

# MEDICINES CONTROL COUNCIL



## COMPLEMENTARY MEDICINES - HEALTH SUPPLEMENTS SAFETY AND EFFICACY

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of Health Supplements. It represents the Medicines Control Council's current thinking on the quality, safety, and efficacy of these medicines. It is not intended as an exclusive approach. Council reserves the right to request any additional information to establish the safety, quality and efficacy of a medicine in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The MCC is committed to ensure that all registered medicines will be of the required quality, safety and efficacy. It is important that applicants also adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar of Medicines and the website [www.mccza.com](http://www.mccza.com).

*This guideline is published in anticipation of the publication of Regulations contemplating the inclusion of Health Supplements as a sub-category of Complementary Medicines. Further Annexures associated but not yet included with this guideline will be published for public comment.*

First publication released for comment	November 2014
Version 2 – deletion of quality aspects for inclusion in separate guideline	June 2016
Version 3 - addition of Annexures G and I for comment	April 2016
Deadline for comment	31 May 2017

Use the Guideline Comments Form<sup>1</sup> available on the MCC website when submitting comments.

Submit comments in hard copy to the Registrar of Medicines, Civitas Building, Thabo Sehume Street, Pretoria. Comments may also be submitted by e-mail to Dr Jeanette Lotter at [Jeanette.Lotter@health.gov.za](mailto:Jeanette.Lotter@health.gov.za)

**DR JC GOUWS**  
**REGISTRAR OF MEDICINES**

<sup>1</sup> 6.13 Guideline Comments Form Dec08 v1.doc

TABLE OF CONTENTS		Page
<b>1</b>	<b>INTRODUCTION</b> .....	<b>3</b>
1.1	Definition.....	4
1.2	Compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Agricultural and Collection Practices (GACP).....	5
1.3	Format of submission.....	5
<b>2</b>	<b>ZA-CTD FORMAT</b> .....	<b>5</b>
2.1	ZA Module 1: Administrative information.....	5
2.2	ZA Module 2: Common Technical Document summaries.....	6
2.3	ZA Module 4: Non-clinical study reports.....	8
2.4	ZA Module 5: Clinical study reports.....	8
<b>3</b>	<b>SAFETY AND EFFICACY REQUIREMENTS</b> .....	<b>9</b>
3.1	General.....	9
3.1.1	Single Substance Formulations.....	9
3.1.2	Multiple Substance Formulations.....	9
3.2	Labelling and Allowable Claims.....	9
3.2.1	Single Substance Formulations.....	10
3.2.2	Multiple Substance Formulation Claim Development.....	10
<b>4</b>	<b>GLOSSARY OF TERMS</b> .....	<b>12</b>
<b>5</b>	<b>UPDATE HISTORY</b> .....	<b>16</b>
<b>ANNEXURE A</b>		<b>17</b>
	Category D Decision Tree.....	17
<b>ANNEXURE B</b>		<b>18</b>
	Motivation for inclusion of Substance as Health Supplement.....	18
<b>ANNEXURE C</b>		<b>19</b>
	Allowable Levels and Claims: Probiotics.....	19
<b>ANNEXURE D</b>		<b>20</b>
	Allowable Levels and Claims: Prebiotics.....	20
<b>ANNEXURE E</b>		<b>21</b>
	Allowable Levels and Claims: Vitamins.....	21
<b>ANNEXURE F</b>		<b>36</b>
	Allowable Levels and Claims: Minerals.....	36

<b>5</b>	<b>UPDATE HISTORY</b> .....	<b>3</b>
<b>ANNEXURE G</b>		<b>4</b>
	Allowable Levels and Claims: Proteins and Amino Acids.....	4
<b>ANNEXURE I</b>		<b>23</b>
	Allowable levels and claims: Fats, Oils and Fatty Acids.....	23

As indicated on the front page, further Annexures to this guideline will be published for public comment.

In the interest of focus only the proposed additional Annexures are included to amend version 2 of the guideline published in June 2016 (*7.04\_SE\_Health\_Supplements\_Jun16\_v2.doc*)

**Sections 1 - 4 are unchanged as in version 2 published June 2016**

**Annexures A - F are unchanged as in version 2 published June 2016**

**Versions G and I are now added:**

### **ANNEXURE G - Allowable Levels and Claims: Proteins and Amino Acids**

In assessing the safety, efficacy and quality of health supplement and preparations the attached Annexure G has been developed to guide the use of proteins and amino acids in Complementary Medicines as Health Supplements.

### **ANNEXURE I - Allowable Levels and Claims: Fats, Oils and Fatty Acids**

In assessing the safety, efficacy and quality of health supplement and preparations the attached Annexure I has been developed to guide the use of fats, oils and fatty acids in Complementary Medicines as Health Supplements.

**Annexures H and J - O** are is still to follow.

## **5 UPDATE HISTORY**

<b>Date</b>	<b>Reason for update</b>	<b>Version &amp; publication</b>
Nov 2014	First publication released for comment	v1 Nov 2013
26 Feb 2015	Deadline for comment	
June 2016	Deletion of section 2 "Quality Requirements" for inclusion in separate guideline Inclusion of new section 2 ZA-CTD format Amendments to 1 i), 1.1, 1.2, 3.1, 3.2, 3.2.1, 4, Annexure E	v2 June 2016
Feb 2017	Inclusion of Annexures G and I	
31 May 2017	Deadline for comment	v3 April 2017

## ANNEXURE G

## Allowable Levels and Claims: Proteins and Amino 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

**1 PROTEINS**

With respect to **sources of proteins**, should no indication or claim be made or inferred by the product then the product may be supplied with claims that are in compliance with legislation pertaining to Foodstuffs.

**General Statements****Pharmacological Action:**

Proteins are constituents of living cells essential for growth and repair of tissues.

**Warnings:**

*For products containing over 30 g per day total protein and/or amino acids (including  $\beta$ -alanine):*

If you have liver or kidney disease, consult a health care provider prior to use.

*Products for increasing exercise performance (including any indication associated herewith):*

Not suitable for children under the age of 18.

*All other products:*

Use in children under the guidance of a registered healthcare provider.

**Dosage and directions for use:**

*Products in powder form:*

Mix product well in 1-2 cups of liquid (water, juice, etc.) immediately before consumption.

*Products for increasing exercise performance (optional):*

Consume 45-90 minutes before exercising.

*Products for repairing body tissues/muscles and restoring plasma glutamine levels (optional):*

Consume no later than 90 minutes after exercising.

Protein	Source Material	Health Supplement Claim (Single and Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Acid casein	Extract - Bos taurus - milk	<p>Source of protein for the maintenance of good health.</p> <p>Source of protein which helps build and repair body tissues.</p> <p>Source of amino acids involved in muscle protein synthesis.</p> <p>Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet.</p> <p>Workout supplement.</p> <p>Athletic support.</p>	Combined dose for all ingredients from proteins in the product.			
Alfalfa protein concentrate	Extract - Medicago sativa – herb top		<p>-</p> <p>30 g</p> <p>2,6 g</p> <p>90 g</p>			
Calcium caseinate	Isolate – Bos taurus - milk					
Calcium sodium caseinate	Bos taurus - milk					
Hydrolyzed casein	Bos taurus - milk					
Defatted wheat germ protein	Triticum aestivum – seed germ					
Flaxseed protein	Linum usitatissimum - seed					
Hemp protein concentrate	Cannabis sativa seed extract					
Hemp protein isolate	Where it consists of a “processed product made from cannabis seeds containing not more than 10 milligram per kilogram (0,001 percent) of tetrahydrocannabinol and does not contain whole cannabis seeds”					
Hemp seed protein						
Casein Micelles	Extract - Bos taurus - milk					
Milk protein concentrate	Extract - Bos taurus - milk					
Milk protein isolate	Extract - Bos taurus - milk					
Pea protein	Pisum sativum seed isolate					
Potato protein	Solanum tuberosum – tuber - Extract dry, Extract dry standardised					
Rice protein	Rice protein concentrate isolate					
Rice protein concentrate	Oryza sativa - seed					
Sodium caseinate	Isolate – Bos taurus - milk					

**Registration of Medicines**

**Health Supplements**

Protein	Source Material	Health Supplement Claim (Single and Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Wheat protein isolate	Extract - Triticum aestivum - seed germ					
Whey protein isolate	Bos taurus - milk or Capra hircus - milk					
Whey protein concentrate	Bos taurus - milk or Capra hircus - milk					
Whey protein hydrolysate	Bos taurus - milk or Capra hircus - milk					

## 2 AMINO ACIDS

**NOTE:** When combining individual amino acids with protein ingredients, applicants must consider the contribution of the protein ingredient(s) to the total dose of each amino acid, in order to respect the maximum doses indicated below.

