

**ANNEXURE I**

**Allowable levels and claims: Fats, Oils and Fatty Acids**

**Note:** Any claims provided may be used with any of the stipulated dosage ranges.

**Minimum:** Minimum Daily Levels Required for use of Health Supplement Claim

**Maximum:** Maximum Daily Levels Permitted as Health Supplement

**SSF:** Single substance formulation

**MSF:** Multiple substance formulation

Unless otherwise stated the dosage form is oral.

**Action:** Source of essential fatty acids.

**General Statements:**

*All Products:*

Store in airtight container, protected from light.

Do not exceed daily dosage level without consulting a registered healthcare practitioner.

Consult a registered health care practitioner for use beyond 6 months.

**Warnings (as appropriate):**

May contain traces of nut products.

Derived from nuts / shellfish / seafood.

**Duration of Use:**

If more than one duration of use statement is indicated for a particular product formulation, only the shortest applicable duration of use statement is permitted on the labelling.

**Dosage forms by age group:**

- **Children 2 years:** The acceptable dosage forms are limited to emulsion/suspension and solution/drops.

## **Registration of Medicines**

## **Health Supplements**

- **Children 3-5 years:** The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/drops.
- **Children 6-12 years, Adolescents 13-17 years, and Adults  $\geq$  18 years:** The acceptable dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.

## **Combination rules and restrictions**

All medicinal ingredients included in this Annexure may be combined with the following restrictions:

- The combined maximum daily dose of oils in a product must not exceed 15,0 g per day.
- Maximum daily doses for individual medicinal ingredient as per the listings apply.
- The combined maximum daily dose of EPA+DHA+DPA in a single product must not exceed 5,0 g per day.
- Maximum daily doses of EPA+DHA+DPA for *Schizochytrium* Oil apply.
- Maximum daily doses of EPA+DHA+DPA for Krill oil, Fish Oil, and Seal Oil apply.
- Maximum daily doses of EPA+DHA, Vitamin A and Vitamin D for Cod liver oil apply.

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>1. Plant Oils regarded as Health Supplements</b>					
Argania spinosa kernel oil <i>Lipofructyl argan</i> Argan Seed Oil	Source of antioxidant(s)/Provides antioxidant(s).  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>		Restrictions on manufacturing: The concentration must be no more than 5 % in the product.	See claim.	
Blackcurrant seed oil <i>Blackcurrant esters</i> <i>Ribes nigrum esters</i> <i>Ribes nigrum</i> (Parts: Seed)	<i>Dependent on required Fatty Acid Constituents.</i>  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>	If you are pregnant or breastfeeding, consult a health care practitioner prior to use.  Refrigerate after opening.		See claim.	10,5 g
Borage Oil <i>Borago officinalis L.</i> ( <i>Boraginaceae</i> ) (Parts: Seed)	Source of essential fatty acids for the maintenance of good health  Source of omega-6 fatty acids for the maintenance of good health  Source of linoleic acid (LA) for the maintenance of good health.		Permitted only if the preparation is fixed oil derived from the seed.  Oil must be demonstrated to be free of pyrrolizidine alkaloids (PA).	<b>Oil Fixed</b>	
				3,7 g	5,0 g
				<b>Oil Fixed Standardised</b>	
				3,7 g 23 % LA 18 % GLA 0,2 % ALA	5,0 g 37 % LA 27 % GLA 10 % ALA
Coconut Oil <i>Cocos nucifera oil</i> Copra oil Unhydrogenated coconut oil Coconut oil - fractionated Copra oil, fractionated Coconut oil - hydrogenated Copra oil, hydrogenated Medium chain triglycerides (Parts: Seed endosperm)	Provides/source of antioxidants.  Assists in the maintenance of skin health when applied topically.			See claim.	15 g
Echium oil <i>Echium plantagineum oil</i>	<u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>		Must be derived only from <i>Echium vulgare</i> seed.	See claim.	Must not contain

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum						
<b>1. Plant Oils regarded as Health Supplements</b>											
<i>Echium vulgare</i> seed oil <b>Source Material(s):</b> <i>Echium plantagineum</i> (Parts: Seed )	<u>MSF: See 3.2.2 of Guideline 7.04.</u>				more than 1 mg of the equivalent dry material.						
<b>Evening Primrose Oil</b> <i>Oenothera (species) seed oil fixed</i> <i>Oenothera biennis</i> (Parts: Seed )	Source of essential fatty acids for the maintenance of good health. Source of omega-6 fatty acids for the maintenance of good health. Source of linoleic acid for the maintenance of good health.		Must contain the following fatty acids in the stipulated ranges: <ul style="list-style-type: none"> <li>• 7 to 14 % gamma-Linolenic acid</li> <li>• 65 to 85 % Linoleic acid</li> </ul> Vitamin E is an optional medicinal ingredient in evening primrose oil products. See also Vitamin E in the Vitamin Annexures.	1 300 mg	6 000 mg						
<b>False flax oil</b> <i>Big-seed false flax</i> <i>False flax</i> <i>Myragrum sativum</i> <i>Camelina sativa</i> (Parts: Seed)	<u>Dependent on required Fatty Acid Constituents.</u>  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>	Refrigerate after opening.		See claim.	15 g						
<b>Flaxseed Oil</b> <i>Linseed oil</i> <i>Linum usitatissimum seed oil (Linaceae) – seed</i>	<b>Group 1:</b> Source of essential fatty acids for the maintenance of good health.  Source of omega-3 fatty acids for the maintenance of good health.  Source of alpha-linolenic acid (ALA) for the	Refrigerate after opening.	Doses indicated relate to seed oil.	<u>Group 1 Claim:</u> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;"><b>2 to 4 years:</b> 0,04 g / 0,17 ml</td> <td style="width: 50%;"><b>2 to 4 years:</b> 5,33 g / 5,67 ml</td> </tr> <tr> <td><b>5 to 9 years:</b> 0,06 g / 0,25 ml</td> <td><b>5 to 9 years:</b> 8 g / 8,5 ml</td> </tr> <tr> <td><b>10 to 14</b></td> <td><b>10 to 14</b></td> </tr> </table>		<b>2 to 4 years:</b> 0,04 g / 0,17 ml	<b>2 to 4 years:</b> 5,33 g / 5,67 ml	<b>5 to 9 years:</b> 0,06 g / 0,25 ml	<b>5 to 9 years:</b> 8 g / 8,5 ml	<b>10 to 14</b>	<b>10 to 14</b>
<b>2 to 4 years:</b> 0,04 g / 0,17 ml	<b>2 to 4 years:</b> 5,33 g / 5,67 ml										
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<b>10 to 14</b>	<b>10 to 14</b>										

