

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 South African Health Product Regulatory Authority's current thinking on the quality, safety, and efficacy of these medicines. It is not intended as an exclusive approach. The SAHPRA 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 SAHPRA 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 SAHPRA website www.sahpra.org.za

Further Annexures associated, but not yet included, with this guideline will be published for public comment prior to implementation.

First publication released for comment	November 2014
Deadline for comment	26 February 2015
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
Version 3_1 – addition of Annexure J for comment	April 2017
Version 3_2 – addition of Annexure H, K and L for comment	June 2018
Version 4 – guideline format, amendment of general provisions of the guideline and addition of Annexure G-L for implementation.	June 2020
Version 4_1 – addition of Annexures M and N for comment	March 2021
Version 4_2 – addition of Annexure O for comment, publication of propose amendment to Annexures C, F, H, J and M for public comment.	10 September 2021
Version 4_3 – addition of Annexure M-O for implementation, amendment to Annexures C, F, H, J for implementation	March 2022

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1 INTRODUCTION

i) Purpose

The purpose of this Guideline is to provide clear guidance with regard to the safety and efficacy (SE) requirements for registration of Health Supplements as a subset of complementary medicines in South Africa in the Common Technical Document (CTD) format. The intent of this document is to ensure that the levels of evidence for SE are rigorous enough to protect public health and maintain consumer confidence, while providing a clearly defined pathway to register health supplements.

It should be read together with the current versions of the following documents, including those referred to therein:

- 6.18 Screening Template for new applications for registration of a Complementary Medicine
- 7.01 Complementary Medicines - Discipline-Specific: Safety and Efficacy
- 7.02 Complementary Medicines - Roadmap and Transitional Process
- 7.03 Complementary Medicines - Use of the ZA CTD format in the preparation of a registration application
- 7.05 Complementary Medicines – Complementary Medicines: Quality
- 7.06 Complementary Medicines - Guidance on Specified Substances

Other SAHPRA guidelines may be referred to where appropriate. A copy of the referenced guideline should also be supplied.

ii) Scope and Overview

This guideline provides information for the registration of health supplements in South Africa. Products which include any substance of discipline-specific origin would need to follow the registration procedure indicated by the Guideline for Complementary Medicines - Quality, Safety and Efficacy (Discipline Specific).

In general Complementary Medicines (CMs) are used and sold by many people in RSA. These guidelines accompany the regulations dealing with the registration and post-marketing control of health supplements that are subject to the Medicines and Related Substances Act, 1965 (Act 101 of 1965) “the Act”. The guidelines give direction with regard to the required information but should not in themselves be regarded as the final reference point. Where the applicant wishes to use and submit information not found in these guidelines these would have to be justified scientifically and technically.

This mechanism of registration is restricted to schedule 0 substances identified as health supplements at specified dosages. It is acknowledged, however, that in some instances developments may dictate alternative approaches. When a deviation from a guideline is required, a detailed motivation giving the reason(s) for the deviation and justification for the alternative approach should be included in the expert report submitted with the application.

Guidelines are constantly evolving as a result of scientific developments and harmonisation of the requirements of regional and international regulatory authorities. The South African Health Products Regulatory Authority (SAHPRA / Authority) endeavours to regularly update the guidelines to reflect current thinking and keep its technical requirements and evaluation policies in line with “best international medicines regulatory practice”.

With respect to any registration of a medicine, it is a legal requirement that data submitted for evaluation should substantiate all claims and should meet technical requirements of quality, safety and efficacy of the product for the purposes for which it is intended. The nature of registration of health supplements is such that the SAHPRA wishes to ensure that products sold to the public which fall under this classification are of good quality and are safe. Efficacy of such products is established by the use of permitted claims

associated with individual ingredients. Allowance is made for the development of multiple substance formulations and their associated claims.

Over time pharmacological classifications that relate to health supplements will be called up in a staged and systematic process. This will be in line with the published recommendations contained in this document relevant to allowable levels and claims for various substances. Multiple substance formulations will be called up for registration when all lists have been populated.

[ANNEXURE A](#) is included to help decide what would be regarded as a Category D (Complementary Medicine) substance.

1.1 Definition

As per the General Regulations made in terms of the Medicines and Related Substances Act, 1965 (Act 101 of 1965):

“**health supplement**” means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by-

- (a) complementing health;
- (b) supplementing the diet; or
- (c) a nutritional effect,

and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act;

Substances that are excluded from being regarded as a health supplement include:

- injectable substances;
- substances scheduled 1 or higher (when indicated for any listed purposes in the schedule);
- substances not specified in the lists of included substances (unless duly motivated for inclusion as a health supplement as per [ANNEXURE B](#)), or
- isolated active ingredients not provided for in the annexures of health supplements.

Unless otherwise stated the dosage form is oral.

Annexure B may also be used for motivating a substance or source of material that is not stated in the annexures hereto.