With respect to the use of branched-chain amino acids (leucine, isoleucine and valine) the combination thereof may not exceed the highest daily maximum of any of the three. The percentage of each BCAA in relation to the total protein content of the product must be stipulated.

### General Statements

#### **Pharmacological Action:**

##### *Essential amino acids:*

Amino-acids are the building blocks of life and constituents of living cells essential for growth and repair of tissues. Essential amino acids cannot be made by the body. As a result, they must come from an external nutrient source.

##### *Non-essential amino acids:*

Non-essential amino acids are those that can be synthesised by the body. These nonessential amino acids serve many functions to create optimal health.

#### **Warnings and special precautions:**

##### *Products containing over 30 g per day total protein and/or amino acids (including $\beta$ -alanine):*

If you have liver or kidney disease, consult a health care practitioner prior to use.

##### *All products:*

The indicated daily dose should not be exceeded.

Not suitable for children unless under the direct supervision of a healthcare provider for any claims by direct indication or implication related to athletic performance, workout supplementation, muscle / protein synthesis

#### **Permitted indications as Workout Supplements (adults only):**

##### *Essential Amino Acids:*

Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet.

##### *Non-Essential Amino Acids:*

Source of (an) amino acid(s) involved in muscle protein synthesis.

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>ESSENTIAL AMINO ACIDS</b>						
<b>L-Isoleucine</b> <b>Sources:</b> Calcium sodium caseinate Ethyl L-isoleucinate Hydrolyzed collagen L-Isoleucine hydrochloride N-Acetyl-L-isoleucine Pea Protein	Source of (an) essential amino acid(s) for the maintenance of good health				66,5 mg	1 065 mg
<b>L- Leucine</b> <b>Sources:</b> Calcium sodium caseinate Hydrolyzed collagen Leucine hydrochloride L-Leucine ethyl ester L-Leucine ethyl ester hydrochloride L-Leucine methyl ester hydrochloride N-Acetylleucine N-Glycyl-L-leucine Pea Protein	Source of (an) (essential) amino acid(s) involved in muscle protein synthesis  Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet.  <b>Products containing all three of L-leucine, L-isoleucine and L-valine, at or above the respective minimum doses indicated in the Dose section</b>		<b>See general statements</b> (Comment invited for maximum level for children)	147 mg	1 824 mg	
<b>L-Valine</b> <b>Sources:</b> Calcium sodium caseinate DL-Valine Hydrolyzed collagen L-Valine ethyl ester L-Valine ethyl ester hydrochloride L-valine hydrochloride N-Acetyl-L-valine Pea Protein	Source of branched chain amino acids, which are involved in protein synthesis  Workout supplement Athletic support			84 mg	1 194 mg	



Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p>L-Histidine</p> <p><b>Sources:</b>  <i>Calcium sodium caseinate</i>  <i>Hydrolyzed collagen</i>  <i>L-Histidine hydrochloride</i>  <i>Whey protein concentrate</i>  <i>Whey protein isolate</i></p>	<p>Source of (an) essential amino acid(s) for the maintenance of good health</p> <p>Source of (an) (essential) amino acid(s) involved in muscle protein synthesis</p> <p>Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet</p>		<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>	49 mg	220 mg	
<p>L-Threonine</p> <p><b>Sources:</b>  <i>Calcium sodium caseinate</i>  <i>dl-Threonine</i>  <i>Hydrolyzed collagen</i>  <i>Whey protein concentrate</i>  <i>Whey protein isolate</i></p>	<p><b>Must contain at least one ingredient at or above the minimum dose</b></p> <p>Workout supplement</p> <p>Athletic support</p>			70 mg	301 mg	
<p>L-Phenylalanine</p> <p><b>Sources:</b>  <i>Calcium sodium caseinate</i>  <i>DL-Phenylalanine</i>  <i>Hydrolyzed collagen</i>  <i>L-Phenylalanine methyl ester</i>  <i>N-Acetyl-L-phenylalanine</i>  <i>Whey protein concentrate</i>  <i>Whey protein isolate</i></p>	<p>Source of (an) essential amino acid(s) for the maintenance of good health</p> <p>Source of (an) (essential) amino acid(s) involved in muscle protein synthesis</p> <p>Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet.</p>	<p>Products for oral use:</p> <ul style="list-style-type: none"> <li>• Phenylketonurics: Contains phenylalanine.</li> <li>• Oral products containing more than 5 mg per MDD:                             <ul style="list-style-type: none"> <li>○ Do not use if pregnant or intending to become pregnant.</li> <li>○ Do not use if breastfeeding.</li> </ul> </li> </ul>	<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>	115,5 mg	339 mg	

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>L-Lysine</b> <b>Sources:</b> <i>Brown Rice Protein</i> <i>Calcium sodium caseinate</i> <i>Hydrolyzed collagen</i> <i>L-Lysine-L-aspartate</i> <i>L-Lysine monohydrochloride</i> <i>Lysine acetate</i> <i>Lysine dihydrochloride</i> <i>Milk protein isolate</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i>	<p>Source of (an) essential amino acid(s) for the maintenance of good health</p> <p>Source of (an) (essential) amino acid(s) involved in muscle protein synthesis</p> <p>Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet</p> <p>Helps in collagen formation</p>		<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>		133 mg	3 000 mg
<b>L-Methionine</b> <b>Sources:</b> <i>Calcium sodium caseinate</i> <i>DL-Methionine</i> <i>Hydrolyzed collagen</i> <i>N-Acetyl-L-methionine</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i>	<p>Source of (an) essential amino acid(s) for the maintenance of good health</p> <p>Source of (an) (essential) amino acid(s) involved in muscle protein synthesis</p> <p>Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet</p> <p>Helps to support liver function</p>	<p>Consult a healthcare practitioner before use if you have acidosis, atherosclerosis, or methylenetetrahydrofolate reductase deficiency.</p>	<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>		66,5 mg	210 mg
<b>L-Tryptophan</b> <b>Sources:</b> <i>Calcium sodium caseinate</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i>	<p>Source of (an) essential amino acid(s) for the maintenance of good health</p> <p>Source of (an) (essential) amino acid(s) involved in muscle protein synthesis</p> <p>Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet</p>	<p>Consult a healthcare provider before use if you have eosinophilia myalgia syndrome or liver disease or have depression.</p>	<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>		17,5 mg	220 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>NON-ESSENTIAL AMINO ACIDS</b>						
<b>L-Alanine</b> <b>Sources:</b> Calcium sodium caseinate DL-Alanine Hydrolyzed collagen L-Alanine ethyl ester hydrochloride Whey protein concentrate Whey protein isolate	Source of (an) amino acid(s) involved in muscle protein synthesis.		See general statements (Comment invited for maximum level for children)		> 0 mg	363 mg
<b>beta-Alanine</b> <b>Sources:</b> Elymus repens subsp. repens Humulus lupulus Malus domestica Prunus cerasus Ribes nigrum Solanum lycopersicum	<u>COMMENT INVITED</u>	May cause a flushing, tingling and/or prickling sensation of the skin, in which case, reduce the dose.	See general statements (Comment invited for maximum level for children)			1 g
<b>L-Arginine</b> <b>Sources:</b> Acetyl-L-carnitine arginate dihydrochloride Arginine bicarbonate Arginine PCA Arginine silicate inositol Brown Rice Protein Calcium sodium caseinate DL-Arginine Hydrolyzed collagen L-Arginine alpha-ketoglutarate L-Arginine DL-Malate	Source of (an) amino acid(s) involved in muscle protein synthesis.  May help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases.	Consult a health care practitioner prior to use if you are pregnant or breastfeeding.  <u>For products providing 0,42 - 9 g per day:</u> <ul style="list-style-type: none"> <li>Consult a health care practitioner if your cardiovascular condition worsens.</li> <li>Consult a health care practitioner prior to use if you have a renal/kidney disease or if you are following a low protein diet.</li> </ul>	See general statements (Comment invited for maximum level for children)		> 0 mg	9 000 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p><i>L-Arginine ketoisocaproic acid</i>  <i>L-Arginine L-aspartate</i>  <i>L-Arginine monohydrochloride</i>  <i>L-Arginine taurinate</i>  <i>Whey protein concentrate</i>  <i>Whey protein isolate</i>  <u>Excluding:</u> <i>L-Arginine hydrochloride</i></p>		<ul style="list-style-type: none"> <li>Consult a health care practitioner prior to use if you suffer from a cardiovascular disease and are attempting an increase in physical activity.</li> <li>Consult your health care practitioner prior to use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners.</li> </ul> <p><b>Contraindication(s):</b>  <u>For products providing 0,42 –9 g per day:</u></p> <ul style="list-style-type: none"> <li>Do not use if you have had a heart attack/myocardial infarction.</li> </ul> <p><b>Known Adverse Reaction(s):</b>  <u>For products providing 0,42 –9 g per day:</u></p> <ul style="list-style-type: none"> <li>Some people may experience gastrointestinal discomfort (such as diarrhoea).</li> </ul>				
<p>L-Asparagine  <b>Sources:</b>  <i>L-Asparagine</i>  <i>L-Asparagine monohydrate</i></p>	Source of (an) amino acid(s) involved in muscle protein synthesis.		<b>See general statements</b> (Comment invited for maximum level for children)		> 0 mg	93,5 mg
<p>L-Aspartic Acid  <b>Sources:</b>  <i>Calcium sodium caseinate</i>  <i>Hydrolyzed collagen</i>  <i>Potassium aspartate</i>  <i>Potassium magnesium aspartate</i></p>	Source of (an) amino acid(s) involved in muscle protein synthesis.		<b>See general statements</b> (Comment invited for maximum level for children)		> 0 mg	650 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Whey protein concentrate Whey protein isolate						
L-Carnitine (L-3-Carboxy-2-hydroxypropyl) trimethylammonium hydroxide, inner salt Carnitine  Also for: L-Carnitine fumarate L-Carnitine hydrochloride L-Carnitine magnesium citrate  <b>Sources:</b> L-Carnitine tartrate L-Carnitine fumarate	Antioxidant Workout support/supplement  <b>L-Carnitine from L-Carnitine tartrate</b>  Aids in the muscle recovery process by reducing muscle tissue damage associated with a resistance training regimen  Helps support muscle tissue repair in individuals involved in resistance training  Helps improve physical performance when used in conjunction with a training regimen  Helps delay fatigue during physical activity  Helps support fat metabolism Helps support fat oxidation	If you are pregnant or breastfeeding, consult a healthcare practitioner prior to use.  If you have a liver disease, a kidney disease, or a seizure disorder, consult a healthcare practitioner prior to use.	<b>See general statements</b> (Comment invited for maximum level for children)		4 000 mg (not more than 2 g per single dose)	
L-Citrulline (S)-N5-Carbamoylornithine N5-(aminocarbonyl)-L-ornithine	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)		2 000 mg	
L-Cystine 3,3'-Dithiobis(2-aminopropanoic acid), (R-(R*,R*))- L-Cystine	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)			

