



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Submitted via email - jian.kong@usp.org

TO: United States Pharmacopeia

FROM: Global Organization for EPA and DHA Omega-3s (GOED)

RE: Review of draft Monograph for DHA from Algal (*Schizochytrium*) Oil

DATE: May 21, 2021

GOED, the Global Organization for EPA and DHA Omega-3s, represents the worldwide EPA and DHA omega-3 industry, with a mission to increase consumption of EPA and DHA omega-3s around the world. The membership is built on a quality standard unparalleled in the market and members must comply with quality and ethics guidelines that ensure members produce quality products that consumers can trust. Our 160+ members represent the entire supply chain of EPA and DHA omega-3s, from fisheries and crude oil suppliers to refiners, concentrators and finished product brands.

GOED writes to provide the following comments on the draft Monograph for “DHA from Algal (*Schizochytrium*) Oil” – FCC Forum proposal of December 2020.

Suggestions and comments:

GOED has asked its members for input on the draft document. Based on our review, GOED has the following comments and suggestions:

1. Title.

With respect to the paragraph “Identification - Fatty acid composition” – this monograph is entitled “DHA from Algal (*Schizochytrium*) Oil.” The monograph revision is scheduled to be expanded with new *Schizochytrium* oil types, such as type II and III, that contain, besides DHA, significant contents of EPA. GOED suggests that USP considers renaming the monograph title to reflect the monograph encompassing identification and acceptance criteria for such EPA-rich oils as well, and not limit the description to DHA from Algal (*Schizochytrium*) Oil. The title could read instead “DHA- and EPA-containing Algal (*Schizochytrium*) Oils.” The alternative would be to create a separate monograph for *Schizochytrium* oils that also contain significant levels of EPA, although that would likely be a lengthy endeavor.

Today, no one in the industry, including those companies selling such oils, refers to commercially available *Schizochytrium* oils containing significant levels of both EPA and DHA as a “DHA oil.” Furthermore, EPA-containing oils cannot always be labeled or used in the same way as DHA oils.



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

Take for example the below reference in the EU novel food legislation, which clarifies the labeling recommendations for a *Schizochytrium* oil rich in EPA/DHA versus a *Schizochytrium* oil rich in DHA and note the difference in the conditions of use for food supplements. If the market and the authorities are not looking at these in the same way, then having DHA-rich and EPA/DHA-rich *Schizochytrium* oils in the same monograph may cause confusion (at best) and non-compliance (at worst). Renaming the monograph to reflect this reality may be a good option.

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements
<i>Schizochytrium sp.</i> oil rich in DHA and EPA	<i>Specified food category</i>	<i>Maximum levels of DHA and EPA combined:</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'DHA and EPA-rich oil from the microalgae <i>Schizochytrium sp.</i> '
	Food Supplements as defined in Directive 2002/46/EC for adult population excluding pregnant and lactating women	3 000 mg/day	

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Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements
<i>Schizochytrium sp.</i> oil	<i>Specified food category</i>	<i>Maximum levels of DHA</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'Oil from the microalgae <i>Schizochytrium sp.</i> '
	Dairy products except milk-based drinks	200 mg/100 g or for cheese products 600 mg/100 g	
	Dairy analogues except drinks	200 mg/100 g or for analogues to cheese products 600 mg/100 g	
	Spreadable fat and dressings	600 mg/100 g	
	Breakfast cereals	500 mg/100 g	
	Food Supplements as defined in Directive 2002/46/EC	250 mg DHA/day for general population	
	450 mg DHA/day for pregnant and lactating women		

If this suggestion is followed, the Description section should also provide a description of EPA, and state "Function: Source of DHA and EPA."

2. Description

- a. GOED recommends widening the scope of extraction methods employed to obtain the oil from the *Schizochytrium* culture. In addition to extraction using organic solvents, companies



GLOBAL ORGANIZATION FOR EPA AND DHA OMEGA-3S

today also employ water-based extraction methods to rupture the algal cell wall, *e.g.* using hydrolytic enzymes, without the use of organic solvents. We suggest changing the sentence, “It is obtained from fermentation of the species of microalgae *Schizochytrium sp.*, usually by solvent extraction” to “It is obtained from fermentation of the species of microalgae *Schizochytrium sp.*, by solvent extraction or aqueous extraction methods.”

- b. Alkali refining is also employed today for the refining of *Schizochytrium* oil. We suggest changing the sentence, “The oil may be winterized, bleached, and deodorized to substantially remove...” to “The oil may be alkali refined, winterized, bleached and deodorized to substantially remove....”

3. Impurities - Arsenic

In chapter “Impurities – Arsenic”, page 3/9, it is understood that the method determines the impurity “arsenic.” However, it is not clear if the method specifies “inorganic arsenic” or “total arsenic” with an acceptance criterion of NMT 0.1 mg/kg. This is important since regulations around the world, as well as applicable methods, apply to either the total or the inorganic forms of arsenic. The method provided in this draft appears to be for the measurement of “total arsenic” given the described digestion conditions. USP may want to consider renaming this section to “Inorganic impurities – Total arsenic.” It is understood that the organic forms of arsenic contribute to the “total arsenic” pool of this impurity and are not of inorganic nature, but for the sake of document clarity at least the scope of the method should be precise.

4. Impurities – Lead

In chapter “Impurities – Lead,” page 5/9, the acceptance criterion is NMT 0.1 mg/kg. GOED suggests that USP aligns this criterion with updated international standards that are stricter. For edible oils, the WHO/FAO Codex Alimentarius Commission’s General Standard for Contaminants in Food and Feed¹ specifies a maximum limit of 0.08 mg/kg in edible fats and oils.

We hope that USP FCC views our comments as constructive.

Thank you for your consideration,

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¹ http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B193-1995%252FCXS_193e.pdf