Substances (S0) that may typically considered to be a health supplement include those substances listed under the following headings as per the attached annexures used alone or together:

Probiotics	ANNEXURE C
Prebiotics	ANNEXURE D
Vitamins	ANNEXURE E
Minerals	ANNEXURE F
Amino Acids	ANNEXURE G
Animal Extracts, Products and Derivatives	ANNEXURE H
Fats, Oils and Fatty Acids	ANNEXURE I
Carotenoids	ANNEXURE J
Polyphenols (including Bioflavonoids)	ANNEXURE K
Aminosaccharides	ANNEXURE L
Saccharides	ANNEXURE M
Enzymes	ANNEXURE N
Other	ANNEXURE O

1.2 Compliance with Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Agricultural and Collection Practices (GACP)

All manufacturers of complementary medicines shall comply with all relevant aspects of Good Manufacturing Practice as outlined in the latest version of the SAHPRA’s “GUIDE TO GOOD MANUFACTURING PRACTICE FOR MEDICINES IN SOUTH AFRICA” and Good Laboratory Practice as well as the WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants, if applicable. Any alternative standards must be specified, referenced and justified.

1.3 Format of submission

Data provided in applications for registration of complementary medicines should be in the latest version of the Common Technical Document (ZA-CTD) format as published by the SAHPRA.

2 ZA-CTD FORMAT

This section applies to the safety and efficacy aspects of an application for registration of complementary medicines submitted in ZA-CTD format. While the completed dossier should be checked for completeness, relevance and correctness, for ease of reference, relevant sections (not a complete list) of Module 1 and Module 2 with which information should be congruent/ should correspond, are indicated.

The requirements for the presentation, labelling, copies and relevant procedures for submission of applications, are stipulated in the General and Module 1 guidance.

The Technical Screening form should be completed to assist with checking of the contents before copying and submission.

Any information below should be provided in line with any further requirements stipulated in this Guideline.

The Guideline “Complementary Medicines - Use of the ZA-CTD Format in the Preparation of a Registration Application” should also be followed to determine completeness.

2.1 ZA Module 1: Administrative information

Refer to the General and Module 1 guidance.

The information under the following headings in particular should correspond with the information in Modules 4 and 5 if provided.

Module	Heading	Comments/Notes
1.0	Letter of application	Include a brief statement as to why the product meets the requirements for Health Supplement registration, specifically addressing the definition of a Health Supplement.
1.1	Comprehensive Table of Contents (ToC) Modules 1 to 5	Ensure that the volume numbers indicated in the Table of Contents (ToC) correlate with the volume numbers of the final submission copies. Refer to the General and Module 1 guidance for ‘Comprehensive Table of Contents’ and ‘Volume identification’
1.2.1	Application form	Ensure that the relevant product and other details correspond with all other Modules, e.g. the dosage form, active ingredient(s), strength, route of administration, manufacturer, packer

Module	Heading	Comments/Notes
1.2.2.3	Dossier product batch information	Ensure that the batch information corresponds with that in the relevant sections of Module 3, e.g. 3.2.P.5 and 3.2.P.8 and also 3.2.R.1
1.3.1	South African Package Insert	
1.3.1.1	Package insert	Ensure that the proprietary name, pharmacological classification dosage form, active ingredient(s), strength, composition, dosage regimen, identification, presentation and storage correspond with the information in all other Modules.
1.3.1.2	Standard References	
1.3.2	Patient Information Leaflet	
1.3.3	Labels	Reference to the relevant Annexures to this guideline to validate claims or in the case of claims pertaining to multiple substance formulation references listed that justify the medicine in terms of efficacy or safety
1.5	Specific requirements for different types of applications	
1.5.1	Literature-based submissions	Brief statement as to why the product meets the requirements for Health Supplement registration, reference to the published Annexures and the Health Supplement definition, expanded in Module 2.5. The suitability of any form of a Multiple Substance Formulation should be suitably briefly motivated and expanded on in Module 2.5.

2.2 ZA Module 2: Common Technical Document summaries

The information under the following headings in particular should correspond with the information in Modules 1.3, 1.5, as well as 4 and 5 if provided.

Module	Heading	Comments/Notes
2.1	CTD Table of Contents (ToC) Modules 2 to 5	Ensure that the volume numbers indicated in the Table of Contents (ToC) correlate with the volume numbers of the final submission copies.
2.2	Introduction	Provide an adequate introduction that would contextualise all presented information of the module including the relevance, necessity and appropriateness of Modules 2.4 and 2.5.
2.4	Non-clinical Overview	Any report on safety data should take into consideration the agreed format for the organisation of the non-clinical overview in the CTD. With respect to single substance formulations (SSF) a statement referencing the relevant Annexures can be included at the end of module 2.4. With respect to multiple substance formulations, in addition to reference to the annexures a list of relevant references for non-clinical data can be included at the end of module 2.4. The applicant will need to demonstrate that the proposed product contains the CM substances which correspond to a CM substance listed in the monograph.