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>1. Plant Oils regarded as Health Supplements</b>					
	maintenance of good health.  <b>Group 2:</b> Source of omega-6 fatty acids for the maintenance of good health.  Source of linoleic acid (LA) for the maintenance of good health.			<b>years:</b> 0,12 g / 0,5 ml <b>15 and over:</b> 0,23 g / 1 ml <i>Group 2 Claim:</i> <b>2 to 4 years:</b> 1,28 g / 1,33 ml <b>5 to 9 years:</b> 1,93 g / 2 ml <b>10 to 14 years:</b> 3,85 g / 4 ml <b>15 and over:</b> 7,7 g / 8 ml	<b>years:</b> 16 g / 17 ml <b>15 and over:</b> 32 g / 34 ml <b>2 to 4 years:</b> 5,33 g / 5,67 ml <b>5 to 9 years:</b> 8 g / 8,5 ml <b>10 to 14 years:</b> 16 g / 17 ml <b>15 and over:</b> 32 g / 34 ml
Hemp Seed Oil <i>Cannabis sativa Seed Oil</i> (Parts: Seed)		If you are pregnant or breastfeeding, consult a health care practitioner prior to use.  Refrigerate after opening.	Processed product made from cannabis seeds containing not more than: a. 10 mg/kg (0,001 %) of tetrahydrocannabinol and does not contain whole cannabis seeds; and b. 50 mg/kg of total cannabinoids.	See claim.	15 g
Pumpkin Seed Oil <i>Pumpkin seed oil</i> <i>Cucurbita pepo seed oil</i> (Parts: Seed)	Source of antioxidant(s)/Provides antioxidant(s).  Contributes to prostate gland health.  Source of phytosterols.  Dependent on required Fatty Acid Constituents.		Only <i>Cucurbita pepo</i> seed oil fixed is permitted.	See claim.	15 g

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>1. Plant Oils regarded as Health Supplements</b>					
	<p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>  <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>				
<p>Safflower Oil  <i>Carthamus tinctorius oil</i>                      (Parts: Seed)</p>	<p>Dependent on required Fatty Acid Constituents.</p> <p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>  <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>			See claim.	15 g
<p>Sea buckthorn oil (omega-7)  <i>Hippophae rhamnoides var. procera</i>  <ul style="list-style-type: none"> <li>• Sallowthorn</li> <li>• Sea buckthorn</li> <li>• Sea-buckthorn</li> <li>• Shaji</li> </ul>                     (Parts:Seed)</p>	<p>Dependent on required Fatty Acid Constituents.</p> <p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>  <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>	<p>If you are pregnant or breastfeeding, consult a health care practitioner prior to use.</p> <p>Refrigerate after opening.</p>		See claim.	5 g
<p>Wheat Germ Oil  <i>Oil of wheat germ</i>  <i>Triticum aestivum seed (grain) embryo (germ) oil fixed</i>  <i>Wheat oils</i>                      (Parts: Seed germ )</p>	<p>Source of antioxidant(s)/Provides antioxidant(s).</p> <p>Dependent on required Fatty Acid Constituents.</p> <p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>  <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>		<p>Wheat germ glycerides to be used as excipient:                      Gluten is a mandatory component of this ingredient when the route of administration is other than topical and mucosal.</p>	See claim.	15 g

