

ACKNOWLEDGED

SCANNED

SUBMISSION TO FSANZ

(DHA OIL)



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Objective:

To amend the specifications related to Hexadecanoic acid (Palmitic acid) and Free fatty acid content.

Role of Palmitic acid formed during processing in DHA

BioDHA (Nutritional Oil derived from micro algae *Schizochitrium Sp*, a rich source of Omega-3 Docosahexaenoic acid) oil specification is set as per the present manufacturer's standards and accepted by end users based on their application studies, Nutritional values and health enhancement reports.

DHA oil contains 35-40% unsaturated fatty acids naturally. Remaining fatty acid profiles are saturated fats like Lauric acid, Myristic acid, Stearic acid, Palmitoleic acid, Gamma linolenic acid, Arachidonic acid, Docosapentaenoic acid, Homo gamma linolenic acid, Alpha linolenic acid, Eicosatetraenoic acid etc in the molecular pathway, produced by the specific microorganism as described above.

The microorganism used in this process for manufacture of DHA by fermentation process will vary the components content (Quantitative composition) based on operating conditions, media, further processing and refining conditions, let alone the minor variations expected in the strain species (generally referred as culture).

The final product specification will also vary within permissible limits due to variations in Downstream and refining process and hence limits are prescribed for these components in the final product. However, the components within the prescribed limits do not cause any effects in their end use.

To elaborate further it is well known that:

Palmitic acid is the first fatty acid produced during fatty acid synthesis and from which longer fatty acids can be produced.

Palmitate negatively feeds back on Acetoacetyl coenzyme which is responsible for converting Acetyl-CoA to Malonyl-CoA which is used to add to the growing acyl chain.

Palmitic acid works to promote natural oil regeneration in human body and thus an important component for the skin to retain its protective barrier. With too little oil the skin will crack and bleed, opening it to a greater risk of infection and disease.

Role of FFA:

Free fatty Acid content is an indicator to quantify the amount of FFA acid present in the oil

FFA is the mass of potassium hydroxide in milligram that is required to neutralize one gram of chemical substance. The acid number is a measure of the amount of carboxylic acid groups in a chemical compound, such as a fatty acid or in a mixture of compounds. In a typical procedure, a known amount of sample dissolved in organic solvent is titrated with a solution of potassium hydroxide with known concentration and with phenolphthalein as a color indicator.

Bioplus DHA process fall on non virgin (refined) process as per the specification (0.5 mg KOH/g).

This value of FFA content in the DHA produced is on par with the other manufacturers and the products manufactured are in use for nearly 2 decades in food and beverage industry as well as administered for pregnant women, aged people and athletes as well.

Conclusion:

In light of the above clarifications, BioDHA can safely be used with the prescribed limits of Palmitic acid and Free fatty acids even though they are well comparable and inline with the globally accepted product specifications.

Seamons, Colleen

From: standards.management@foodstandards.gov.au
Sent: Monday, 31 January 2011 10:04 PM
To: standards management
Subject: FSANZ: Applications and Submissions - Submission [SEC=INCONFIDENCE]
Attachments: Submission DHA-FSANZ.doc

Categories: Blue Category



FSANZ: Applications and Submissions - Submission

Monday, 31 January, 2011

- 1. Assessment Report Number:** Proposal P1013
- 2. Assessment Report Title:** Code Maintenance IX
- 3. Organisation Name:** Bioplus Life Sciences Private Limited
- 4. Organisation Type:** Other
- 5. Representing:** Bioplus Life Sciences Private Limited
- 6. Street Address:** Pharmed Gardens, Whitefield Road, Bangalore-560048 INDIA
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- 11. Email Address:** sundeep@bioplus.in
- 12. Submission Text:** We are supporting the new specifications mentioned in the proposal P1013 for oil derived from marine micro-algae (*Schizochytrium* sp.) rich in Docosahexaenoic acid (DHA). In addition, we are also proposing amendments with respect to free fatty acid content and Palmitic acid content. The justification for the same is provided in the attachment.