Module	Heading	Comments/Notes
		<p>For multiple substance formulations (MSF) the assessment should not only focus on the single CM substances, but also an assessment of the combination is necessary.</p> <p>If risks have been identified, the report must explain why a positive benefit/risk-balance for its use is justified.</p>
2.5	Clinical overview	<p>For single substance formulations (SSF) reference to the relevant SAHPRA annexure will suffice provided that the indication used aligns with that annexure cited.</p> <p>For multiple substance formulations (MSF), reference to the relevant SAHPRA annexure(s) will be required in addition to:</p> <ul style="list-style-type: none"> • Justification of the selected indication; • The plausibility of the intended effects or efficacy of the medicinal product as well as information on the safety of use; and • The safety / efficacy assessments should not only focus on the single CM substances, but also an assessment of the combination is necessary. <p>The safety report for the multiple substance formulation (MSF) should ideally consider the following aspects of safety:</p> <ul style="list-style-type: none"> • the nature of the patient population and the extent of patient exposure/world-wide marketing experience to date • common and non-serious adverse events • serious adverse events <ul style="list-style-type: none"> methods to prevent, mitigate or manage adverse events • reactions due to overdose • long-term safety if relevant data is available • special patient populations e.g. children and pregnant or lactating women <p>If risks have been identified, the report must explain why a positive benefit/risk-balance for its use is justified. For example, if there are reports of serious adverse events, this must be balanced by sufficient evidence of appropriate benefit.</p> <p>In summary, 5 pivotal pieces of information must be discussed in this section of the dossier</p> <ol style="list-style-type: none"> a) citation of the relevant annexures b) indication wording c) strength/type of substance d) posology e) specific information on safe use and evidence of safety (multiple substance formulation only)

2.3 ZA Module 4: Non-clinical study reports

The information under the following headings in particular should correspond with the information in Modules 1.3, 1.5 and 2.

Module	Heading	Comments/Notes
4.1	Table of contents of Module 4	
4.2	Study Reports	If data are available or have been requested these should be provided and summarised in Module 2.6, for which the corresponding non-clinical overview would be included in Module 2.4 Any reports or studies referenced should be provided in full. Product specific study reports should be provided if available.
4.3	Literature References	Such references should be indexed following the agreed format for the organisation of Module 4.

2.4 ZA Module 5: Clinical study reports

Module	Heading	Comments/Notes
5.1	Table of contents of Module 5	
5.2	Study Reports	Not applicable for Health Supplements.
5.3	Literature References	Not applicable for Health Supplements.

3 SAFETY AND EFFICACY REQUIREMENTS

3.1 General

Underlying general principles regarding the registration and subsequent sale of Health Supplements, all products associated within this classification of Complementary Medicines shall:

- not contain any other substances except those stated on the label;
- not contain any human part or substance derived from any part of the human body;
- not contain substances declared by the Authority to be undesirable
- not contain scheduled substances listed as Schedule 1 or higher (when indicated for any listed purposes in the schedule);
- not be in the form of an injectable;
- not contain any active substance which is a chemically-defined isolated constituent of plants, fungi, algae, seaweeds, lichens, animals or minerals, or a combination of any one or more of these, that is documented to exert pharmacological action for medicinal use unless otherwise explicitly provided for in the list of substances associated with each classification;
- not contain agents that can lead to animal-transmissible diseases such as Transmissible Spongiform Encephalopathy (TSE), if they contain ingredients derived from animal sources; or
- not contain any additives as stipulated in 7.05 Complementary Medicine Registration Application ZA-CTD - Quality, Section 3.2.P.1 Additives including Flavouring and Colouring Agents.

Unless otherwise stipulated or provided for in another manner, health supplements may contain inactive ingredients that are classified as being Generally Regarded as Safe (GRAS) (<http://www.fda.gov/food/IngredientPackagingLabeling/GRAS/>). Where required make reference to the relevant GRAS listing and ensure that the substance complies with specified requirements.

All ingredients that may be delivered by a particular source material used in a health supplement should be identified and quantified (e.g. Magnesium ascorbate which may yield Magnesium and Vitamin C).

In general, health supplements should not be intended for supply to any children under the age of seven (7) months old unless where supplementation is medically warranted. Applicants are expected to include such information on their labelling (label/s, PIL, and PI).

3.1.1 Single Substance Formulations

Products containing single substances must conform to the dosage range provided in the relevant **ANNEXURE**. All products are required to display any prescribed warnings on the label, Package Insert and Patient Information Leaflet.

3.1.2 Multiple Substance Formulations

Applicants must present sufficient data demonstrating that the combination of such substances is safe in the dosages indicated. Ideally, specific data demonstrating the safe administration that is product specific should be included in any application. Literature (including references, history of use, other acceptable sources and monographs) must be submitted in substantiation of the safety profile of the product.

Any multiple substance formulation which contains a substance of discipline specific origin and other substances defined as health supplements must be submitted as a “combination product” Discipline Specific product. Applicants will need to demonstrate explicit, cogent philosophies of use amongst all ingredients and the traditional use and/or associated clinical evidence should accord with the provided claim. *For combination products refer to Guideline for Complementary Medicines - Discipline Specific: Safety and Efficacy.*

3.2 Labelling and Allowable Claims

Health supplements should be labelled according to labelling regulations as stipulated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

In general and unless specifically pre-approved as a disease risk reduction claim, indications that refer (explicitly or implied) to the treatment, or cure of specific diseases are not suitable for use for health supplements.

Reference to the relative Nutrient Reference Value (NRV) as a percentage may also be included on the label where relevant.

Any use of artificial sweeteners must be clearly stated as the Guideline: Complementary Medicines: Registration Application ZA-CTD - Quality.