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum																				
<b>2. Fish Oils regarded as Health Supplements</b>																									
<p>Cod Liver Oil <i>Oleum morrhuae</i> <i>Lecoris Aselli Oleum</i> <b>Source:</b> <i>Liver of Atlantic cod, Gadus morhua L. (Gadidae)</i> <i>Liver of Greenland cod, Gadus ogac</i> <i>Liver of Pacific cod, Gadus macrocephalus Tilesius (Gadidae)</i> <i>Liver from Arctic cod, Arctogadus glacialis</i> <i>Liver from all species of Gadidae (Cod family)</i> (Parts: Liver)</p>	<p>Helps to support cognitive health and/or brain function</p> <p><b>For products providing daily doses of vitamin A at or above the RDA or AI (adjusted for the life stage groups):</b> Source of vitamin A, a factor in the maintenance of good health.</p> <p><b>For products providing daily doses of vitamin D at or above the RDA or AI (adjusted for the life stage groups):</b> Source of vitamin D, a factor in the maintenance of good health.</p> <p><b>For products providing 138 to 1 500 µg retinol activity equivalents (RAE) (µg vitamin A/all-trans retinol (palmitate)), per day:</b> Helps to maintain eyesight, skin membranes and immune function. Helps in the development and maintenance of night vision. Source of vitamin A, a factor in the maintenance of good health.</p> <p><b>For products providing 1,15 to 25 µg vitamin D3 (cholecalciferol), per day:</b> Helps in the development and maintenance of bones and teeth. Helps in the absorption and use of calcium and phosphorus. Source of vitamin D, a factor in the maintenance of</p>	<p>Refrigerate after opening.</p>	<p>If vitamin A is claimed as a component then the ingredient must conform to the BP monograph for cod-liver oil.</p>	<p>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p> <table border="1" data-bbox="1753 564 2114 943"> <tr> <td data-bbox="1753 564 1935 600"><b>0 to 3 years</b></td> <td data-bbox="1935 564 2114 600"><b>0 to 3 years</b></td> </tr> <tr> <td data-bbox="1753 600 1935 635">0,83 ml / 0,77 g</td> <td data-bbox="1935 600 2114 635">0,87 ml / 0,80 g</td> </tr> <tr> <td data-bbox="1753 635 1935 670"><b>4 to 8 years</b></td> <td data-bbox="1935 635 2114 670"><b>4 to 8 years</b></td> </tr> <tr> <td data-bbox="1753 670 1935 705">0,83 ml / 0,77 g</td> <td data-bbox="1935 670 2114 705">1,3 ml / 1,2 g</td> </tr> <tr> <td data-bbox="1753 705 1935 740"><b>9 to 13 years</b></td> <td data-bbox="1935 705 2114 740"><b>9 to 13 years</b></td> </tr> <tr> <td data-bbox="1753 740 1935 775">0,83 ml / 0,77 g</td> <td data-bbox="1935 740 2114 775">2,4 ml / 2,2 g</td> </tr> <tr> <td data-bbox="1753 775 1935 810"><b>14 to 18 years</b></td> <td data-bbox="1935 775 2114 810"><b>14 to 18 years</b></td> </tr> <tr> <td data-bbox="1753 810 1935 845">0,83 ml / 0,77 g</td> <td data-bbox="1935 810 2114 845">4,0 ml / 3,7 g</td> </tr> <tr> <td data-bbox="1753 845 1935 880"><b>&gt; 18 years</b></td> <td data-bbox="1935 845 2114 880"><b>&gt; 18 years</b></td> </tr> <tr> <td data-bbox="1753 880 1935 916">0,83 ml / 0,77 g</td> <td data-bbox="1935 880 2114 916">4,3 ml / 4,0 g</td> </tr> </table>		<b>0 to 3 years</b>	<b>0 to 3 years</b>	0,83 ml / 0,77 g	0,87 ml / 0,80 g	<b>4 to 8 years</b>	<b>4 to 8 years</b>	0,83 ml / 0,77 g	1,3 ml / 1,2 g	<b>9 to 13 years</b>	<b>9 to 13 years</b>	0,83 ml / 0,77 g	2,4 ml / 2,2 g	<b>14 to 18 years</b>	<b>14 to 18 years</b>	0,83 ml / 0,77 g	4,0 ml / 3,7 g	<b>&gt; 18 years</b>	<b>&gt; 18 years</b>	0,83 ml / 0,77 g	4,3 ml / 4,0 g
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Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>2. Fish Oils regarded as Health Supplements</b>					
	<p>good health.</p> <p><b>For products providing 100 to 1 360 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA), per day:</b></p> <p>Source of omega-3 fatty acids for the maintenance of good health.</p> <p>Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health.</p> <p><b>For products providing 100 to 1 360 mg EPA + DHA including at least 100 mg DHA, per day:</b></p> <p>Helps support cognitive health and/or brain function.</p> <p><b>For products providing 150 to 1 360 mg EPA + DHA including at least 150 mg DHA, per day + DHA:</b></p> <p>Helps support the development of the brain, eyes and nerves in children up to 12 years of age.</p>				
<p>Fish oil</p> <p><i>Ammodytidae - Whole</i> <i>Carangidae - Whole</i> <i>Clupeidae - Whole</i> <i>Engraulidae - Whole</i> <i>Osmeridae - Whole</i> <i>Salmonidae - Whole</i> <i>Scombridae - Whole</i></p> <p><b>Note:</b> The above corresponds to oil from the body of one or more of the stated species in its natural</p>	<p><b>For products providing 100 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, per day:</b></p> <p>Source of omega-3 fatty acids for the maintenance of good health.</p> <p>Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health.</p> <p><b>For products providing 200 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid</b></p>	<p>Active: Concentrated omega-3 triglycerides-fish (only for oral use).</p> <p>Refrigerate after opening.</p>	<p>Concentrated fish oil (ethyl esters): Icosapent (all-Z)-5,8,11,14,17-Eicosapentaenoic acid Eicosapentaenoic acid EPA Fish oil fatty acid Icosapentaenoic acid Timnodonic acid</p>	<p>Oil fixed standardised</p>	<p>100 mg</p> <p>3 000 mg</p> <p>of Eicosapentaenoic acid + Docosahexaenoic acid per day</p>