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>L-Cysteine</b> <b>Sources:</b> <i>Cysteine hydrochloride</i> <i>Cysteine hydrochloride monohydrate</i> <i>D-Ribose-L-cysteine</i> <i>N-Acetyl-L-cysteine</i>	Source of (an) amino acid(s) involved in muscle protein synthesis.		<b>See general statements</b> (Comment invited for maximum level for children)		> 0 mg	1 000 mg
<b>L-Glutamic Acid</b> <b>Sources:</b> <i>Calcium sodium caseinate</i> <i>Glutamic acid hydrochloride</i> <i>Hydrolyzed collagen</i> <i>Monosodium glutamate</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i>	Source of (an) amino acid(s) involved in muscle protein synthesis.		<b>See general statements</b> (Comment invited for maximum level for children)		> 0 mg	1 500 mg
<b>L-Glutamine</b> <b>Sources:</b> <i>Alanylglutamine</i> <i>Glutamic acid</i> <i>L-Glutamine ethyl ester</i> <i>L-Glutamine methyl ester</i> <i>Magnesium glycyl glutamine chelate</i> <i>N-Acetyl-L-glutamine</i> <i>Pea Protein</i>	Source of (an) amino acid(s) involved in muscle protein synthesis.  Helps restore plasma glutamine levels depleted after periods of physical stress (e.g. prolonged exhaustive exercise).  Helps support immune system health after periods of physical stress.  Helps support digestive system health after periods of physical stress.  Helps to assist in muscle cell repair after exercise.	Consult a health care practitioner prior to use if you are following a low protein diet.  Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	<b>See general statements</b> (Comment invited for maximum level for children)		> 0 mg	9 000 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
	<p><b>Products containing L-glutamine:</b>                      Helps restore plasma glutamine levels depleted after periods of physical stress (e.g. prolonged exhaustive exercise).                      Helps to assist in muscle cell repair after exercise.                      Workout supplement.                      Athletic support.</p>					
<p>Glycine  <i>Aminoacetic acid</i>  <i>2-aminoacetic acid</i>  <i>E640</i>  <b>Sources:</b>  <i>Calcium sodium caseinate</i>  <i>Glycine hydrochloride</i>  <i>Hydrolyzed collagen</i>  <i>N-Glycyl-L-leucine</i>  <i>Whey protein concentrate</i>  <i>Whey protein isolate</i></p>	<p>Source of (an) amino acid(s) involved in muscle protein synthesis.</p>		<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>		>0 mg	320 mg
<p>L-Proline  <b>Sources:</b>  <i>Calcium sodium caseinate</i>  <i>Glycine hydrochloride</i>  <i>Hydrolyzed collagen</i>  <i>N-Glycyl-L-leucine</i>  <i>Whey protein concentrate</i>  <i>Whey protein isolate</i></p>			<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>		> 0 mg	519 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
L-Serine <b>Sources:</b> <i>Calcium sodium caseinate</i> <i>Hydrolyzed collagen</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i>			<b>See general statements</b> (Comment invited for maximum level for children)		> 0 mg	351 mg
L-Tyrosine <b>Sources:</b> <i>Brown Rice Protein</i> <i>Calcium sodium caseinate</i> <i>Casein</i> <i>Hydrolyzed collagen</i> <i>L-Tyrosine ethyl ester</i> <i>N-Acetyl tyrosine</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i>	Source of (an) amino acid(s) involved in muscle protein synthesis.  Helps to decrease cognitive fatigue due to physically stressful situations (e.g. extended wakefulness, exposure to cold, excessive noise)	Consult a health care practitioner prior to use if you are following a low protein diet.  Consult a health care practitioner prior to use if you are pregnant or breastfeeding.	<b>See general statements.</b> (Comment invited for maximum level for children)		> 0 mg	3 600 mg



Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>OTHER AMINO ACIDS</b>						
Acetyl L-Carnitine <i>Acetyllevocarnitine hydrochloride</i> 1-Propanaminium, 2-(acetyloxy)-3-carboxy-N,N,N-trimethyl-, chloride, (R)- <i>Acetylcarnitine hydrochloride, L-form</i> <i>Acetyl-L-carnitine hydrochloride</i> <i>N-Acetyl L-carnitine hydrochloride</i>	Acetyl-l-carnitine helps to support and maintain healthy brain function.		See general statements (Comment invited for maximum level for children)			3 g
Acetylcysteine Cysteine, N-acetyl-, L- L-alpha-Acetamido-beta-mercaptopropionic acid NAC N-Acetylcysteine N-Acetyl-L-cysteine	<u>COMMENT INVITED</u>		See general statements (Comment invited for maximum level for children)			600 mg
N-Acetyl-L-Methionine	<i>See L-Methionine</i>					
(s)-s-adenosyl methionine <b>Including:</b> <i>Ademetionine disulfate ditosylate dihydrate</i> <i>Ademetionine disulfate tosylate</i> <i>Ademetionine disulfate tritosylate dihydrate</i> <i>Ademetionine hexasulfate dihydrate</i> <i>Ademetionine hexatosylate dihydrate</i>	Maintenance of emotional well-being  Joint health, mobility and joint comfort	Do not use if you are taking prescription antidepressants except under the supervision of a registered healthcare practitioner.  Do not use if you have bipolar depression except under the supervision of a registered healthcare practitioner.	See general statements (Comment invited for maximum level for children)			400 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p><i>Ademetionine pentasulfate dihydrate</i>  <i>Ademetionine pentatosylate dihydrate</i>  <i>Ademetionine tetrasulfate dihydrate</i>  <i>Ademetionine tetratosylate dihydrate</i>  <i>Ademetionine trisulfate ditosylate dihydrate</i></p>						
<p><b>Creatine</b>  <i>(α-Methylguanido) acetic acid</i>  <i>Glycine, N-(aminoimino-methyl)-N-methyl-</i>  <i>Kre-Alkalyn</i>  <i>N-Amidinosarcosine</i></p>	<u>COMMENT INVITED</u>	Consult a healthcare practitioner before long term use.	<b>See general statements</b> (Comment invited for maximum level for children)			
<p><b>Creatine hydrochloride</b>  <i>Creatine HCl</i>  <i>Glycine, N-(aminoimino-methyl)-N-methyl-, monohydrochloride</i>  <i>N-(aminoiminomethyl)-N-methyl-glycine monohydrochloride</i></p>	<u>COMMENT INVITED</u>	Consult a healthcare practitioner before long term use.	<b>See general statements</b> (Comment invited for maximum level for children)			3 g
<p><b>Creatine monohydrate</b>  <i>Creatine hydrate</i>  <i>Glycine, N-(aminoimino-methyl)-N-methyl-, monohydrate</i></p>	<p>Increases [body/muscle/lean] [mass/size] when used in conjunction with a resistance training regimen.</p> <p>Improves [strength/ power/ performance] in repetitive bouts of brief, highly-intense physical activity (e.g. sprints, jumping, resistance training) (by increasing [muscle / intramuscular] [creatine /</p>	<p>Consult a healthcare practitioner before long term use.</p> <p>Consult a health care practitioner prior to use if you have a kidney disorder</p> <p>Consult a health care practitioner prior to use if you are pregnant or breastfeeding.</p> <p>May result in weight gain.</p>	<b>See general statements</b> (Comment invited for maximum level for children)			20 g not to exceed 5 g per dose

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
	phosphocreatine / energy] levels)					
Creatine phosphate <i>Glycine, N-(imino (phosphonoamino )methyl)-N-methyl-N-(Phosphonoamidino) sarcosine</i> Phosphocreatine	<u>COMMENT INVITED</u>	Consult a healthcare practitioner before long term use.	<b>See general statements</b> (Comment invited for maximum level for children)			20 g
L-Cysteine hydrochloride <i>Cysteine hydrochloride monohydrate</i> E920 <i>L-2-amino-3-mercaptopropanoic acid hydrochloride monohydrate</i> L-Cysteine HCl L-Cysteine hydrochloride L-Cysteine monohydrate monochloride L-Cysteine monohydrochloride	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)		800 mg	1 g
Glucose glutamate	<u>COMMENT INVITED</u>	Permitted only in products for external use. Approved for topical use only. Glucose is a mandatory component of this ingredient.	<b>See general statements</b> (Comment invited for maximum level for children)			6,8 g
L-Glutamic acid hydrochloride <i>(S)-2-Aminopentanedioic acid, hydrochloride</i> <i>2-aminopentanedioic acid hydrochloride</i> L-glutamic acid hydrochloride	<u>COMMENT INVITED</u>	Permitted only in products for external use.	<b>See general statements</b> (Comment invited for maximum level for children)			20 g

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Glutathione <i>Glycine, L-gamma-glutamyl-L-cysteinyl-L-glutathione</i> <i>N-(N-L-gamma-Glutamyl-L-cysteinyl) glycine</i>	<u>COMMENT INVITED</u>	Permitted only in products for external use.  Approved for topical use only.	<b>See general statements</b> (Comment invited for maximum level for children)			4,5 g
Histidine hydrochloride <i>(S)-alpha-amino-1H-imidazole-4-propanoic acid, monohydrochloride</i> <i>Histidine monohydrochloride</i>	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)		3,6 g	2,5 g
Hydroxylysine <i>5-Hydroxylysine</i> <i>delta-Hydroxylysine</i> <i>erythro-5-Hydroxy-L-lysine</i>	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)		2 g	5,6 g
l-Hydroxyproline <i>4-Hydroxy-2-pyrrolidinecarboxylic acid</i> <i>4-Hydroxy-L-proline</i> <i>L-4-Hydroxyproline</i>	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)			10 g if used alone or 16 g of the combination with other branch chain amino acids i.e. leucine or valine
L-Lysine hydrochloride <i>Lysine hydrochloride</i> <i>(S)-2,6-Diaminohexanoic monohydrochloride</i>	<u>COMMENT INVITED</u>		<b>See general statements</b> (Comment invited for maximum level for children)			1,4 g
L-Ornithine <i>Ornithine</i> <i>(S)-2,5-Diaminopentanoic acid</i> <i>2,5-diaminopentanoic acid</i>	Ornithine helps to support liver function.		<b>See general statements</b> (Comment invited for maximum level for children)		4,8 g	6 g

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
L-Ornithine aspartate <i>Ornithine aspartate</i> <i>Aspartic acid, L-, compd. with L-ornithine (1:1)</i> <i>Ornithine anhydrous</i> <i>Ornithine L-form aspartate</i> <i>Ornithylaspartate</i>	<u>COMMENT INVITED</u>		See general statements (Comment invited for maximum level for children)			
Ornicetil <i>L-Ornithine alpha-ketoglutarate</i> <i>(L)-Ornithine 2-oxoglutarate</i> <i>L(+)-Ornithine alpha-ketoglutarate</i> <i>L-Ornithine 2-oxoglutarate</i> <i>L-Ornithine, mixt. with 2-oxopentanedioic acid</i> <i>OKG</i> <i>Ornithine alpha-ketoglutarate</i> <i>Ornithine-alpha-ketoglutarate</i>	<u>COMMENT INVITED</u>		See general statements (Comment invited for maximum level for children)			6 g
Ornithine monohydrochloride <i>2,5-Diaminopentanoic acid hydrochloride</i> <i>L-(+)-2,5-Diaminopentanoic acid</i> <i>L-Ornithine hydrochloride</i> <i>L-Ornithine monohydrochloride</i> <i>Ornithine hydrochloride</i> <i>Ornithine L-monohydrochloride</i>	<u>COMMENT INVITED</u>		See general statements (Comment invited for maximum level for children)			2 g
I-Selenomethionine <i>Butanoic acid, 2-amino-4-(methylseleno)-, (S)-</i> <i>L-Selenomethionine</i> <i>Selenium-L-methionine</i>	<u>COMMENT INVITED</u>	Selenium is toxic in high doses.  Do not exceed the maximum daily dose of 60 micrograms as stated for Selenium.	As stipulated for Selenium.			

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p>Taurine                      2-Aminoethane sulfonic acid                      2-Aminoethylsulfonic acid                      beta-Aminoethylsulfonic acid                      L-taurine</p>	<p>Amino acid that plays a role in the support of the immune system.</p> <p>Antioxidant.</p> <p>Contributes to the total antioxidant capacity of the body.</p> <p>Taurine is important for the energy metabolism / the transformation of food into energy.</p>		<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>			<p>5 g</p>
<p>L-Theanine                      (2S)-2-amino-5-(ethylamino)-5-oxopentanoic acid                      N-Ethyl-L-glutamine                      suntheanine                      theanin</p>	<p>Helps to temporarily promote relaxation.</p> <p>Helps to support the relaxation.</p> <p>Supports maintenance of healthy sleep.</p> <p>Caffeine antagonist.</p>		<p><b>See general statements</b>                      (Comment invited for maximum level for children)</p>			<p>250 mg</p>

## 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

Unless otherwise stated the dosage form is oral.

#### General Statements

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

#### **Storage instructions:**

*All Products:*

Store in airtight container, protected from light.