The Patient Information Leaflet (PIL) should contain the statement that: "A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance."

3.2.1 Single Substance Formulations (SSF)

With reference to single substance formulations, only those claims provided in relevant **ANNEXURES** shall be permitted. The claim must match the intention of the product for the intended age or sex of the intended user, where applicable.

Dosage ranges provided for in the relevant **ANNEXURE** must be accounted for. Any substance which falls above the maximum will not permit registration as a Health Supplement. In the case of single substance formulations that fall below the minimum dosage, no claim may be used from those stipulated for the relevant substance(s). Claims for such products may be motivated provided that efficacy for the product (backed up by appropriate clinical evidence) can be proven related to such claim.

Products of single substance formulation sold without any claims will still be required to be registered and as such duly comply with any relevant Quality and Safety standards as provided herein.

For any substance contained in the **ANNEXURES** that does not carry an allowed health claim, an **ANNEXURE B** submission is required to be submitted for consideration prior to the consideration of any application which contains the substance as a SSF.

3.2.2 Multiple Substance Formulation (MSF) Claim Development

Claims for multiple substance formulations that conform to the definition of a health supplement may be formulated by the applicant should such not be provided for. Such claims will only be allowed should they conform to general principles contemplated below and with specific motivation that all ingredients would reasonably allow for the maintenance of such claim(s).

Due to the nature of multiple substance formulations, standardised claims are not always provided in the relevant **ANNEXURES** below. As such, applicants may be required to propose acceptable health supplement claim(s) that will adequately provide for the intended action(s) of the product.

A health supplement claim is a statement that indicates the intended beneficial effect of a product when used in accordance with its recommended conditions of use. The term "recommended use or purpose" is often used interchangeably with "health claim" or "indications for use." Claims associated with single substances may be used for the generation of claims related to multiple substance formulations, provided that the claim is sufficiently substantiated and accords with the other substances found in the formulation.

The choice of wording would include any of:

- General health enhancement without any reference to specific diseases¹
- Health maintenance, including nutritional support.

The use of the words “contributes”, “assists”, “helps”, “aids”, or “maintains” are the basis for claim formulation together with a beneficial physiological effect based on generally accepted scientific evidence. The applicant is expected to formulate a claim which matches the intention of the product with the intended age or sex of the intended user, where applicable.

The use of any claim must take account of minimum and maximum dosage levels prescribed for all substances where the claim must relate to levels permitted in the relevant **ANNEXURE** and must also account for the action of all other included substances in the product. A suitable justification from various allowable sources is required to substantiate any developed claim.

Below in **Table 1** is a list of terms and claims (including wording of similar meaning) that may **not** be used in association with the development of any claim. The list is not exhaustive and will be updated from time to time.

Table 1. Undesirable Terms and Claims for Health Supplements

Magical	Anti-ageing
Miracle / Miraculously	Longevity
The only product to use	Breast enhancement, enlargement, growth
World’s best	Penis enlargement
100 % safe	Height enhancement / growth
No side effects	Enhance intelligence / Increase IQ
Guaranteed	Hormone releaser/enhancer/amplifier
Other drugs/products cannot compare with it	Enhancement of sexual organs
Sensational relief	Sexual powers
The No. 1 (unless substantiated)	Arousal, Libido
Efficacious/Effective	Reference to the cure, treatment or diagnosis of any disease unless specifically provided for.
Perpetual youth	
<i>Or any terms that would reasonably infer a similar meaning or intention in English or any other language. Terms that generally imply or infer a superior action will not be permitted.</i>	

For multiple substance formulations where any constituents fall below the allowable minimums, no claim may be used from those stipulated for the relevant substance(s). Applicants may motivate for a claim for such products provided that efficacy for the product (backed up by appropriate clinical evidence) can be proven related to such claim.

¹Health enhancement claims apply to enhancement of normal health. They do not relate to enhancement of health from a compromised state.

4 GLOSSARY OF TERMS

This glossary is not exhaustive and does not include all terms applicable to the regulation of medicines and medical devices.

Refer also to the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, for definitions.

This glossary provides clarity on not only the use of terms in this document but also to the terminology that may be relevant to the registration process or CMs in general.

Act

The Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended

Active ingredient

The therapeutically active component in a medicine's final formulation that is responsible for its physiological or pharmacological action which may include a whole substance such as a single herb, and includes an Active Pharmaceutical Ingredient (API).

Active pharmaceutical ingredient (API)

Therapeutically active component in the final formulation of the medicine, or

A substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active ingredient.

Animal

An invertebrate or vertebrate member of the animal kingdom.

Applicant

means a person who submits an application for the registration of a medicine, an update or amendment to an existing registration.

Application

An application for registration made to the Authority in terms of the provisions of Act 101 of 1965.

Batch

"batch" or "lot" in relation to a medicine means a defined quantity of a medicine manufactured in a single manufacturing cycle and which has homogeneous properties;

To describe further, it is a quantity of a product that is:

- a) uniform in composition, method of manufacture and probability of chemical or microbial contamination; and
- b) made in one cycle of manufacture and, in the case of a product that is sterilised or freeze dried, sterilised or freeze dried in one cycle.