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>2. Fish Oils regarded as Health Supplements</b>					
<p><i>triglyceride/triacylglycerol form and/or its concentrated esterified form.</i></p>	<p><b>and containing a ratio of Eicosapentaenoic acid: Docosahexaenoic acid between 0,5:1 and 2:1, per day:</b> Helps maintain/support cardiovascular health</p> <p><b>For products providing 1 000 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid and containing a ratio of Eicosapentaenoic acid: Docosahexaenoic acid between 0,5:1 and 2:1, per day:</b> Helps to reduce serum triglycerides/triacylglycerols</p> <p><b>For products providing 2 800 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid and containing a ratio of Eicosapentaenoic acid: Docosahexaenoic acid between 0,5:1 and 2:1, per day:</b> In conjunction with conventional therapy, helps to reduce the pain of rheumatoid arthritis in adults</p> <p><b>For products providing 100 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, including at least 100 mg Docosahexaenoic acid, per day:</b> Helps support cognitive health and/or brain function</p> <p><b>For products providing 150 to 2 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, including at least 150 mg Docosahexaenoic acid, per day:</b> Helps support the development of the brain, eyes and nerves in children up to 12 years of age</p>		<p>Consult a healthcare practitioner before use if you have a sensitivity to aspirin or high blood pressure.</p> <p><u>Oxidative stability parameter</u> <i>Maximum value</i> Peroxide value (PV) 5 mEq/kg p-Anisidine value (AV) 20 mEq/kg Totox value 26 mEq/kg (calculated as (2 x PV) + AV)</p> <p><u>Dioxin and dioxin-like polychlorinated biphenyl contaminants</u> <i>Maximum level</i> Sum of PCDDs + PCDFs 2,0 pg TEQ TEF/g oil</p> <p>p-Sum of dioxins and dioxin-like PCBs 10,0 pg TEQ TEF/g oil</p>		

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>2. Fish Oils regarded as Health Supplements</b>					
	<p>For products providing 1 500 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid and containing a ratio of Eicosapentaenoic acid: Docosahexaenoic acid between 1.75:1 and 2:1, including at least 1 000 mg Eicosapentaenoic acid, per day:</p> <p>Helps to promote healthy mood balance</p>				
Fish Liver Oil	<p><i>See also Cod Liver Oil.</i></p> <p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u></p> <p><u>MSF: See 3.2.2 of Guideline 7.04.</u></p>	<p>The potencies of vitamin A, vitamin D and/or EPA+DHA, in addition to the dose of Fish liver oil, must be indicated on the product application and label.</p>	<p>The peroxide, anisidine, and totox values, as well as the dioxin, polychlorinated dibenzo-para-dioxin (PCDD) and polychlorinated dibenzofuran (PCDF), the dioxin-like polychlorinated biphenyl (DL PCB), and the polychlorinated biphenyl (PCB) contaminants of fish liver oil and omega-3 fatty acids derived from fish liver oil must be in accordance with the Cod Liver Oil entry.</p>	<p>If health claims are made for vitamin A or colestiferol (vitamin D), refer to the restrictions for vitamin A or colestiferol.</p> <p>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p>	
<p>Halibut Liver Oil</p> <p><i>Hippoglossus hippoglossus</i></p> <p><i>Atlantic halibut</i></p>	<p><i>See Fish Liver Oil / Cod Liver Oil.</i></p>			<p>If health claims are made for vitamin A or colestiferol (vitamin D), refer to the restrictions for vitamin A or colestiferol.</p> <p>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p>	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>2. Fish Oils regarded as Health Supplements</b>					
<b>Krill oil</b> <i>Euphausia pacifica</i> (north pacific krill) (Parts: Whole) <i>Euphausia superba oil</i> (Antartica krill) <i>Euphausia superba</i> (Parts: Whole)	Source of omega-3 fatty acids for the maintenance of good health.  Source of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health.	Contains crustacean shellfish. [OR] Derived from seafood.  Hypersensitivity/allergy has been known to occur (with shellfish); if this occurs, discontinue.  If you are pregnant or breastfeeding, consult a registered health care practitioner prior to use.  Refrigerate after opening.		-	4,1 g
<b>Pollack-liver oil</b> <i>Theragra chalcogramma</i> Alaska pollock Pacific pollock wall-eye pollock whiting (Parts: Whole)	<i>See Fish Oil.</i>	Derived from seafood.		If health claims are made for vitamin A or coealcalciferol (vitamin D), refer to the restrictions for vitamin A or coealcalciferol.  Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.	
<b>Salmon Oil</b> <i>Oncorhynchus gobuscha</i> <i>Oncorhynchus nerka</i> <i>Oncorhynchus tshawytscha</i> <i>Salmo salar</i>	<i>See Fish Oil.</i>			<i>See Fish Oil.</i>	
<b>Squid oil</b> <i>Todarodes pacificus</i> - whole <i>Docidicus gigas</i> - whole <i>Illex argentinus</i> - whole	<i>Dependent on required Fatty Acid Constituents.</i>	Derived from seafood.  If you are pregnant or	Must be derived only from species of the order Teuthida of the class Cephalopoda AND	See claim.	5 g

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>2. Fish Oils regarded as Health Supplements</b>					
<i>Illex illecebrosus</i> - whole	<p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u></p> <p><u>MSF: See 3.2.2 of Guideline 7.04.</u></p>	<p>breastfeeding, consult a health care practitioner prior to use.</p> <p>Hypersensitivity/allergy has been known to occur (with shellfish); if this occurs, discontinue use.</p> <p>Refrigerate after opening.</p>	<p>be in combination with other ingredients in the product.</p>		
Tuna fish oil/Skipjack liver oil	<p><i>See also Fish Oil.</i></p> <p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u></p> <p><u>MSF: See 3.2.2 of Guideline 7.04.</u></p>		<p>The ingredient must conform to the BP monograph for fish oils.</p>		<p>If health claims are made for vitamin A or coledalciferol (vitamin D), refer to the restrictions for vitamin A or coledalciferol. Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p>

