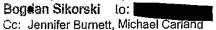


### RE: Euphausia superba oil draft CG [SEC=UNCLASSIFIED]

Bogelan Sikorski lo:



04/02/2010 12:39 PM



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 coe

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tel: (02) 6232 8001 fax: (02) 6203 1001

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## Australian Government

## Department of Health and Ageing Therapeutic Goods Administration

# Compositional Guideline for Euphausia superba oil

### Name of the ingredient

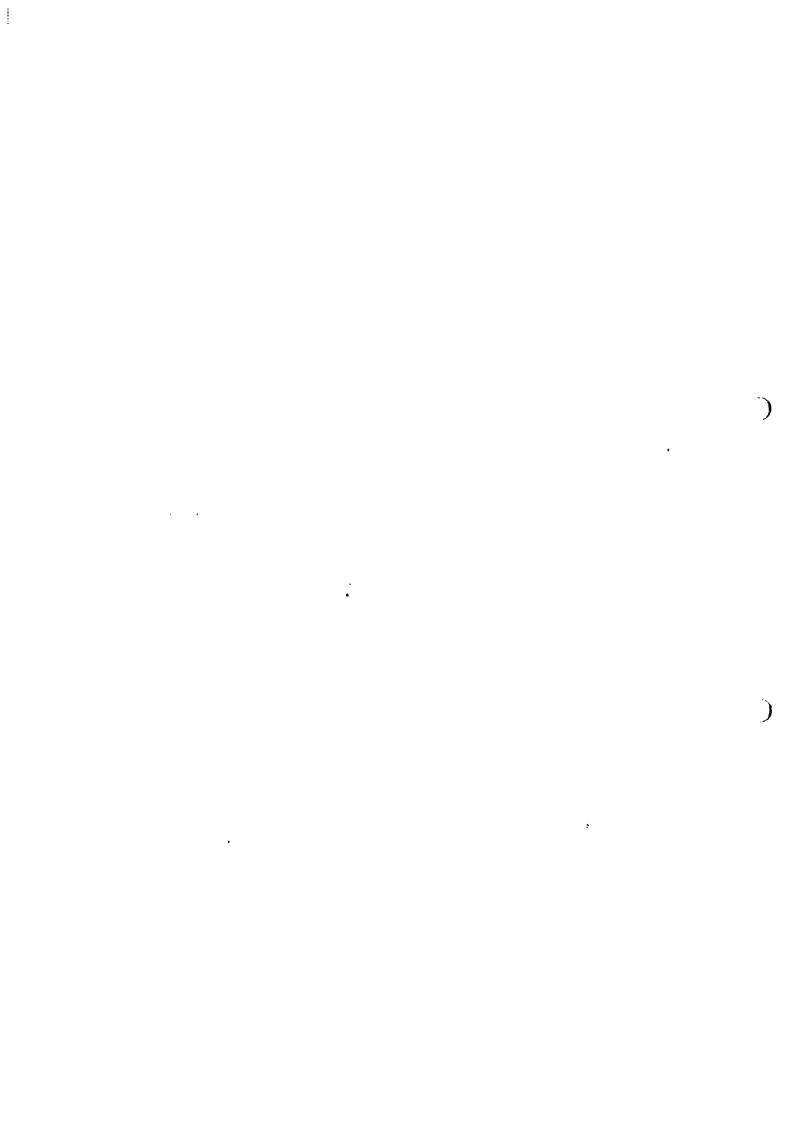
Euphausia superba oil

#### 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	
<i>p</i> -anisidine	A.O.C.S. Cd·18-90	<20 g <sup>-1</sup>	
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 <sub>2</sub> /100g	
Identification			
Chromatographic fmgerprint	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

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