Bioburden

The quantity and characteristics of micro-organisms present in the medicines or substances or to which the medicines or substances may be exposed in a manufacturing environment.

Biological product

Products in which the active ingredient is a biological substance including antisera, antivenins, monoclonal antibodies and products of recombinant technology.

Biological substance

Substance of biological origin, which is frequently chemically complex and has a molecular mass greater than 1 000, such as hormones, enzymes and related substances, but not including herbal substances and antibiotics. Biological substances are not uniquely defined by a chemical name because their purity, strength and composition cannot readily be determined by chemical analysis. Substances which can be

isolated as a low molecular mass pure substance, such as purified steroids, digoxin and ergotamine, are considered to be chemical substances.

Clinical trial

means an investigation in respect of a medicine for use in humans or animals that involves human participants or animals and that is intended to-

- (a) discover or verify the clinical, pharmacological or pharmacodynamics effects of the medicine;
- (b) identify any adverse events;
- (c) study the absorption, distribution, metabolism and excretion of the medicine; or
- (d) ascertain its safety or efficacy.

Combination product

A single product that contains:

- a) a mixture of substances of various discipline-specific origin or philosophy;
- b) a mixture of at least one substance of discipline-specific origin and one or more health supplements; or
- c) a mixture of at least one substance of discipline-specific origin and one or more of its isolated constituents,

but does not include a multiple substance formulation of Health Supplements.

Complementary medicine

means any substance or mixture of substances that-

- (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by the Authority;
- (b) is used or purporting to be suitable for use or manufactured or sold for use-
 - (i) in maintaining, complementing or assisting the physical or mental state; or
 - (ii) to diagnose, treat, mitigate, modify, alleviate or prevent disease or illness or the symptoms or signs thereof or abnormal physical or mental state of a human being or animal; and
- (c) is used-
 - (i) as a health supplement; or
 - (ii) in accordance with those disciplines as determined by the Authority;

Dosage form

The pharmaceutical form in which the active ingredients and excipients, and physical formulation of a medicine is presented. *See also General Information Guideline*

Drug

See **Medicine**.

Excipient

Any component of a finished dosage form other than an active ingredient (in some cases the distinction between an active ingredient and an excipient may not be clear cut, e.g. use of sodium chloride to adjust tonicity of an injection is an excipient). An inactive ingredient.

Expiry date

means the date up to which a medicine will retain the strength and other properties which are mentioned on the label which strength and other properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used

Formulation

A list of the ingredients used in the manufacture of a dosage form and a statement of the quantity of each ingredient in a defined weight, volume, unit or batch.

Good manufacturing practice (GMP)

Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the medicine registration or product specification and is concerned with both production and quality control.

The acronym GMP is used internationally to describe a set of principles and procedures which, when followed by manufacturers of medicines, helps ensure that the products manufactured will have the required quality. A basic tenet of GMP is that quality cannot only be tested into a batch of product but must be built into each batch of product during all stages of the manufacturing process.

Health supplement

means any substance, extract or mixture of substances as determined by the Authority, sold in dosage forms used or purported for use in restoring, correcting or modifying any physical or mental state by-

- (a) complementing health;
- (b) supplementing the diet; or
- (c) a nutritional effect,

and excludes injectable preparations, medicines or substances listed as Schedule 1 or higher in the Act.

Inactive ingredient(s)

A substance or compound that is used in the manufacture of a pharmaceutical product and does not contribute to the therapeutic effect of the product, but is intended to enhance the consistency, appearance, integrity, stability, release characteristics, or other features of the product.

Indications

The specific therapeutic uses of medicines.

Individual patient data

In relation to complementary medicines, individual patient data means information, derived from clinical trials or observational data recorded during clinical practice, relating to individuals before, during and after the administration of the medicines to those individuals, including but not limited to, demographic, biochemical and haematological information.

Label

A display of printed information:

- a) on or attached to the complementary medicine **OR**
- b) on or attached to a container or primary pack in which the medicines are supplied **OR**
- c) supplied with such a container or pack **AND**

in accordance with Regulation 8 of the Regulations to the Medicines Act.

Manufacture

means all operations including purchasing of material, processing, production, packaging, releasing, storage and shipment of medicines and related substances in accordance with quality assurance and related controls.

Manufacturer

A person manufacturing a medicine and includes a manufacturing pharmacy.

Medicine

any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in-

- a) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in man; or

b) restoring, correcting or modifying any somatic or psychic or organic function in man, and includes any veterinary medicine.

Medicinal product

An alternative term to medicine for the finished, packaged product.

Pack size

The size of the product in terms of the quantity contained in the container (e.g. volume in a multi-use container) and / or the number of items in the primary / unit pack (e.g. number of tablets in a bottle).

Presentation

The way in which the complementary medicines are presented for sale, and includes matters relating to the name of the medicines, the labelling and packaging of the medicines, and any advertising or other informational material associated with the medicines.

Primary pack

The complete pack in which the complementary medicine, or the medicines and their container, are to be supplied to consumers.

Product

The commercial presentation or marketed entity of complementary medicine, *excluding pack size*.