Fat / Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>3. Other Fats or Oils regarded as Health Supplements</b>					
<p><b>Algal oil</b>  <i>DHA/EPA rich Schizochytrium algal oil</i>  <i>docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) rich oil derived from microalgae Schizochytrium sp.</i>                      Genus Species:  <i>Cryptocodinium cohnii</i>  <i>Nannochloropsis oculata</i>  <i>Schizochytrium spp.</i>                      (Parts: Whole)</p>	<p>Helps to support cognitive health and/or brain function.</p>	<p>Refrigerate after opening.</p>	<p><b>For DHA/EPA rich Schizochytrium algal oil:</b>                      Permitted only in products for oral use.                       The ratio of DHA to EPA must be 2:1, and must be present in combination with other ingredients.</p>	<p>A quantity of oil providing no less than 200 mg DHA/day</p>	<p>A quantity of oil providing no less than 2 000 mg DHA/day.</p>
<p><b>Emu oil</b>  <i>Dromiceius oil</i>  <i>Dromaius novaehollandiae</i>                      (Parts: Fat)</p>	<p>A source of polyunsaturated and monounsaturated fatty acids.</p>		<p>Must be derived only from <i>Dromaius ovaehollandiae</i>.</p>	<p>See claim.</p>	
<p><b>Lecithin</b>  <i>Lecithin - hydrogenated</i>  <i>Hydrogenated egg yolk phospholipids</i>  <i>Lecithin liquid - soy phosphatidylserine-enriched soy</i>  <i>Lecithin powder - soy phosphatidylserine-enriched soy</i>  <i>Soy phosphatidylserine-enriched soy lecithin liquid</i>  <i>1,2-Diacylglycerol-3-phosphocholine</i>  <b>Sub-ingredients:</b> Choline; Phosphatidic acids, Phosphatidylethanolamin, Phosphatidylinositol  <b>Source Material:</b> Brassica napus (Parts: Seed); Glycine max (Parts: Seed); Helianthus annuus (Parts: Seed); Salmo salar (Parts: Egg)  <b>Source Ingredients:</b> Soya Oil</p>	<p>Helps to support liver function.</p>		<p>The concentration must not exceed 5 % (hydrogenated lecithin)                       The concentration of soy phosphatidylserine must not exceed 15 %.</p>	<p>1 g</p>	<p>6 g</p>
<p><b>Phospholipids</b>                      (including Phosphatidylcholine and Phosphatidylserine)</p>	<p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>  <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>			<p>See claim.</p>	
<p><b>Source Material:</b> Clupea harengus (Parts: Egg); Euphausia superba (Parts: Whole); Helianthus annuus (Parts: Seed); Pandalus borealis (Parts: Internal shell); Squid oil Squid (Parts: Whole)</p>					

Fat / Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum				
<b>3. Other Fats or Oils regarded as Health Supplements</b>									
<p>Phytosterols <i>Phytosterols</i> <i>Plant sterols</i></p>	<p>Plant sterols/stanols contribute to the maintenance of healthy blood cholesterol levels.</p>		<p>In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of at least 0,8 g of plant sterols/stanols.</p>	<p>"Phytosterols" must be standardised to one or more of these specific sub-ingredients in order to support the claim.</p>					
<p><b>Sub-ingredients:</b> Free plant stanols , Plant stanol esters , Plant sterol esters</p>									
<p><b>Source material:</b> <i>Cissus quadrangularis (Parts: Leaf); Cissus quadrangularis (Parts: Stem); Helianthus annuus (Parts: Seed); Oil of vegetable (Parts: Seed); Phleum pratense (Parts: Pollen); Pinus elliottii (Parts: Trunk bark oleogum resin); Pinus taeda (Parts: Trunk bark oleogum resin); Prunus africana (Parts: Stem bark); Prunus africana (Parts: Trunk bark); Secale cereale (Parts: Pollen); Zea mays (Parts: Pollen)</i></p>									
<p>Plant sterols <i>Free plant sterols</i> <i>Phytosterols</i></p>	<p>Helps maintain healthy cholesterol levels.</p>	<p>Consult a health care practitioner prior to use if you are pregnant or breastfeeding</p> <p><b>Directions For Use:</b> With food</p>	<p>This product is not intended for people who do not need to control their blood cholesterol level</p>	<p><b>Adult dose(s):</b></p> <table border="1" data-bbox="1753 756 2114 1018"> <tr> <td data-bbox="1753 756 1935 788">0,74 g</td> <td data-bbox="1935 756 2114 788">3 g</td> </tr> <tr> <td colspan="2" data-bbox="1753 788 2114 1018">including at least 80 % Combined beta-Sitosterol, campesterol and Stigmasterol per day</td> </tr> </table>		0,74 g	3 g	including at least 80 % Combined beta-Sitosterol, campesterol and Stigmasterol per day	
0,74 g	3 g								
including at least 80 % Combined beta-Sitosterol, campesterol and Stigmasterol per day									
<p><b>Source Material:</b> <i>Arachis hypogaea (Whole); Brassica napus (Whole); Glycine max (Seed); Gossypium herbaceum (Seed); Olea europaea (Whole); Secale cereale (Whole); Triticum aestivum (Whole); Zea mays (Whole)</i></p>									
<p><b>Sub-ingredients:</b> beta-Sitosterol , Campesterol , Combined beta-Sitosterol, Campesterol and Stigmasterol , Stigmasterol</p>									
<p>Plant sterol esters</p>	<p>Helps maintain healthy cholesterol levels</p>	<p>Consult a health care practitioner prior to use if you are pregnant or breastfeeding.</p> <p><b>Directions For Use:</b> With food</p>	<p>This product is not intended for people who do not need to control their blood cholesterol level.</p>	<p><b>Adult dose(s):</b></p> <table border="1" data-bbox="1753 1114 2114 1367"> <tr> <td data-bbox="1753 1114 1935 1145">0,8 g</td> <td data-bbox="1935 1114 2114 1145">4,8 g</td> </tr> <tr> <td colspan="2" data-bbox="1753 1145 2114 1367">including at least 80 % Combined beta-Sitosterol, Campesterol and Stigmasterol per day</td> </tr> </table>		0,8 g	4,8 g	including at least 80 % Combined beta-Sitosterol, Campesterol and Stigmasterol per day	
0,8 g	4,8 g								
including at least 80 % Combined beta-Sitosterol, Campesterol and Stigmasterol per day									
<p><b>Source Material:</b> <i>Arachis hypogaea (Whole); Brassica napus (Whole); Glycine max (Seed); Gossypium herbaceum (Seed); Olea europaea (Whole); Secale cereale (Whole); Triticum aestivum (Whole); Zea mays (Whole)</i></p>									