#### 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	Maximum
<b>PLANT OILS</b>				
<b>A Plant Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
Almond Oil <i>Oil of sweet almond</i> <i>Prunus amygdalus dulcis oil</i> <i>Sweet almond oil</i> <i>Prunus amygdalus dulcis (Parts: Seed)</i>			Must not contain amygdalin. The concentration of hydrocyanic acid from all ingredients must not exceed 1 microgram/kg or 1 microgram/L or 0,0000001 %.	15 g
Apple seed oil <i>Malus domestica</i> <i>(Parts: Seed)</i>			Must be derived only from seeds of <i>Malus domestica</i> .	
Arganiaspinosa kernel oil <i>Lipofructylargan</i> <i>Argan Seed Oil</i>			Restrictions on manufacturing: The concentration must be no more than 5 % in the product.	
Blackcurrant seed oil <i>Blackcurrant esters</i> <i>Ribes nigrum esters</i> <i>Ribesnigrum</i> <i>(Parts: Seed)</i>		If you are pregnant or breastfeeding, consult a health care practitioner prior to use. Refrigerate after opening.		10,5 g
Canola Oil <i>Brassica juncea, Brassica napus or Brassica rapa oil</i> <i>Rapeseed oil</i> <i>(Parts: Seed)</i>		Allyl isothiocyanate is a mandatory component of this ingredient.	The quantity of allyl isothiocyanate in the MDD must not exceed 20 mg.	15 g
Carrot seed oil <i>Daucus carota</i> <i>(Parts: Seed)</i>				



Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>PLANT OILS</b>				
<b>A Plant Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
Chia seed oil <i>Salvia hispanica</i> (Parts: Seed)		Refrigerate after opening.		4,5 g
Hemp Seed Oil <i>Cannabis sativa</i> Seed Oil (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 10 mg/kg (0,001 %) of tetrahydrocannabinol and does not contain whole cannabis seeds. ["Processed" means treated by mechanical, chemical or other artificial means but does not include - (a) harvesting; or (b) the natural process of decay"]	
Oat kernel oil <i>Avena sativa</i> (oat) kernel oil Oat kernel oil Oat Oil			<i>Label information to be added:</i> Products for internal use containing more than 0,3 % gluten: <b>Contains gluten.</b>	
Perilla Oil <i>Perilla Ocymoides</i> Seed Oil (Parts: Seed)				
Rice bran oil <i>Oryza Sativa</i> (Rice) Bran Oil (Parts: Seed coat, Husk, Seed bran)			Only <i>Oryza sativa</i> seed (grain) husk or seed coat (bran) with/out seed embryo (germ) oil fixed is permitted.	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>PLANT OILS</b>				
<b>A Plant Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
Sea buckthorn oil (omega-7) <i>Hippophae rhamnoides</i> var. <i>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)		If you are pregnant or breastfeeding, consult a health care practitioner prior to use. Refrigerate after opening.		5 g

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum												
<b>B Plant Oils regarded as Health Supplements</b>																
Borage Oil <i>Borago officinalis L.</i> (Boraginaceae) (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).	<table border="1"> <thead> <tr> <th colspan="2" data-bbox="1617 379 2040 419">Oil Fixed</th> </tr> <tr> <th data-bbox="1617 419 1832 459"><i>Minimum</i></th> <th data-bbox="1832 419 2040 459"><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="1617 459 1832 499">3,7 g</td> <td data-bbox="1832 459 2040 499">5,0 g</td> </tr> <tr> <th colspan="2" data-bbox="1617 499 2040 539">Oil Fixed Standardised</th> </tr> <tr> <th data-bbox="1617 539 1832 579"><i>Minimum</i></th> <th data-bbox="1832 539 2040 579"><i>Maximum</i></th> </tr> <tr> <td data-bbox="1617 579 1832 727">                             3,7 g                              23 % LA                              18 % GLA                              0,2 % ALA                         </td> <td data-bbox="1832 579 2040 727">                             5,0 g                              37 % LA                              27 % GLA                              10 % ALA                         </td> </tr> </tbody> </table>	Oil Fixed		<i>Minimum</i>	<i>Maximum</i>	3,7 g	5,0 g	Oil Fixed Standardised		<i>Minimum</i>	<i>Maximum</i>	3,7 g 23 % LA 18 % GLA 0,2 % ALA	5,0 g 37 % LA 27 % GLA 10 % ALA
Oil Fixed																
<i>Minimum</i>	<i>Maximum</i>															
3,7 g	5,0 g															
Oil Fixed Standardised																
<i>Minimum</i>	<i>Maximum</i>															
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 Fractionated coconut oil Coconut oil - hydrogenated Copra oil, hydrogenated Hydrogenated coconut oil Medium chain triglycerides Fractionated coconut oil Medium-chain triglycerides (Parts: Seed endosperm)	Provides/source of antioxidants			15 g												
Cottonseed Oil Cottonseed oil Cotton oil <i>Gossypium barbadense</i> <i>Gossypium herbaceum</i> (Parts: Seed)																

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Plant Oils regarded as Health Supplements</b>				
<p>Curcumin oil  <i>Oleo-resin Turmeric</i>                      1-(4-hydroxy-phenyl)-7-(4-hydroxy-3-methoxyphenyl)-hepta-1,6-diene-3,5-dione                      1,7-Bis(4-hydroxy-3-methoxyphenyl)hepta-1,6-diene-3,5-dione  <i>Curcuma longa oleoresin</i>  <i>Curcuma oil</i>  <i>Turmeric oil</i>  <i>Turmeric oleoresin</i>                      (Parts: Rhizome)</p>				
<p>Echium oil  <i>Echium plantagineum oil</i>  <i>Echium vulgare seed oil</i>  <b>Source Material(s):</b>  <i>Echium plantagineum</i>                      (Parts: Seed )</p>				
<p>Evening Primrose Oil  <i>Oenothera (species) seed oil fixed</i>  <i>Oenotherabiennis</i>                      (Parts: Seed )</p>			<p>Must contain the following fatty acids in the stipulated ranges:</p> <ul style="list-style-type: none"> <li>• 7-14 % gamma-Linolenic acid</li> <li>• 65-85 % Linoleic acid</li> </ul>	<p>1 300 mg</p>
<p>False flax oil  <i>Big-seed false flax</i>  <i>False flax</i>  <i>Myragrumsativum</i>  <i>Camelina sativa</i>                      (Parts: Seed)</p>		<p>Refrigerate after opening.</p>		

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Plant Oils regarded as Health Supplements</b>				
<p>Flaxseed Oil <i>Linseed oil</i> <i>Linum usitatissimum seed oil</i> <i>(Linaceae) – seed</i></p>	<p>Source of essential fatty acids for the maintenance of good health (IOM 2006)</p> <p>Source of omega-3 fatty acids for the maintenance of good health (IOM 2006)</p> <p>Source of alpha-linolenic acid (ALA) for the maintenance of good health (IOM 2006)</p> <p>Source of omega-6 fatty acids for the maintenance of good health (IOM 2006)</p> <p>Source of linoleic acid (LA) for the maintenance of good health (IOM 2006)</p>	<p>Refrigerate after opening.</p>		<p><b>Children 2 - 4 years:</b> <u>essential fatty acids; omega-3 fatty acids; ALA</u> <b>Dose(s):</b> 0,04 – 5,33 g, seed oil <b>Dose(s):</b> 0,17 – 5,67 ml, seed oil <u>omega-6 fatty acids; linoleic acid</u> <b>Dose(s): 1,28 – 5,33 g, seed oil</b> <b>Dose(s):</b> 1,33 – 5,67 ml, seed oil</p> <p><b>Children and adolescents 5 - 9 years:</b> <u>essential fatty acids; omega-3 fatty acids; ALA</u> <b>Dose(s):</b> 0,06 - 8 g, seed oil <b>Dose(s):</b> 0,25 – 8,5 ml, seed oil <u>omega-6 fatty acids; linoleic acid</u> <b>Dose(s):</b> 1,93 - 8 g, seed oil <b>Dose(s):</b> 2 – 8,5 ml, seed oil</p> <p><b>Adolescents 10 - 14 years:</b> <u>essential fatty acids; omega-3 fatty acids; ALA</u> <b>Dose(s):</b> 0,12 - 16 g, seed oil <b>Dose(s):</b> 0,5 - 17 ml, seed oil</p>

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Plant Oils regarded as Health Supplements</b>				
				<p><u>omega-6 fatty acids; linoleic acid</u>  <b>Dose(s):</b> 3,85 - 16 g, seed oil  <b>Dose(s):</b> 4 - 17 ml, seed oil  <b>Adults and adolescents 15 and over:</b>  <u>essential fatty acids; omega-3 fatty acids; ALA</u>  <b>Dose(s):</b> 0,23 - 32 g, seed oil  <b>Dose(s):</b> 1 - 34 ml, seed oil  <u>omega-6 fatty acids; linoleic acid</u>  <b>Dose(s):</b> 7,7 - 32 g, seed oil  <b>Dose(s):</b> 8 - 34 ml, seed oil</p>
<p>Grape Seed Oil  <i>Vitis vinifera seed oil</i>  <i>Vitis vinifera</i></p>			<p>Only <i>Vitis vinifera</i> seed oil fixed is permitted.                      May only be used as an excipient.</p>	<p>15 g</p>
<p>Pumpkin Seed Oil  <i>Pumpkin seed oil</i>  <i>Cucurbita pepo seed oil</i>                      (Parts: Seed)</p>	<p>Source of antioxidant(s)/Provides antioxidant(s).                      Source of antioxidant(s)/Provides antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.</p>		<p>Only Cucurbita pepo seed oil fixed is permitted.                      May only be used as a excipient.</p>	<p>15 g</p>
<p>Safflower Oil  <i>Carthamus tinctorius oil</i>                      (Parts: Seed)</p>				<p>15 g</p>