Proprietary name

"proprietary name", "brand name" or "trade name" means the name which is unique to a particular medicine and by which the medicine is generally identified and which in the case of a registered medicine is the name approved in terms of section 15(5) of the Act.

Quality

Includes the composition, strength, potency, stability, sterility, purity, bioburden, design, construction and performance characteristics of the medicine.

Regulations

Regulations to the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended.

Route of administration

Route by which a complementary medicine is applied on or introduced into the body.

Sell

'sell' means sell by wholesale or retail and includes import, offer, advertise, keep, expose, transmit, consign, convey or deliver for sale or authorize, direct or allow a sale or prepare or possess for purposes of sale, and barter or exchange or supply or dispose of to any person whether for a consideration or otherwise; and 'sale' and 'sold' have corresponding meanings;

Strength

The quantity or quantities of an ingredient or ingredients in a medicine or a formulation expressed, for discrete units, as the nominal weight of the ingredient in the unit for other dosage forms, as the nominal weight or volume per unit weight or volume.

Therapeutic use / Therapeutic role

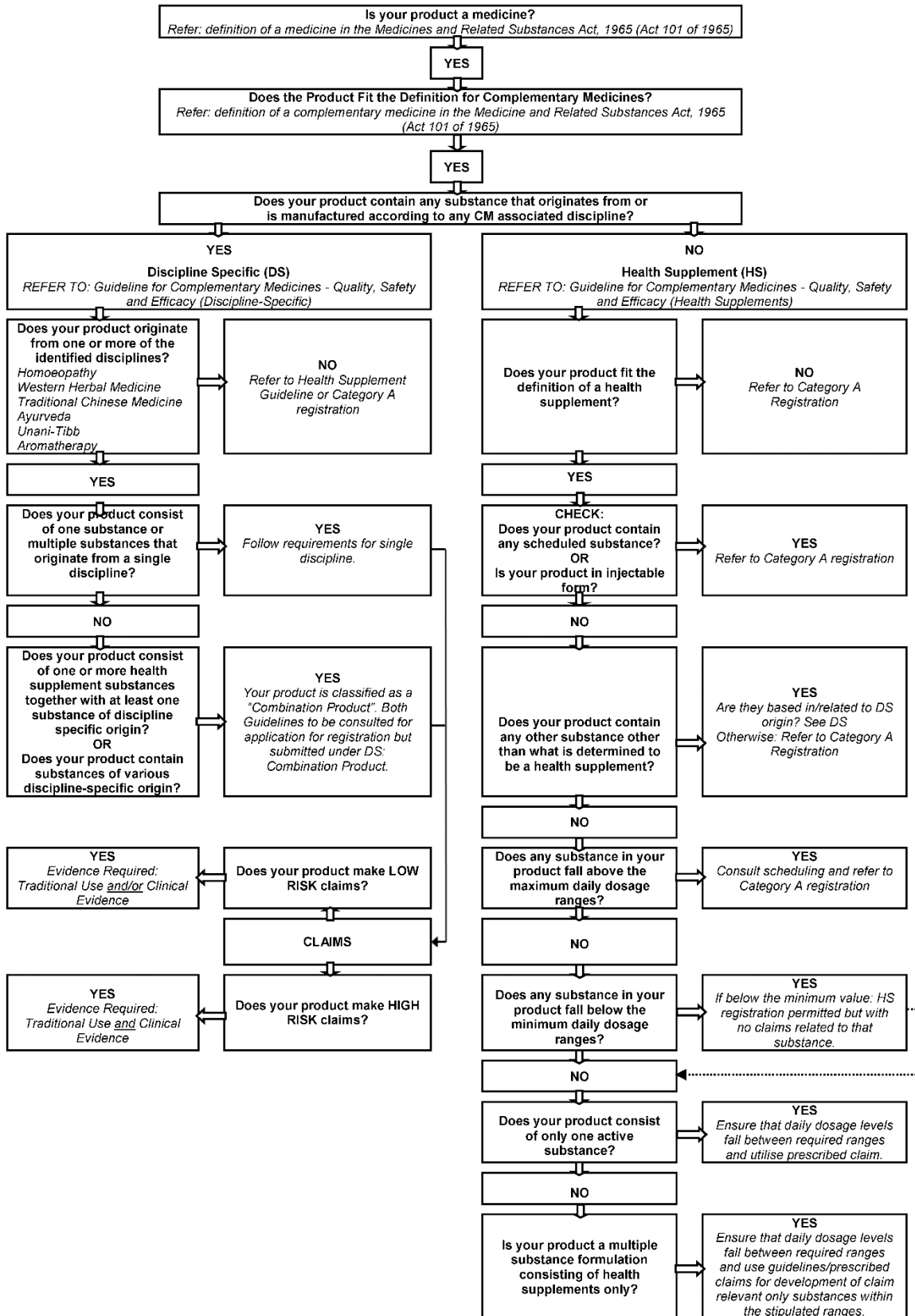
In the case of health supplements, means maintaining, complementing, or assisting the innate healing power or physical or mental state.