Fat / Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>3. Other Fats or Oils regarded as Health Supplements</b>					
Plant stanol esters	Helps maintain healthy cholesterol levels	Consult a health care practitioner prior to use if you are pregnant or breastfeeding  <b>Directions For Use:</b> With food	This product is not intended for people who do not need to control their blood cholesterol level.	<b>Adult dose(s):</b>	
				1,8 g	5,1 g
				including at least 80 % combined Sitostanol and campestanol per day	
<b>Source Material:</b> <i>Arachis hypogaea (Whole); Brassica napus (Whole); Glycine max (Seed); Gossypium herbaceum (Seed); Olea europaea (Whole); Secale cereale (Whole); Triticum aestivum (Whole); Zea mays (Whole)</i>					

Fatty Acid	Health Supplement Claim	Specified Warning(s)	Other Instructions/Directives	Minimum	Maximum
<p><b>4. Fatty Acid Constituents</b> – To guide recommended use for oils and fats based on FA content; levels if not stated determined by source material otherwise Annex. B submission required.</p>					
<p>Alpha-Linolenic Acid (ALA) <i>Linolenic acid (9Z,12Z,15Z)-9,12,15-octadecatrienoic acid cis,cis,cis-9,12,15-octadecatrienoic acid</i></p>	<p>Source of alpha-linolenic acid (ALA) for the maintenance of good health.</p> <p>Source of omega-3 fatty acid for the maintenance of good health.</p> <p>Source of an essential fatty acid for the maintenance of good health.</p>			80 mg	As for source / Annexure B submission
	<p>ALA contributes to the maintenance of healthy blood cholesterol levels</p>		Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA.	2 g	As for source / Annexure B submission.
<p><b>Source ingredients:</b> <i>Borago officinalis (Parts: Seed); Buglossoides arvensis (Parts: Seed); Cannabis sativa (Parts: Seed); Echium plantagineum (Parts: Seed); Linum usitatissimum (Parts: Seed); Oenothera biennis (Parts: Seed); Perilla frutescens (Parts: Seed); Plukenetia volubilis (Parts: Seed); Ribes nigrum (Parts: Fruit); Rubus idaeus (Parts: Seed); Salvia hispanica (Parts: Seed); Salvia sclarea (Parts: Seed); Vaccinium macrocarpon (Parts: Seed)</i></p>					
<p>Linoleic acid (LA) <i>(Z,Z)-9,12-Octadecadienoic acid 9,12-Linoleic acid alpha-Linoleic acid cis,cis-9,12-Octadecadienoic acid Linolic acid</i></p>	<p>Source of linoleic acid (LA) for the maintenance of good health.</p> <p>Source of omega-6 fatty acid for the maintenance of good health.</p> <p>Source of an essential fatty acid for the maintenance of good health.</p>			850 mg	As for source / Annexure B submission for all.
	<p>Linoleic acid contributes to the maintenance of normal blood cholesterol levels.</p>		The claim may be used only when source provides at least 1,5 g of linoleic acid (LA) per 100 g and per 100 kcal.	Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 10 g of LA.	
	<p>Essential fatty acids are needed for normal growth and development of children.</p>			Information to the consumer that the beneficial effect is obtained with a daily intake of 2 g of -linolenic acid	

