RE: Euphausia superba oil draft CG [SEC=UNCLASSIFIED]

Bogdan Sikorski to: [redacted] 04/02/2010 12:39 PM

Cc: Jennifer Burnett, Michael Carland

Hi [redacted]

I am pleased to inform you that we have reached a decision which I believe will please not just you and your manufacturer but also other potential suppliers of similar krill oils in the market.
Please see the draft version of the "final" CG for Krill oil extracted with solvents. We envisage that any new material not obtained by solvent extraction must be controlled by a separate CG.
Please provide any comments you may have to Michael Carland as we would like to finalise this as soon as possible.
regards

Krill oil_final.doc

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Department of Health and Ageing
Therapeutic Goods Administration

Compositional Guideline for *Euphausia superba* oil

Name of the ingredient

Euphausia superba oil

Definition of the ingredient

The above named substance is a solvent-extracted oil derived solely from *Euphausia superba* (Antarctic Krill), harvested from the Atlantic section of the Austral-Antarctic Circumpolar Ocean. The oil is obtained through crushing the krill biomass (without or with heating up to 90°C) and isolating the lipid fraction using a BP-compliant solvent.

Table 1. Ingredient specific requirements

Test	Method reference	Acceptance criteria
Description		
Appearance	Visual	Reddish opaque oil
Odour	Olfactory	Light shrimp odour
Viscosity	Brookfield 021, 1.5 rpm, 25°C	400 - 5000 cP
Peroxide value	A.O.A.C.965.33	≤2 mEq peroxide/kg
p-anisidine	A.O.C.S. Cd 18-90	<20 g^{-1}
Saponification value	A.O.A.C.920.160	<19.5 g KOH/100g
Iodine value	A.O.C.S. Ja 14-91	100.0-165.0 I_2/100g
Identification		
Chromatographic fingerprint	A.O.A.C.996.06	complies
Total phospholipids	A.O.C.S. Ja7-86	28.0 - 50.0% w/w
Assay		
Total phospholipids	A.O.C.S. Ja7-86	40.0 - 50.0 g/100g
Total lipids as fatty acids	A.O.A.C.996.06	73.0 - 93.0 g/100g
Omega-3 fatty acids	A.O.A.C.991.39, 963.22, 996.06	12.0 - 41.0 g/100g
EPA	A.O.A.C.991.39, 963.22, 996.06	7.0 - 19.0 g/100g
DHA	A.O.A.C.991.39, 963.22, 996.06	3.0 - 16.0 g/100g
DPA	A.O.A.C.991.39, 963.22, 996.06	0.2 - 0.7 g/100g
Omega-6 fatty acids	A.O.A.C.991.39, 963.22, 996.06	0.5 - 5.0 g/100g
Linoleic acid	A.O.A.C.991.39, 963.22, 996.06	0.1 - 5.0 g/100g
Omega-9 fatty acids	A.O.A.C.991.39, 963.22, 996.06	<13.0 g/100g
Oleic acid	A.O.A.C.991.39, 963.22, 996.06	<13.0 g/100g

Test	Method reference	Acceptance criteria
Saturated fatty acids	A.O.A.C.996.06	19.0 - 30.0 g/100g
Monounsaturated fatty acids	A.O.A.C.996.06	12.0 - 28.0 g/100g
Polyunsaturated fatty acids	A.O.A.C.996.06	13.0 - 44.0 g/100g
Total *Trans* fat	A.O.A.C.996.06	≤0.2 g/100g
Astaxanthin	Spectrophotometry	<150 mg/100g
Esterified astaxanthin	HPLC	<190.0 mg/100g
Moisture	A.O.A.C.984.20	0.1 - 1.5 g/100g
Vitamin A	J. Sci. Agri. Vol 29 p697-702	0 - 15 mg/100 g
alpha-tocopherol	J. Sci. Agri. Vol 29 p697-702	16 - 100mg/100 g

Table 2. Incidental constituents

Test	Method reference	Acceptance criteria
Solvent residues		
Total solvent residues included in *BP*	*BP* (Vol IV, Appendix VIII L, Residual solvents; *Ph. Eur.* method 2.4.24)	complies
Incidental metals and non-metals		
Arsenic (inorganic)	Hydride Generation Atomic Absorption Spectrometry	<0.1 ppm
Cadmium	A.O.A.C.986.15, 971.21, 999.11	<0.1 ppm
Mercury	A.O.A.C.986.15, 971.21, 999.11	<0.1 ppm
Lead	A.O.A.C.986.15, 971.21, 999.11	<0.1 ppm
Copper	ICP	<10 ppm
Tin	ICP	<10 ppm
Antimony	ICP	<1 ppm
Microbiology	The Therapeutic Goods Order No. 77 'Microbiological Standards for Medicines' mandates that any finished product which contains the ingredient, alone or in combination, must comply with the microbial acceptance criteria set by Clause 9 of the Order.	

Key to abbreviations:

A.O.A.C. = Association of Analytical Communities; A.O.C.S. = American Oil Chemists' Society.

BP = British Pharmacopoeia (currently promulgated edition); Ph. Eur = European Pharmacopoeia

HPLC = high-pressure liquid chromatography; ICP = Inductively-coupled plasma (optical emission spectrometry)

ppm = parts per million (equivalent to: mg/kg)

EPA = Eicosapentaenoic acid; DHA = Docosahexaenoic acid; DPA = Docosapentaenoic acid