Synergistic compositions

The invention concerns novel compositions comprising a combination of two different blended marine-sourced components comprising at least two components including at least hoki roe (HR) powder or oil and preferably in combination with green-lipped mussel (GLM) powder or oil.

The invention further extends to the use of that composition in human and veterinary applications, particularly in supplements or nutraceuticals thereby providing nutritional support in health and in particular in joint health.

Background

Nutraceuticals, food and health supplements are often utilised to improve or support joint structure and maintain joint mobility in mammals, including humans and animals.

The biological inflammatory pathway is directly linked with joint health including, for example, joint mobility. Potentially, lipids including pro-resolving lipid mediators, and bioactive peptides may also have a role, but may act via different pathways.

An effect has been shown to be derived from essential fatty acids (EFAs). Several enzymes implicated in the biological inflammatory pathway are thought to be impacted by the presence or absence of these EFAs and is also dependent of the type of EFA.

A significant level of omega (ω) polyunsaturated fatty acids, particularly ω-3, is likely to support the body's natural anti-inflammatory process and may therefore be useful. In particular, these EFAs are metabolised into anti-inflammatory eicosanoids. The presence of ω-3 bolsters the existing anti-inflammatory pathway because they will be preferentially acted upon in the process, but in their absence the natural substrate, including other EFAs such as arachidonic acid, would metabolise to generate pro-inflammatory agents.

Although GLM powder can be utilised for the purpose of providing a ω-3 source within supplement compositions, the quality and content of the ω-3 fatty acid is not always reliable and may not always be sufficient for products intended for maintaining joint health in humans or animals.

However, it remains desirable to provide effective compositions for use in supporting joint health, whether as a long term maintenance product, e.g. in food stuffs or nutritional supplements, or as a short term dietary solution. In particular, the ability to provide high specification sources of GLM powders that correlate with a desired technical specification that is sufficient to meet these applications is increasingly challenging.

The invention therefore comes about from the continued need to provide new compositions that are useful in the aforementioned commercial applications.

Summary

The present disclosure concerns a composition comprising a combination of two powder or oil components including: a green-lipped mussel (GLM) powder or oil component; and at least 5% (w/w) of a hoki roe (HR) powder or oil component.

The present disclosure also concerns a composition comprising: a blend of at least two different powder or oil components each comprising ω-3 fatty acids, wherein a first of the at least two different powder or oil components comprises 5% (w/w) or more of HR powder or oil and wherein the blend of the at least two different powder or oil components together provides at least 3.3% (w/w) total ω-3 fatty acids in the composition. Preferably, a second of the at least two powder components is GLM powder or oil.

In an aspect of the present disclosure, there is provided a composition comprising a combination of two powder or two oil components including:

a green-lipped mussel (GLM) powder or oil; and

at least 5% (w/w) of a Hoki Roe (HR) powder or oil.

In another aspect of the present disclosure, there is provided a composition comprising: a blend of at least two different powder or oil components each comprising ω-3 fatty acids, wherein a first of the at least two different powder or oil components comprises 5% (w/w) or more of HR powder or oil and wherein the blend of the at least two different powder or oil components together provides at least 3.3% total ω-3 fatty acids in the composition.

In a further aspect of the present disclosure, there is provided a food stuff, nutraceutical or supplement comprising the composition disclosed herein.

In another aspect of the present disclosure, there is provided a composition, food stuff or supplement disclosed herein, for use in the treatment or maintenance of health, preferably joint health, of a human or animal.

In a further aspect of the present disclosure, there is provided a use of a composition disclosed herein, in the manufacture of a medicament for treating a subject, wherein the subject is a human or an animal.

In another aspect of the present disclosure, there is provided a composition disclosed herein, or a food stuff, nutraceutical or supplement disclosed herein, for use in therapy.

In the first instance, the applicant made the observation that when providing a composition for the before-described application, the selection of the ω-3 fatty acid source is very important. The ω-3 fatty acids in any given powder source on the market varies considerably. The applicant's preliminary investigations confirmed that some GLM powder specifications did not provide enough ω-3 to meet the technical criteria for the intended purpose, as compared to a higher specification product which is rare and less easily available to the market.

However, GLM remains an important base source of ω-3 fatty acids, even when low and the inventors further investigated other ways in which GLM-based compositions would nonetheless provide a solution. In doing so it was determined that including a minimum amount of a different, specifically selected, ω-3 fatty acid source, in combination with the lower specification GLM powder, raised the ω-3 content to an acceptable level. It was elucidated through testing that using at least 5% of HR powder, blended with the lower specification GLM powder achieved this solution.

It was further elucidated through *in vitro* assay testing that an unexpected, enhanced level of inhibitory or modulatory activity can be observed in a composition by introducing a particular

selection or combining sources of ω-3 content. Such activity is highly relevant to supporting the inflammatory response pathway and maintaining optimum joint health. The anti-inflammatory activity of a blend of HR powder and GLM powder is preferably measured as a co-efficient of between 0.05 and 0.25, determined according to the methods described herein below.

The applicant was further able to demonstrate that, provided the source remained the same, the HR component and/or the GLM component could be used in oil form to yield a composition with an equivalent technical effect, thereby providing an additional solution to the problem based on the fundamental inventive concept.

During similar assays, as were undertaken for the powder components, the effect of this specific two-oil component combination on the inflammatory pathway is greater than would be expected from the sum of the individual component parts.