Fatty Acid	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<p><b>4. Fatty Acid Constituents</b> – To guide recommended use for oils and fats based on FA content; levels if not stated determined by source material otherwise Annex. B submission required.</p>					
				(ALA) and a daily intake of 10 g of linoleic acid (LA).	
<p><b>Source Material:</b> <i>Borago officinalis</i> (Parts: Seed); <i>Cannabis sativa</i> (Parts: Seed); <i>Carthamus tinctorius</i> (Parts: Seed); <i>Cucurbita pepo</i> (Parts: Seed); <i>Echium plantagineum</i> (Parts: Seed); <i>Helianthus annuus</i> (Parts: Seed); <i>Linum usitatissimum</i> (Parts: Seed); <i>Nigella sativa</i> (Parts: Seed); <i>Oenothera biennis</i> (Parts: Seed); <i>Perilla frutescens</i> (Parts: Seed); <i>Persea Americana</i> (Parts: Fruit); <i>Plukenetia volubilis</i> (Parts: Seed); <i>Ribes nigrum</i> (Parts: Fruit); <i>Rubus idaeus</i> (Parts: Seed); <i>Salvia hispanica</i> (Parts: Seed); <i>Vaccinium macrocarpon</i> (Parts: Seed); <i>Vitis vinifera</i> 'Chardonnay' (Parts: Seed); <i>Vitis vinifera</i> (Parts: Seed)</p>					
ALA + LA	Source of essential fatty acids for the maintenance of good health.			80 mg ALA 850 mg LA	As for source / Annexure B submission.
<p>Alpha-lipoic acid <i>R-alpha lipoic acid</i> (+)-1,2-Dithiolane-3-pentanoic acid <i>1,2-Dithiolane-3-valeric acid</i> <i>Lipoic acid</i> <i>Thioctic acid, d form</i> 2 forms: (±)-1,2-Dithiolane-3-pentanoic acid <i>DL-alpha-Lipoic acid</i> AND (+)-alpha-Lipoic acid <i>R-alpha-Lipoic acid</i></p>	<p>Provides antioxidants for the maintenance of good health</p> <p>Helps to promote healthy glucose metabolism</p>	<p>If you are pregnant or breastfeeding, consult a health care practitioner prior to use.</p> <p>Consumers should discontinue use and consult a healthcare provider if they experience symptoms of low blood sugar such as sweating, paleness, chills, headache, dizziness and/or confusion.</p>	<p>If you have diabetes, consult a health care practitioner prior to use</p>	<p>As for source / Annexure B submission.</p>	<p>600 mg</p>
<p>Arachidonic Acid <i>Arachidonic acid</i> <i>5,8,11,14-Eicosatetraenoic acid</i> <i>Icosa-5,8,11,14-tetraenoic acid</i></p>	<p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u></p> <p><u>MSF: See 3.2.2 of Guideline 7.04.</u></p>		<p>Permitted only in products for external use.</p>	<p>See claim.</p>	
<p>Caprylic Acid <i>Caprylic/capric triglyceride</i> <i>Capric acid, triglyceride</i> <i>Glycerin/caprylic/capric triester</i> <i>Miglyol</i> <i>Octanoic/decanoic acid triglyceride</i> <i>Octanoic acid</i></p> <p><b>Source materials:</b> <i>Cocos nucifera</i> (Parts: Seed endosperm)</p>	<p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u></p> <p><u>MSF: See 3.2.2 of Guideline 7.04.</u></p>		<p>Permitted only in products for external use.</p> <p>The concentration must not exceed 2 %.</p>	<p>See claim.</p>	

Fatty Acid	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<p><b>4. Fatty Acid Constituents</b> – To guide recommended use for oils and fats based on FA content; levels if not stated determined by source material otherwise Annex. B submission required.</p>					
<p><b>Source ingredients:</b> Calcium caprylate; Magnesium caprylate; Zinc caprylate</p>					
<p>Conjugated Linoleic acid (CLA)</p>	<p>May help to support a modest improvement to body composition when used with a program of reduced intake of dietary calories and increased physical activity</p>	<p>Consult a registered health care practitioner prior to use if you are obese or have cardiovascular disease (CVD) risk factors (e.g. high blood pressure, high cholesterol and/or triglycerides)</p> <p>Consult a registered health care practitioner prior to use if you are pregnant or breastfeeding</p> <p>Consult a registered health care practitioner prior to use if your goal is to achieve weight loss.</p>	<p><b>Contraindication(s):</b> Do not use if you have cardiovascular disease, diabetes, metabolic syndrome or insulin resistance.</p> <p><b>Known Adverse Reaction(s):</b> Some people may experience gastrointestinal upset.</p>	<p>3 g</p>	<p>5 g</p>
<p>Dihomo-gamma-linolenic acid <i>all-cis-8,11,14-Eicosatrienoic acid</i> DGLA</p>	<p><u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>			<p>See claim.</p>	
<p>Docosahexaenoic Acid (DHA) <i>(4Z,7Z,10Z,13Z,16Z,19Z)-4,7,10,13,16,19-Docosahexaenoic acid</i> Doconexent</p>	<p>Source of docosahexaenoic acid (DHA) for the maintenance of good health.</p>			<p>In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 100 mg of DHA.</p>	<p>In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained</p>
	<p>DHA contributes to maintenance of normal brain function.</p>		<p>The claim may be used when the source contains at least 40 mg of DHA per 100 g and per 100 kcal.</p>		