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Plant Oils regarded as Health Supplements</b>				
Sesame Seed Oil <i>Oleum sesami</i> <i>Sesamum indicum oil</i> Heizhima (Parts: Seed)				
Walnut Oil <i>Juglans cinerea, Juglans nigra &amp; Juglans regia seed (nut kernel) oil fixed</i>			Only <i>Juglans cinerea</i> , <i>J. nigra</i> and <i>J. regia</i> seed (nut kernel) oil fixed is permitted. May only be used as excipient.	
Wheat Germ Oil <i>Oil of wheat germ</i> <i>Triticum aestivum seed (grain) embryo (germ) oil fixed</i> Wheat oils (Parts: Seed germ )	Source of antioxidant(s)/Provides antioxidant(s).  Source of antioxidant(s)/Provides antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.		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.	15 g

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions / Directives	Maximum
<b>FISH OILS</b>				
<b>A Fish Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
Blue mussel oil <i>Mytilus edulis</i>		Derived from seafood		
Green-lipped mussel oil <i>Perna canaliculus</i> <i>Green-lipped mussel</i> <i>Greenshell mussel</i> <i>kuku [Maori]</i> <i>kukutai [Maori]</i> <i>kutai [Maori]</i> <i>Mytilus canalicula</i> <i>Mytilus canaliculatus</i> <i>Mytilus durus</i> (Parts: Whole)		Derived from seafood		
Seal oil <i>Arctocephalus pusillus</i> <i>Cystophora cristata</i> <i>Erignathus barbatus</i> <i>Halichoerus grypus</i> <i>Pagophilus groenlandicus</i> <i>Phoca vitulina</i> <i>Pusa hispida</i> (Parts: Blubber)		Refrigerate after opening.		
Shark Liver Oil <i>Oils, shark liver</i> <i>Carcharhiniformes</i> <i>Heterodontiforme</i> <i>Hexanchiformes</i> <i>Lamniformes</i> <i>Orectolobiformes</i> <i>Pristiophoriformes</i> <i>Squaliformes, and</i> <i>Squatiniiformes.</i> (Parts: Liver)				If health claims are made for vitamin A or colexcalciferol (vitamin D), refer to the restrictions for vitamin A or colexcalciferol.  Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.



Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum																									
<b>B Fish Oils regarded as Health Supplements</b>																													
<p>Algal oil DHA/EPA rich Schizochytrium algal oil docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) rich oil derived from microalgae Schizochytrium sp. Genus Species: Crypthecodinium cohnii Nannochloropsis oculata Schizochytrium spp. (Parts: Whole)</p>	<p>Helps to support cognitive health and/or brain function.</p>	<p>Refrigerate after opening.</p>	<p>Permitted only in products for oral use.  The ratio of docosahexaenoic acid (DHA) to eicosapentaenoic acid (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 and no more than 2 000mg DHA/day.  30 mL</p>																									
<p>Cod Liver Oil Oleum morrhuae Lecoris Aselli Oleum Source: Liver of Atlantic cod, Gadus morhua L. (Gadidae) Liver of Greenland cod, Gadus ogac Liver of Pacific cod, Gadus macrocephalus Tilesius (Gadidae) Liver from Arctic cod, Arctogadus glacialis Liver from all species of Gadidae (Cod family) (Parts: Liver)</p>	<p>Helps to support cognitive health and/or brain function.  <b>For products providing daily doses of vitamin A at or above the RDA or AI (adjusted for the life stage groups):</b> Helps to prevent vitamin A deficiency.  <b>For products providing daily doses of vitamin D at or above the RDA or AI (adjusted for the life stage groups):</b> Helps to prevent vitamin D deficiency.</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="1644 890 2033 1299"> <thead> <tr> <th colspan="2" data-bbox="1644 890 2033 933"><i>Minimum</i></th> <th colspan="2" data-bbox="1644 933 2033 976"><i>Maximum</i></th> </tr> </thead> <tbody> <tr> <td data-bbox="1644 976 1839 1019"><b>0-3 years</b></td> <td data-bbox="1839 976 2033 1019">0,83 ml / 0,77 g</td> <td data-bbox="1644 1019 1839 1062"><b>0-3 years</b></td> <td data-bbox="1839 1019 2033 1062">0,87 ml / 0,80 g</td> </tr> <tr> <td data-bbox="1644 1062 1839 1106"><b>4-8 years</b></td> <td data-bbox="1839 1062 2033 1106">0,83 ml / 0,77 g</td> <td data-bbox="1644 1106 1839 1149"><b>4-8 years</b></td> <td data-bbox="1839 1106 2033 1149">1,3 ml / 1,2 g</td> </tr> <tr> <td data-bbox="1644 1149 1839 1192"><b>9-13 years</b></td> <td data-bbox="1839 1149 2033 1192">0,83 ml / 0,77 g</td> <td data-bbox="1644 1192 1839 1235"><b>9-13 years</b></td> <td data-bbox="1839 1192 2033 1235">2,4 ml / 2,2 g</td> </tr> <tr> <td data-bbox="1644 1235 1839 1278"><b>14-18 years</b></td> <td data-bbox="1839 1235 2033 1278">0,83 ml / 0,77 g</td> <td data-bbox="1644 1278 1839 1321"><b>14-18 years</b></td> <td data-bbox="1839 1278 2033 1321">4,0 ml / 3,7 g</td> </tr> <tr> <td data-bbox="1644 1321 1839 1364"><b>&gt; 18 years</b></td> <td data-bbox="1839 1321 2033 1364">0,83 ml / 0,77 g</td> <td data-bbox="1644 1364 1839 1407"><b>&gt; 18 years</b></td> <td data-bbox="1839 1364 2033 1407">4,3 ml / 4,0 g</td> </tr> </tbody> </table>		<i>Minimum</i>		<i>Maximum</i>		<b>0-3 years</b>	0,83 ml / 0,77 g	<b>0-3 years</b>	0,87 ml / 0,80 g	<b>4-8 years</b>	0,83 ml / 0,77 g	<b>4-8 years</b>	1,3 ml / 1,2 g	<b>9-13 years</b>	0,83 ml / 0,77 g	<b>9-13 years</b>	2,4 ml / 2,2 g	<b>14-18 years</b>	0,83 ml / 0,77 g	<b>14-18 years</b>	4,0 ml / 3,7 g	<b>&gt; 18 years</b>	0,83 ml / 0,77 g	<b>&gt; 18 years</b>	4,3 ml / 4,0 g
<i>Minimum</i>		<i>Maximum</i>																											
<b>0-3 years</b>	0,83 ml / 0,77 g	<b>0-3 years</b>	0,87 ml / 0,80 g																										
<b>4-8 years</b>	0,83 ml / 0,77 g	<b>4-8 years</b>	1,3 ml / 1,2 g																										
<b>9-13 years</b>	0,83 ml / 0,77 g	<b>9-13 years</b>	2,4 ml / 2,2 g																										
<b>14-18 years</b>	0,83 ml / 0,77 g	<b>14-18 years</b>	4,0 ml / 3,7 g																										
<b>&gt; 18 years</b>	0,83 ml / 0,77 g	<b>&gt; 18 years</b>	4,3 ml / 4,0 g																										

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Fish Oils regarded as Health Supplements</b>				
	<p><b>For products providing 138 - 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 - 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 good health.</p> <p><b>For products providing 100 - 1 360 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA), per day:</b>                      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.</p>			