The combination of these two components, whether powder or oil form, is therefore better at inhibiting or modulating levels of inflammation, as measured by the relative COX 2 activity, than would be predicted from the level disclosed in the art. In other words, the applicant has demonstrated there is a synergistic effect which is useful to maintain a better level of support for the anti-inflammatory system when the component combination is selected from either the powder or oil form.

The *in-vitro* inhibition or modulation activity observed by the applicant is considered to be far greater than the mere additive effect that would be expected from the ω-3 EFA levels combination alone. Therefore, the applicant has determined a most unexpected synergistic effect can be

achieved by the present disclosure. That is, the specific introduction of HR at a de minimus level and/or further a specific selection of this powder or oil component with a lower specification GLM extract maintains a higher level of competitive enzyme activity than would be expected based purely on ω-3 EFA content. In examples, the present disclosure therefore concerns a food product, supplement or nutraceutical comprising the composition having the components as recited in the claims and as described herein.

Such a composition would meet or exceed the technical criteria required, in terms of content and/or activity and thus enable consistent and improved efficacy of a GLM-based product for the purpose of supporting joint health. The present disclosure is useful in the provisions of a food stuff or supplement comprising the composition as described herein. The food stuff or supplement may further comprise one or more useful excipients desirable to make the supplement more palatable, or may provide other benefits. The excipient may include one or more of the following excipients including, but not limited to: Glucosamine, Hyaluronic Acid and Chondroitin Sulphate.

In preferred examples of the present disclosure the HR powder or oil is in the range from 5% to 95% (w/w) of the total composition mass. In examples, the HR powder or oil component comprises a total fat content of 14% to 40% (w/w) but importantly may comprise a total ω-3 fatty acid content from 2% to 20% (w/w).

As regards the GLM content, the GLM powder or oil comprises a total fat content from 7% to 13% (w/w). It is envisaged that in examples the GLM powder or oil comprises a total ω-3 fatty acid content in the range of 2.0% to 7.0% (w/w) ideally 2.0% to 5.0% (w/w).

The compositions of the present disclosure are particularly useful as a supplement for humans or a veterinary product and may be used to prevent inflammation, to maintain low levels of inflammation and/or to treat inflammation. The composition itself and/or food stuff or supplement comprising that composition, may be for use in the treatment and/or maintenance of health, preferably joint health of a human or animal. Further, the treatment and/or maintenance involves support of anti-inflammatory pathways in the human or animal.

The present disclosure further extends to a method of maintaining joint health comprising administering to an animal in need thereof the composition disclosed herein. In examples, the maintenance of health involves supporting anti-inflammatory pathways of the animal including the prevention of inflammation.

The present disclosure extends to a method of treating a subject, the method comprising administering to the subject the composition as disclosed herein, wherein the subject is a human or an animal. In examples the method treats inflammation or maintains low levels of inflammation in the subject, wherein the subject is an animal. In examples, the method maintains health or joint health of the subject.

Claims:

1. A composition comprising a combination of two powder or two oil components including:
a green-lipped mussel (GLM) powder or oil; and
at least 5% (w/w) of a Hoki Roe (HR) powder or oil.

2. A composition comprising: a blend of at least two different powder or oil components each comprising ω-3 fatty acids, wherein a first of the at least two different powder or oil components comprises 5% (w/w) or more of HR powder or oil and wherein the blend of the at least two different powder or oil components together provides at least 3.3% total ω-3 fatty acids in the composition.

3. The composition of claim 2, wherein a second component, of the at least two different powder or oil components, is a GLM oil or powder.

4. The composition of any of claim 1 to 3, wherein the HR powder or oil is present in a range from 5% to 95% (w/w) of the total composition.

5. The composition of any previous claim, wherein the GLM powder or oil comprises a total fat content from 7% to 13% (w/w).

6. The composition of any previous claim, wherein the GLM powder or oil comprises a total ω-3 fatty acid content in a range of 2.0% to 5.0% (w/w).

7. The composition of any previous claim, wherein the HR powder or oil comprises a total fat content of 14% to 40% (w/w).

8. The composition of any previous claim, wherein the HR powder or oil comprises a total ω-3 fatty acid content from 2% to 20% (w/w).

9. A food stuff, nutraceutical or supplement comprising the composition of any preceding claim.

10. The food stuff or supplement of claim 9, further comprising one or more excipients selected from Glucosamine and/or Hyaluronic Acid.

11. The composition, food stuff or supplement according to any previous claim, for use in the treatment or maintenance of health, preferably joint health, of a human or animal.

12. The composition according to claim 11, wherein the treatment or maintenance involves support of anti-inflammatory pathways in the human or animal.

13. Use of a composition of claim 1 in the manufacture of a medicament for treating a subject, wherein the subject is a human or an animal.

14. The use of claim 13, wherein the use treats inflammation or maintains low levels of inflammation in the subject, wherein the subject is an animal.

15. The use of claim 13, wherein the use maintains health of the subject.

16. The use of claim 13, wherein the use maintains joint health of the subject.

17. A food stuff, nutraceutical, or supplement comprising the composition of claim 2.

18. The food stuff, nutraceutical, or supplement of claim 17, further comprising at least one excipient chosen from glucosamine or hyaluronic acid.

19. Use of a composition of claim 2 in the manufacture of a medicament for treating a subject, wherein the subject is a human or an animal.

20. The use of claim 19, wherein the use treats inflammation or maintains low levels of inflammation in the subject, wherein the subject is an animal.

21. The use of claim 19, wherein the use maintains joint health of the subject.

22. A composition of any one of claims 1-8, or a food stuff, nutraceutical or supplement of claim 9 or claim 10, for use in therapy.