Fatty Acid	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>4. Fatty Acid Constituents</b> – To guide recommended use for oils and fats based on FA content; levels if not stated determined by source material otherwise Annex. B submission required.					
	DHA contributes to the maintenance of normal blood triglyceride levels.		The claim may be used only when a daily intake of 2 g of DHA is provided and contains DHA in combination with eicosapentaenoic acid (EPA).	with a daily intake of 250 mg of DHA.	When the claim is used information shall also be given to consumers not to exceed a supplemental daily intake of 5 g of EPA and DHA combined.
	DHA contributes to the maintenance of normal vision.		The claim may be used only for sources which contain at least 40 mg of DHA per 100 g and per 100 kcal.		In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 250 mg of DHA.
<p><b>Source Material:</b> Arctocephalus pusillus (Parts: Blubber); Arctogadus glacialis (Parts: Liver); Clupea harengus (Parts: Egg); Clupea harengus (Parts: Fish semen); Cod Liver Oil fish (Parts: Liver); Cryptecodinium cohnii (Parts: Whole); Cystophora cristata (Parts: Blubber); Erignathus barbatus (Parts: Blubber); Euphausia pacifica (Parts: Whole); Euphausia superba (Parts: Whole); fish oil fish (Parts: Whole); Gadus macrocephalus (Parts: Liver); Gadus morhua (Parts: Liver); Gadus ogac (Parts: Liver); Halichoerus grypus (Parts: Blubber); Illex illecebrosus (Parts: Whole); Mytilus edulis (Parts: Whole); Pagophilus groenlandicus (Parts: Blubber); Pandalus borealis (Parts: Internal shell); Pandalus borealis (Parts: Whole); Phoca vitulina (Parts: Blubber); Pusa hispida (Parts: Blubber); Schizochytrium spp. (Parts: Whole) Shark (Parts: Liver); Squid oil Squid (Parts: Whole); Theragra chalcogramma (Parts: Liver); Theragra chalcogramma (Parts: Whole); Thunnus thynnus (Parts: Whole); Ulkenia amoeboidea (Parts: Whole); Ulkenia spp. (Parts: Whole)</p> <p><b>Source Ingredients:</b> Omega-3 acid ethyl ester; Omega-3 Fatty acids</p>					
Docosapentaenoic acid (DPA) <i>(all-Z)-7,10,13,16,19-Docosapentaenoic acid</i> <i>cis-7,10,13,16,19-Docosapentaenoic acid</i>	Source of docosapentaenoic acid (DPA) for the maintenance of good health.			100 mg	As for source / Annexure B submission.
	<u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>				See claim. As per source.
<p><b>Source material:</b> Arctocephalus pusillus (Parts: Blubber); Cystophora cristata (Parts: Blubber); Erignathus barbatus (Parts: Blubber); Halichoerus grypus (Parts: Blubber); Pagophilus groenlandicus (Parts: Blubber); Phoca vitulina (Parts: Blubber); Pusa hispida (Parts: Blubber)</p>					
Eicosapentaenoic Acid (EPA)	Source of eicosapentaenoic acid (EPA) for the maintenance of good health.	Refrigerate after opening.		100 mg	As for source /

Fatty Acid	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>4. Fatty Acid Constituents</b> – To guide recommended use for oils and fats based on FA content; levels if not stated determined by source material otherwise Annex. B submission required.					
Icosapent (ethyl ester) (all-Z)-5,8,11,14,17- Eicosapentaenoic acid Eicosapentaenoic acid EPA Fish oil fatty acid Icosapentaenoic acid Timnodonic acid	<u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u>  <u>MSF: See 3.2.2 of Guideline 7.04.</u>	Consult a healthcare practitioner before use if you have a sensitivity to aspirin or high blood pressure		See claim. As per source.	Annexure B submission.
DHA + DPA + EPA	Source of omega-3 fatty acids for the maintenance of good health.	As for any constituent contained therein.	As for any constituent contained therein.	100 mg of the combination thereof.	As for source / Annexure B submission.
DHA + EPA	Helps support/maintain (normal) heart/ cardiovascular health/function.	As for any constituent contained therein.	As for any constituent contained therein.	250 mg of the combination thereof.	As for source / Annexure B submission.
	Helps to support/maintain normal serum/blood triglyceride/triacylglycerol levels.			2 g of the combination thereof.	As for source / Annexure B submission.
gamma-Linolenic acid (GLA) Gamolenic acid (6Z,9Z,12Z)-6,9,12- Octadecatrienoic acid cis-6,cis-9,cis-12- Octadecatrienoic acid	Source of gamma-linoleic acid.			100 mg	As for source / Annexure B submission.
<b>Source materials:</b> <i>Arthrospira platensis</i> (Parts: Whole); <i>Borago officinalis</i> (Parts: Seed); <i>Carthamus tinctorius</i> (Parts: Seed); <i>Echium plantagineum</i> (Parts: Seed); <i>Oenothera biennis</i> (Parts: Seed); <i>Ribes nigrum</i> (Parts: Seed)					
Oleic acid (OA) (Z)-octadec-9-enoic acid 9-octadecenoic acid butter acids cis-oleic acid	Source of oleic acid.			100 mg	As for source / Annexure B submission.

Fatty Acid	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Minimum	Maximum
<b>4. Fatty Acid Constituents</b> – To guide recommended use for oils and fats based on FA content; levels if not stated determined by source material otherwise Annex. B submission required.					
<i>medium chain fatty acids</i> <i>omega-9 Fatty Acids</i>					
Omega-3 fatty acids without EPA/DHA	For the maintenance of good health.  As per source.  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>			See claim. As per source.	
<i>Arctogadus glacialis (Parts: Liver); Cod Liver Oil fish (Parts: Liver); Gadus macrocephalus (Parts: Liver); Gadus morhua (Parts: Liver); Gadus ogac (Parts: Liver)</i>					
Omega-6 fatty acids	As per source.  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>			See claim. As per source.	
<i>Borago officinalis (Parts: Seed); Buglossoides arvensis (Parts: Seed); Hippophae rhamnoides (Parts: Fruit); Linum usitatissimum (Parts: Seed); Oenothera biennis (Parts: Seed); Persea Americana (Parts: Fruit); Plukenetia volubilis (Parts: Seed); Vitis vinifera (Parts: Seed)</i>					
Omega-7 fatty acids <i>Hippophae rhamnoides</i> (Parts: Fruit)	As per source.  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>			See claim. As per source.	
Omega-9 fatty acids	As per source.  <u>SSF: See 3.2.1 of Guideline 7.04. Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>			See claim. As per source.	
<i>Buglossoides arvensis (Parts: Seed); Hippophae rhamnoides (Parts: Fruit); Persea americana (Parts: Fruit); Vitis vinifera (Parts: Seed)</i>					