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Fish Oils regarded as Health Supplements</b>				
	<p><b>For products providing 100 - 1 360 mg EPA + DHA including at least 100 mg DHA, per day:</b> Helps support cognitive health and/or brain function.</p> <p><b>For products providing 150 - 1 360 mg EPA + DHA including at least 150 mg DHA, per day + DHA:</b> Helps support the development of the brain, eyes and nerves in children up to 12 years of age.</p>			
<p>Fish oil <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> <i>Note: The above corresponds to oil from the body of one or more of the following species in its natural triglyceride / triacylglycerol form and/or its concentrated esterified form</i></p>	<p><b>For products providing 100 - 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, per day:</b> 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.</p> <p><b>For products providing 200 - 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 maintain/support cardiovascular health.</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>Consult a healthcare practitioner before use if you have a sensitivity to aspirin or if you have high blood pressure.</p>	<p>Preparation: Oil fixed standardised Dose(s): 100 - 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid per day</p>

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Fish Oils regarded as Health Supplements</b>				
	<p><b>For products providing 1 000 - 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 - 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 - 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><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-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	Maximum
<b>B Fish Oils regarded as Health Supplements</b>				
	<p><b>For products providing 150 - 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><b>For products providing 1 500 - 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:</b> Helps to promote healthy mood balance.</p>			
Fish Liver Oil		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 registration application and label.	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),	If health claims are made for vitamin A or coledcalciferol (vitamin D), refer to the restrictions for vitamin A or coledcalciferol.  Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Fish Oils regarded as Health Supplements</b>				
			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>Halibut Liver Oil <i>Hippoglossus hippoglossus</i> <i>Atlantic halibut</i></p>				<p>If health claims are made for vitamin A or colesteciferol (vitamin D), refer to the restrictions for vitamin A or colesteciferol.</p> <p>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p>
<p>Krill oil <i>Euphausia pacifica</i> (north pacific krill) (Parts: Whole) <i>Euphausia superba</i> oil (Antartica krill) <i>Euphausia superba</i> (Parts: Whole)</p>	<p>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.</p>	<p>Contains crustacean shellfish. [OR] Derived from seafood. If you are pregnant or breastfeeding, consult a health care practitioner prior to use. Hypersensitivity/allergy has been known to occur (with shellfish); if this occurs, discontinue use). Refrigerate after opening.</p>		<p>4,1 g including at least 100 mg Eicosapentaenoic acid + Docosahexaenoic acid</p>

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Fish Oils regarded as Health Supplements</b>				
Pollack-liver oil <i>Theragra chalcogramma</i> <i>Alaska pollock</i> <i>Pacific pollock</i> <i>Wall-eye pollock</i> <i>Whiting</i> (Parts: Whole)		Derived from seafood.		If health claims are made for vitamin A or coledcalciferol (vitamin D), refer to the restrictions for vitamin A or coledcalciferol.  Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.
Salmon Oil <i>Oncorhynchus gobuscha</i> <i>Oncorhynchus nerka</i> <i>Oncorhynchus tshawytscha</i> <i>Salmo salar</i>				
Squid oil Parts – whole		Derived from seafood.  If you are pregnant or breastfeeding, consult a health care practitioner prior to use.  Hypersensitivity/allergy has been known to occur (with shellfish); if this occurs, discontinue use.  Refrigerate after opening.	Must be derived only from species of the order Teuthida of the class Cephalopoda AND be in combination with other ingredients in the product.	5 g
Tuna fish oil/Skipjack liver oil			The ingredient must conform to the BP monograph for fish oils.	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>OTHER</b>				
<b>A Other Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
<p>Caprylic Acid  <i>Caprylic/capric triglyceride</i>  <i>Capric acid, triglyceride</i>  <i>Glycerin/caprylic/caprictriester</i>                      Miglyol  <i>Octanoic/decanoic acid triglyceride</i>                      Octanoic acid</p>			<p>Products for external use only.                       The concentration must not exceed 2 %.</p>	
<p><b>Source materials:</b> <i>Cocos nucifera</i> (Parts: Seed endosperm)  <b>Source ingredients:</b> <i>Calcium caprylate; Magnesium caprylate; Zinc caprylate</i></p>				
<p>Eicosapentaenoic Acid  <i>Icosapent (ethyl ester) (all-Z)-5,8,11,14,17-</i>  <i>Eicosapentaenoic acid</i>  <i>Eicosapentaenoic acid</i>                      EPA                      Fish oil fatty acid  <i>Icosapentaenoic acid</i>                      Timnodonic acid</p>		<p>Refrigerate after opening.                       Consult a healthcare practitioner before use if you have a sensitivity to aspirin or if you have high blood pressure.</p>		
<p><b>Source Material:</b> <i>Arctocephalus pusillus</i> (Parts: Blubber); <i>Arctogadus glacialis</i> (Parts: Liver); <i>Clupea harengus</i> (Parts: Egg); <i>Clupea harengus</i> (Parts: Fish semen); <i>Cod Liver Oil fish</i> (Parts: Liver); <i>Cystophora cristata</i> (Parts: Blubber); <i>Erignathus barbatus</i> (Parts: Blubber); <i>Euphausia pacifica</i> (Parts: Whole); <i>Euphausia superba</i> (Parts: Whole); <i>fish oil fish</i> (Parts: Whole); <i>Gadus macrocephalus</i> (Parts: Liver); <i>Gadus morhua</i> (Parts: Liver); <i>Gadusogac</i> (Parts: Liver); <i>Halichoerus grypus</i> (Parts: Blubber); <i>Illex illecebrosus</i> (Parts: Whole); <i>Mytilus edulis</i> (Parts: Whole); <i>Pagophilus groenlandicus</i> (Parts: Blubber); <i>Pandalus borealis</i> (Parts: Internal shell); <i>Pandalus borealis</i> (Parts: Whole); <i>Phoca vitulina</i> (Parts: Blubber); <i>Pusa hispida</i> (Parts: Blubber); <i>Schizochytrium spp</i> (Parts: Whole); <i>Shark</i> (Parts: Liver); <i>Squid oil Squid</i> (Parts: Whole); <i>Theragra chalcogramma</i> (Parts: Liver); <i>Theragra chalcogramma</i> (Parts: Whole); <i>Thunnus thynnus</i> (Parts: Whole)</p> <p><b>Source Ingredients:</b> <i>Omega-3 acid ethyl ester; Omega-3 Fatty acids</i></p>				



Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>OTHER</b>				
<b>A Other Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
gamma-Linolenic acid <i>Gamolenic acid</i> (6Z,9Z,12Z)-6,9,12- Octadecatrienoic acid <i>Gamma-linolenic acid</i> GLA cis-6,cis-9,cis-12- Octadecatrienoic acid				
<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)				
Linoleic acid (LA) (Z,Z)-9,12-Octadecadienoic acid 9,12-Linoleic acid alpha-Linoleic acid cis,cis-9,12-Octadecadienoic acid Grape seed oil Linolic acid	Essential fatty acid  Linoleic acid contributes to the maintenance of normal blood cholesterol levels.  Essential fatty acids are needed for normal growth and development of children.		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.  Information to the consumer that the beneficial effect is obtained with a daily intake of 2 g of alpha- linolenic acid (ALA) and a daily intake of 10 g of linoleic acid (LA).
<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)				

