

as *cis* and *trans*-isomeric forms, while synthetic compounds are frequently racemic mixtures.

Carotenoids have been of interest as a source of added colour for food and drink products. However, their insolubility in water and poor solubility in the conventional oils used in food products and their sensitivity to oxidation has limited their use, particularly in water-based products such as beverages and syrups and products to which water is to be added.

FR-A-2 187 291 discloses a process for preparing optically clear products comprising oil soluble ingredients using organic solvents which are miscible with water, however these solvents are not suitable for food use.

UK patent specification 1 407 779 (Hoffman-La Roche) describes a carotenoid colouring composition which is dispersible in water to form optically clear aqueous dispersions. These known compositions essentially contain large amounts of the emulsifiers polysorbate 60 and 80 along with a particular mixture of low molecular weight saturated coconut fatty acids and saturated fractions of coconut oil triglycerides. However it is generally undesirable to have large amounts of these emulsifiers present. In particular polysorbate 80 has undesirable taste characteristics such that if used in the amounts specified the predominantly 'oily' or 'fatty' taste would be inappropriate for most beverages. Also the amounts required would add significantly to the cost. We have now developed a composition which does not rely on large amounts of fatty acids triglycerides and emulsifiers to create a stable formulation.

The present invention therefore provides an aqueous composition for the preparation of optically clear products for human or animal healthcare comprising 0.1 to 2.0 % w/w of an oil-soluble ingredient as a 20-30% w/w dispersion in a suitable oil or 0.1 to 5.0 % w/v as the pure crystalline ingredient, 2-20 % of an emulsifier having an HLB (hydrophilic/lipophilic balance) value of between 10 and 18 or where a blend of emulsifiers is employed, a calculated HLB value of between 10 and 18 and 0.1 to 1.0 % of an antioxidant or a mixture of antioxidants.

An example of a blend of emulsifiers is a blend containing 4 parts of Span 20 (sorbitan monolaurate) and 6 parts of Tween 60 (polyoxyethylene sorbitan monostearate) having an effective HLB value of $0.4 \times 8.6 + 0.6 \times 14.9 = 12.3$.

By 'optically clear' we mean a product exhibiting a percentage transmittance value of not less than about 95%, preferably 98%, determined at a wavelength of 800 nm in a 1 cm path length cuvette. Preferably the composition is a colour composition wherein the oil-soluble ingredient comprises a colouring agent and/or an antioxidant or a mixture of antioxidants.

Surprisingly it has been found that the composition of the present invention is able to yield a product with desirable properties, particularly high water solubility

other than beverages, such as vitamin and cough syrups, throat sprays, lotions and mouthwashes, particularly where optical clarity is important.

Certain carotenoids can act as vitamins and provitamins. In the compositions of the present invention the carotenoids and other oil-soluble components are believed to be finely dispersed in a micellar form or as microemulsions because they exhibit certain characteristics eg. transparency when viewed by transmitted light.

Therefore a further advantage of the compositions according to the present invention is that the fine dispersion of these oil-soluble vitamins, pro-vitamins and other oil-soluble materials in aqueous preparations will help to promote the efficient uptake of such materials by body tissues when the composition is presented to the body. Whilst the small particle size of the particles of oil-soluble ingredients favour uptake of the oil-soluble materials, the simultaneous presentation or ingestion of oil-soluble active compounds with an emulsifier will also encourage efficient transfer of these substances across membranes.

The formulations according to the invention also have surprising acid resistance. This is advantageous because prior to absorption from the intestinal tract, the preparation is able to survive the strongly acid conditions of the stomach.

In a further aspect of the invention there is provided a composition according to claims 3 - 9 for use in therapy. Preferably the composition is administered orally, for example in the form of a liquid composition.

The composition obtained according to the present invention is an aqueous dispersion which is capable of dissolution in water-based products to yield optically clear finished products.

It will be appreciated that further ingredients may optionally be included in the composition of the present invention or to the final food product, for example sweeteners, preservatives (eg. sulphur dioxide, benzoic acid and sorbic acid), proteins, fats, vitamins, minerals and other materials employed in the preparation of food and drink products. Optionally the compositions also contain antioxidant cofactors such as zinc, selenium and manganese which are needed for the body's naturally occurring antioxidant enzymes. Preferably the final product is flavoured; this can be achieved by the addition of naturally flavoured foods such as fruit juices and concentrates, extracts and compounds or flavouring additives. Preferably further nutritive ingredients are added to the final drink such as other vitamins and minerals as described in "The Food Labelling Regulations 1984" Statutory Instrument No. 1305 (1984) H.M.S.O., London.

6. A composition as claimed in claim 4 or 5 wherein the amount of carotenoid is 0.1-1.0%.

7. A composition as claimed in any preceding claim wherein the amount of emulsifier is between 8 and 10%.

8. A composition as claimed in any preceding claim wherein the amount of antioxidant is 0.3 -0.5 %.

9. A composition according to any preceding claim in which ascorbic acid or alpha-tocopherol or both are present.

10. A product for human or animal use comprising a composition according to any of claims 1 to 9.

11. A composition according to any one of claims 3 to 9 for use in therapy.