Pat. Off. .
165492	12/1985	European Pat. Off. .
199331	10/1986	European Pat. Off. .
201741	11/1986	European Pat. Off. .
225109	6/1987	European Pat. Off. .
2316197	8/1987	European Pat. Off. .
324227	7/1989	European Pat. Off. .

(List continued on next page.)

OTHER PUBLICATIONS

Barbul et al, *Surgery*, vol. 108, No. 2, pp. 331–337, 1990.

Berthold et al, *Metabolism*, vol. 44, No. 4, pp. 466–473, Apr. 1995.

Albina et al, *Arginine metabolism in wounds*, Am.J. Physiol., pp. E459–E467 (1988).

Albina et al, *Temporal Expression of Different Pathways in l–Arginine Metabolism in Healing Wounds*, The Journal of Immunobiology, vol. 144, No. 10, pp. 3877–3880 (1990).

Barbul et al, *Arginine enhances wound healing and lymphocyte immune responses in humans*, Surgery, vol. 108, pp. 331–336 (1990).

Berthold et al, *Isotopic Evidence for the Differential Regulation of Arginine and Proline Synthesis in Man*, Metabolism, vol. 44, No. 4, pp. 466–473 (1995).

(List continued on next page.)

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[57] **ABSTRACT**

The present invention provides an enteral nutritional formulation that meets the nutrient requirements of patients with wounds. The present invention meets the unique nutrient needs of the acute or chronic patient that are generated due to tissue repair and healing requirements of wounds. To this end, in an embodiment, the present invention provides a method for providing nutritional support to a patient with an acute or chronic wound comprising the step of administering a therapeutically effective amount of composition comprising a protein source including an arginine source and a proline source in the ratio by weight of approximately 1:0.5 to about 4:1. The composition may also include a carbohydrate source, a lipid source including an appropriate n6:n3 ratio, and at least the U.S. RDA for vitamins and minerals provided in an amount of formula supplying 1000 kcal, with vitamin A, beta-carotene, vitamin C, vitamin E, thiamine, pyridoxine, biotin and zinc being supplied in amounts above the U.S. RDAs.

20 Claims, No Drawings