5 UPDATE HISTORY

Date	Reason for update	Version & publication
Nov 2014	First publication released for comment	v1 Nov 2013
26 Feb 2015	Deadline for comment	
June 2016	Deletion of 2 Quality Requirements for inclusion in separate guideline Inclusion of new section 2 ZACTD format Amendments to 1 i), 1.1, 1.2, 3.1, 3.2, 3.2.1, 4, Annexure E	v2 June 2016
April 2016	Addition of Annexures G and I for comment	v3 April 2016
April 2017	Addition of Annexure J for comment	v3_1 April 2017
June 2018	Addition of Annexure H, K and L for comment	v3_2 June 2018
June 2020	Addition of SAHPRA branding, naming and process and minor editing Section 1: Document sources, Definitions, updated list of annexures Section 3.2: PIL statement Glossary: updated for legislative changes Annexure A: Correction of line direction Annexure B: Amendment of format required Annexure C: Amendment and addition of substance listing Annexure E: Table formatting, Vitamin B3 sources and children maximums, Folic acid - sources and maximum amended. Annexure F: Clarification of which minerals are excluded for use in children, Boron - minimum amended, Chromium - maximum amended, Iodine - maximum amended, Selenium - maximum amended, Zinc - source statement added regarding Zinc picolinate. Annexure G-L: Added to Guideline 7.04.	v4 June 2020
March 2021	Version 4_1 – addition of Annexures M and N for comment	v4_1 March 2021
Sep 2021	Version 4_2 – addition of Annexure O for comment, publication of propose amendment to Annexures C, F, H, J and M for public comment.	v4_2 September 2021
Mar 2022	Version 4_3 – addition of Annexure M-O for implementation, amendment to Annexures C, F, H, J for implementation	v4_3 March 2022

ANNEXURE A

Category D Decision Tree



ANNEXURE B

Motivation for the inclusion of a non-listed Substance as Health Supplement

If any substance is not listed in the Health Supplement Annexures, an application may be submitted to the SAHPRA for consideration for the inclusion of any substance in the Health Supplement Annexures addressing the following:

- **EXECUTIVE SUMMARY:** An overview of the application and its justification.
- **TABLE OF CONTENT**
- **SECTION 1:** The recognition of another international regulatory body with a similar regulatory mechanism/standard as a nutritional substance, dietary supplement, nutritional form or health supplement.
- **SECTION 2:** The safety profile of the substance, including:
 - Therapeutic profile;
 - Minimum effective doses;
 - Maximum safe values (with specific age range values as appropriate);
 - Known side effects;
 - Contraindications; and
 - All known interactions (including interactions with medicines, other complementary medicines, health supplements, disease processes or diagnostics procedures).
- **SECTION 3:** The wording of the proposed health claim (indication) of the substance, including any supportive clinical evidence in support of the health claim and levels proposed.
- **SECTION 4:** Any other literature or motivation in substantiation of such substance as a health supplement and under specific circumstances.
- **FINAL PROPOSAL:** Consisting of a table composed of columns identical to the Annexure into which the substance is proposed to be introduced.

The origin of any complementary medicine is defined to be from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Authority. Where any medicine is not to be of plants, fungi, algae, seaweeds, lichens, minerals or animals the applicant should demonstrate that such a substance accords with its use as a health supplement with respect to substantiation of complementing health, dietary supplementation or nutritional support.

NOTE: Scheduled substances or injectable forms of substances will not be considered as health supplements. Chemically-defined isolated constituents of plants, fungi, algae, seaweeds, lichens or animals, or a combination of any one or more of these will generally not be regarded as health supplements, unless explicit motivation including recognition by other international regulatory bodies with a similar regulatory mechanism/standard and sufficient safety data is presented.

ANNEXURE C

Allowable Levels and claims: Probiotics

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

¹Minimum: Minimum Daily Levels Required for use of Health Supplement Claim

Probiotic	Health Supplement Claim	Minimum ¹
<p><i>Bifidobacterium adolescentis</i> <i>Bifidobacterium animalis</i> subsp. <i>animalis</i> <i>Bifidobacterium animalis</i> subsp. <i>lactis</i> <i>Bifidobacterium bifidum</i> <i>Bifidobacterium breve</i> <i>Bifidobacterium lactis</i> <i>Bifidobacterium longum</i> subsp. <i>infantis</i> <i>Bifidobacterium longum</i> subsp. <i>longum</i> <i>Lactobacillus acidophilus</i> <i>Lactobacillus brevis</i> <i>Lactobacillus caucasicus</i> <i>Lactobacillus casei</i> <i>Lactobacillus delbrueckii</i> <small>(including: <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> and <i>Lactobacillus delbrueckii</i> subsp. <i>delbrueckii</i>)</small> <i>Lactobacillus fermentum</i> <i>Lactobacillus gasseri</i> <i>Lactobacillus helveticus</i> <i>Lactobacillus johnsonii</i> <i>Lactobacillus paracasei</i> <i>Lactobacillus plantarum</i> <i>Lactobacillus reuteri</i> <i>Lactobacillus rhamnosus</i> <i>Lactobacillus salivarius</i> <i>Lactococcus lactis</i></p>	<p>“When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.”</p>	<p>≥1 x 10⁹ CFU per dosage unit (the minimum applies to an SSF or MSF in total)</p>