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>OTHER</b>				
<b>A Other Oils as Health Supplements requiring justification, including proposed claim and maximum levels</b>				
Medium Chain Triglycerides <i>Fractionated coconut oil</i> <i>Medium-chain triglycerides</i>				
<b>Source Material:</b> <i>Cocos nucifera</i> (Parts: Fruit flesh); <i>Elaeis guineensis</i> (Parts: Seed); <i>Elaeis guineensis</i> (Parts: Seed endosperm)				
Octacosanol <i>1-Octacosanol</i> <i>cluytyl alcohol</i> <i>montanyl alcohol</i> <i>octacosyl alcohol</i>			Policosanol / Blend of aliphatic alcohols - consisting primarily of <b>1-Octacosanol</b> , 1-Triacontanol, 1-Tetracosanol and 1-Hexacosanol – from sugar cane ( <i>Saccharum officinarum</i> ).	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
Alpha-Linolenic Acid	ALA contributes to the maintenance of normal blood cholesterol levels.			Information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 2 g of ALA.
<p><b>Source ingredients:</b> <i>Borago officinalis</i> (Parts: Seed); <i>Buglossoides arvensis</i> (Parts: Seed); <i>Cannabis sativa</i> (Parts: Seed); <i>Echium plantagineum</i> (Parts: Seed); <i>Linum usitatissimum</i> (Parts: Seed); <i>Oenothera biennis</i> (Parts: Seed); <i>Perilla frutescens</i> (Parts: Seed); <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>Salvia sclarea</i> (Parts: Seed); <i>Vaccinium macrocarpon</i> (Parts: Seed)</p>				
<p>Alpha-lipoic acid  <i>R-alpha lipoic acid</i>  <i>(+)-1,2-Dithiolane-3-pentanoic acid</i>  <i>1,2-Dithiolane-3-valeric acid</i>  <i>Lipoic acid</i>  <i>Thioctic acid, d form</i>                      2 forms  <i>(±)-1,2-Dithiolane-3-pentanoic acid</i>  <i>DL-alpha-Lipoic acid</i>                      AND  <i>(+)-alpha-Lipoic acid</i>  <i>R-alpha-Lipoic acid</i></p>	<p>Provides antioxidants for the maintenance of good health.                       Helps to promote healthy glucose metabolism.</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>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>Permitted only in products for external use.</p>	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
Conjugated Linoleic acid (CLA)	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	Consult a 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).  Consult a health care practitioner prior to use if you are pregnant or breastfeeding  Consult a health care practitioner prior to use if your goal is to achieve weight loss.	<b>Contraindication(s):</b> Do not use if you have CVD, diabetes, metabolic syndrome or insulin resistance.  <b>Known Adverse Reaction(s)</b> Some people may experience gastrointestinal upset.	3 - 5 g
Dihomo-gamma-linolenic acid <i>all-cis-8,11,14-Eicosatrienoic acid</i> DGLA				
Docosahexaenoic Acid (DHA) <i>(4Z,7Z,10Z,13Z,16Z,19Z)-4,7,10,13,16,19-Docosahexaenoic acid</i> Doconexent	DHA contributes to maintenance of normal brain function.		The claim may be used when the source contains 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.

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
	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).	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> <i>Arctocephalus pusillus</i> (Parts: Blubber); <i>Arctogadus glacialis</i> (Parts: Liver); <i>Clupea harengus</i> (Parts: Egg); <i>Clupea harengus</i> (Parts: Fish semen); <i>Cod Liver Oil fish</i> (Parts: Liver); <i>Cryptecodinium cohnii</i> (Parts: Whole); <i>Cystophora cristata</i> (Parts: Blubber); <i>Erignathus barbatus</i> (Parts: Blubber); <i>Euphausia pacifica</i> (Parts: Whole); <i>Euphausia superba</i> (Parts: Whole); <i>fish oil fish</i> (Parts: Whole); <i>Gadus macrocephalus</i> (Parts: Liver); <i>Gadus morhua</i> (Parts: Liver); <i>Gadus ogac</i> (Parts: Liver); <i>Halichoerus grypus</i> (Parts: Blubber); <i>Illex illecebrosus</i> (Parts: Whole); <i>Mytilus edulis</i> (Parts: Whole); <i>Pagophilus groenlandicus</i> (Parts: Blubber); <i>Pandalus borealis</i> (Parts: Internal shell); <i>Pandalus borealis</i> (Parts: Whole); <i>Phoca vitulina</i> (Parts: Blubber); <i>Pusa hispida</i> (Parts: Blubber); <i>Schizochytrium</i> spp. (Parts: Whole)</p> <p><i>Shark</i> (Parts: Liver); <i>Squid oil Squid</i> (Parts: Whole); <i>Theragra chalcogramma</i> (Parts: Liver); <i>Theragra chalcogramma</i> (Parts: Whole); <i>Thunnus thynnus</i> (Parts: Whole); <i>Ulkenia amoeboides</i> (Parts: Whole); <i>Ulkenia</i> spp. (Parts: Whole)</p> <p><b>Source Ingredients:</b> Omega-3 acid ethyl ester; Omega-3 Fatty acids</p>				

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
Docosapentaenoic acid (DPA) <i>(all-Z)-7,10,13,16,19-Docosapentaenoic acid</i> <i>cis-7,10,13,16,19-Docosapentaenoic acid</i>				
<b>Source materials:</b> <i>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)</i>				
Emu oil <i>Dromiceius oil</i> <i>Dromaius novaehollandiae</i> (Parts: Fat)			Must be derived only from <i>Dromaius novaehollandiae</i> .	
Omega-3 fatty acids without EPA/DHA				
<b>Source materials:</b> <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				
<b>Source materials:</b> <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)				
Omega-9 fatty acids				
<b>Source materials:</b> <i>Buglossoides arvensis (Parts: Seed); Hippophae rhamnoides (Parts: Fruit); Persea Americana (Parts: Fruit); Vitis vinifera (Parts: Seed)</i>				
Cholesterol (Pure form)			Approved for topical use only as an excipient.	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
<p>Lecithin  <i>Lecithin - hydrogenated</i>  <i>Hydrogenated egg yolk phospholipids</i>  <i>Hydrogenated lecithin</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>Lecithin liquid - soy phosphatidylserine-enriched soy</i>  <i>Soy phosphatidylserine-enriched soy lecithin powder</i>  <i>Lecithin powder - soy phosphatidylserine-enriched soy</i>  <i>1,2-Diacylglycero-3-phosphocholine</i>  <i>1,2-diacyl-sn-glycero-3-phosphocholine</i>                      Lecithin</p>			<p>The concentration must not exceed 5 % (hydrogenated lecithin)</p> <p>The concentration of soy phosphatidylserine must not exceed 15 %.</p>	
<p><b>Sub-ingredients:</b> Choline; Phosphatidic acids , Phosphatidyl ethanolamin, Phosphatidyl inositol  <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>Phospholipids</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>				
<p>Phytosterols  <i>Phytosterols</i>  <i>Plant sterols</i></p>	<p>Plant sterols/stanols contribute to the maintenance of normal 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>	

Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
<p>"Phytosterols" must be standardized 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  <b>Source material:</b> <i>Cissus quadrangularis</i> (Parts: Leaf); <i>Cissus quadrangularis</i> (Parts: Stem); <i>Helianthus annuus</i> (Parts: Seed); <i>Oil of vegetable</i> (Parts: Seed); <i>Phleum pratense</i> (Parts: Pollen); <i>Pinus elliottii</i> (Parts: Trunk bark oleogum resin); <i>Pinus taeda</i> (Parts: Trunk bark oleogum resin); <i>Prunus africana</i> (Parts: Stem bark); <i>Prunus africana</i> (Parts: Trunk bark); <i>Secale cereale</i> (Parts: Pollen); <i>Zea mays</i> (Parts: Pollen)</p>				
<p>Plant sterols Free plant sterols Phytosterols</p>	<p>Helps lower blood total and LDL cholesterol.  Helps maintain healthy cholesterol levels.</p>	<p>Consult a healthcare practitioner prior to use if you are pregnant or breastfeeding.  <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>1,49 g including at least 80 % Combined beta-Sitosterol, campesterol and Stigmasterol per day</p>
<p><b>Source Material:</b> <i>Arachis hypogaea</i> (Whole); <i>Brassica napus</i> (Whole); <i>Glycine max</i> (Seed); <i>Gossypium herbaceum</i> (Seed); <i>Olea europaea</i> (Whole) ; <i>Secale cereale</i> (Whole); <i>Triticum aestivum</i> (Whole); <i>Zea mays</i> (Whole)  <b>Sub-ingredients:</b> beta-Sitosterol, Campesterol, Combined beta-Sitosterol, Campesterol and Stigmasterol, Stigmasterol</p>				
<p>Plant sterol esters</p>	<p>Helps lower blood total and LDL cholesterol.  Helps maintain healthy cholesterol levels.</p>	<p>Consult a healthcare practitioner prior to use if you are pregnant or breastfeeding.  <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> 0,8 – 4,35 g including at least 80 % combined beta-Sitosterol, Campesterol and Stigmasterol per day</p>
<p><b>Source Material:</b> <i>Arachis hypogaea</i> (Whole); <i>Brassica napus</i> (Whole); <i>Glycine max</i> (Seed); <i>Gossypium herbaceum</i> (Seed); <i>Olea europaea</i> (Whole); <i>Secale cereale</i> (Whole); <i>Triticum aestivum</i> (Whole); <i>Zea mays</i> (Whole)</p>				



Oil	Health Supplement Claim	Specified Warning(s)	Other Instructions/ Directives	Maximum
<b>B Other Oils regarded as Health Supplements</b>				
Plant stanol esters	Helps lower blood total and LDL cholesterol.  Helps maintain healthy cholesterol levels.	Consult a healthcare 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>Adults dose(s):</b> 1,8 – 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>				