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ORAL FAT EMULSIONS

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The present invention is an oral fat emulsion for use in human and animal nutrition.

Oral fat emulsions have been used for the treatment of the underweight, the ill and convalescent who have lost weight, are losing weight or are unable to eat adequately for a variety of reasons, and as sources of "quick energy." Such oral fat emulsions have generally consisted of suspensions of from 40 to 50 percent of a fat, such as peanut oil, in an aqueous sucrose or glucose solution comprising from 5 to 10 percent by weight of the saccharide based on the volume of the emulsion, together with an emulsifying agent, such as lecithin or purified soybean phosphatide, and a small proportion of a synthetic emulsifier, for example, an alkylarylpolyether alcohol.

Such oral fat emulsions have often supplied all or a portion of the caloric needs of the ill or convalescent patient. At those times, when the nutritional requirements of a patient may be greater, the consumption of food by the patient is frequently diminished, resulting in a caloric deficit and consequent metabolic conversion of ingested protein for energy. This leads to a loss of weight and lack of protein to replace lost tissue, as revealed in a negative nitrogen balance. The loss of weight that is not directly attributable to the original causes, may produce a variety of complaints, such as restlessness, weakness, insomnia, excessive fatigue and further anorexia, which further decreases the already inadequate food intake. Accentuation of these complaints is found particularly in illnesses that are associated with increased metabolic rates.

Oral fat emulsions have made it possible to supply some of the caloric deficit that could not be adequately provided by dietary supplements containing large amounts of carbohydrate and protein. Such dietary supplements have a caloric value of only 4 calories per gram, while that of fat itself is 9 calories per gram. Fat emulsions tend to overcome the problem of inadequate caloric intake by increasing palatability. Their principal virtue is their combination of caloric density with palatability.

The oral fat emulsions heretofore described lack certain desirable features. Because of the nature of the fats used (peanut oil, corn oil, etc., which have high iodine numbers) they were unstable toward atmospheric oxidation and developed rancidity rapidly. The emulsion itself, because of the nature of the emulsifying agents and other ingredients that were used, also lacked shelf stability, that is, the emulsion broke and settled on standing for long periods. Instability in the presence of acids such as are encountered in the stomach has also been a feature of such emulsions that it would be desirable to overcome, if possible. The palatability of such emulsions oftentimes changes on aging and the appearance of an emulsion that has separated is not only referred to as pharmaceutically "inelegant" but is likely to create revulsion in the patient to its ingestion. The addition of flavoring agents is not normally sufficient to compensate for these undesirable features; on the contrary, the patient may, during the course of treatment, develop an aversion to the flavoring material itself, especially over long periods.

The principal object of the present invention is to provide an oral fat emulsion of high caloric value that is characterized by exceptional palatability and stability to atmospheric oxidation or rancidification. It is a further object of the present invention to provide such an oral fat emulsion that does not readily separate on standing and that is not readily broken by contact with acidic fluids. A still further object of the invention is to provide such an emulsion that is easily digested and is well assimilated. Other objects and advantages of the invention, some of which are referred to specifically hereinafter, will be apparent from the purview of this specification.

A preferred example of an oral fat emulsion of the present invention is that composed of the following substances in the following proportions, which are specified in weight/volume percentages [these percentages represent parts by weight of the ingredients to parts by volume of the finished emulsion; that is, "50% weight/volume" of the refined coconut oil refers to 50 grams (or other parts by weight) of coconut oil which, together with the other ingredients, is brought with water to a combined volume of 100 milliliters (or other parts by volume)]:

	Percent weight/volume
Refined coconut oil (solidification point 76° F.)	50
Sucrose	12.5
Tert.-butylhydroxyanisole	0.01
Glyceryl monostearate (emulsifying grade as specified herein)	1.5
Polyoxyethylene sorbitan monostearate (approximately 20 ethylene oxide molecules per molecule)	2
Water, sufficient to make 100% by volume.	

The refined coconut oil has a low acid value, a low iodine number, and a solidification point of approximately 76° F. (approximately 25° C.). When used in the oral fat emulsions of this invention it has a completely bland taste, imparting to the composition maximum palatability. It is also much more inherently resistant to oxidation than other fatty oils which have heretofore been used in such compositions. To retard any incidental oxidation, however, the specified small amount of tertiary-butylhydroxyanisole may be added to commercial preparations or to preparations that are not destined for use within short periods. It is essential, if the product is to be stable and not discolor on storage, that it be free from ester antioxidants such as propyl gallate and others normally used in fats to retard rancidification. The proportion of oil in the emulsion, which has a caloric value of 9 calories per gram, may be varied within rather wide limits, dependent upon the caloric value desired, but is preferably maintained within the range between 40 and 55 percent by weight/volume.

The sucrose is the major source of readily available carbohydrate but may be replaced entirely or partially by glucose or other water-soluble nutrient saccharides, especially if a reduction in sweetness is desirable. The content of saccharide may be varied within rather wide limits, dependent upon the palatability and sweetness desired. Sucrose has a caloric value of approximately 5 calories per gram. Preferred ranges of sucrose are between 5 and 20 percent by weight/volume.

The emulsifying agent, glycerol stearate, is an essential ingredient of the composition and its composition and proportions require control. The glyceryl stearate should be an emulsifying grade which contains approximately 10% by weight of sodium stearate and whose glycerides fall within the following distribution ranges:

	Percent
Monoglycerides	30–40
Diglycerides	40–50
Triglycerides	10–20