ANNEXURE D

Allowable Levels and claims: Prebiotics

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

¹**Minimum:** Minimum Daily Levels Required for use of Health Supplement Claim

²**Maximum:** Maximum Daily Levels Permitted as Health Supplement

Prebiotic	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Minimum¹	Maximum²
Inulin	Source of fibre for the maintenance of good health.	Prebiotics such as <i>[name of specific prebiotic]</i> beneficially affects the intestinal flora by selectively stimulating the growth of the good/ beneficial gut flora/micro-organisms / positively affects intestinal health. An average of 6 g prebiotics is needed daily for general digestive health	2 g Advisory: Average of 6 g daily	15 g
Fructooligosaccharides (FOS)	Prebiotics such as <i>[name of specific prebiotic]</i> beneficially affects the intestinal flora by selectively stimulating the growth of the good/ beneficial gut flora/micro-organisms / positively affects intestinal health.			
Galactooligosaccharides (GOS)				
Oligofructose				
Polydextrose				
Trans-galactooligosaccharide				
Xylooligosaccharides (fXOS)	An average of 6 g prebiotics is needed daily for general digestive health			

ANNEXURE E

Allowable Levels and claims: Vitamins

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

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin A To be calculated as retinol or retinol activity equivalents (RAE) i Vitamin A / All-trans retinol ii Vitamin A acetate/ All-trans retinyl acetate iii Vitamin A palmitate / All-trans retinyl palmitate iv Beta-carotene / All-trans beta-carotene* v Alpha-carotene / All-trans alpha-carotene* vi Beta-cryptoxanthin / All-trans beta-cryptoxanthin*	Contributes to the maintenance of normal vision	Contributes to the maintenance of eyesight, skin, membranes and immune function	10 months to 3 years 30 µg	600 µg	65 µg	≤ 5 000 I.U. (1 500 µg)
	Contributes to the development and maintenance of night vision	Contributes the development and maintenance of night vision	4 to 8 years 30 µg	900 µg		
	Has a role in the process of cell differentiation	Contributes to the development and maintenance of bones and teeth	9 to 13 years 30 µg	≤1 500 µg		
	Contributes to normal growth	A factor in the maintenance of good health				
	Contributes to normal iron metabolism	Multi-vitamin supplement/ Multi-vitamin/mineral supplement	14 to 18 years 65 µg	≤1 500 µg		
	Contributes to the maintenance of normal mucous membranes					
	Contributes to the maintenance of normal skin					

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
	Contributes to the normal function of the immune system Contributes to the development and maintenance of bones and teeth A factor in the maintenance of good health					
<p> <i>*1 µg Retinol Activity Equivalent (RAE) = 1 µg of all-trans-retinol</i> <i>1 µg Retinol Activity Equivalent (RAE) = 3,3 I.U. (international units) vitamin A</i> <i>1 µg Retinol Activity Equivalent (RAE) = 0,87 µg all-trans retinyl acetate</i> <i>1 µg Retinol Activity Equivalent (RAE) = 0,55 µg all-trans retinyl palmitate</i> </p> <p> Carotenes <i>From food sources:</i> <i>1 µg of all-trans-retinol = 12 µg all-trans dietary beta-carotene</i> <i>1 µg of all-trans-retinol = 24 µg other dietary pro-vitamin A carotenoids namely alpha-carotene and beta-cryptoxanthin information appears partly Food Cosmetics and Disinfectants Act</i> </p> <p> <i>From red palm oil:</i> <i>1 µg of all-trans-retinol = 2 µg all-trans-beta-carotene from red palm oil.</i> <i>1 µg of all-trans-retinol = 4 µg all-trans-alpha-carotene from red palm oil.</i> </p>						

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin B1 (Thiamine) To be calculated as Thiamine i thiamine hydrochloride ii thiamine monochloride iii thiamine mononitrate iv thiamine monophosphate v thiamine diphosphate vi thiamine pyrophosphate	Helps to metabolise carbohydrates Helps to metabolise proteins Helps to metabolise fats Contributes to normal energy-yielding metabolism Contributes to the normal functioning of the nervous system Contributes to normal psychological function Contributes to the normal function of the heart Contributes to normal growth A factor in the maintenance of good health	Helps to metabolise carbohydrates, fats and proteins Contributes to normal growth A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 13 years 0,04	≤100 mg	0,07 mg	≤ 100 mg
			14 to 18 years 0,07 mg	≤ 100 mg		
Vitamin B2 (riboflavin) To be calculated as riboflavin i riboflavin 5'-phosphate, sodium	Helps to metabolise carbohydrates Helps to metabolise fats and proteins Contributes to normal energy-yielding metabolism Contributes to the normal functioning of the nervous system	Helps to metabolise carbohydrates, fats and proteins Contributes to tissue formation A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 13 years 0,04 mg	≤100 mg	0,08 mg	≤ 100 mg
			14 to 18 years 0,08 g	≤1 00 mg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin B2 (riboflavin) cont.	<p>Contributes to the maintenance of normal mucous membranes</p> <p>Contributes to the maintenance of normal skin</p> <p>Contributes to the maintenance of normal vision</p> <p>Contributes to the normal metabolism of iron</p> <p>Contributes to the protection of cells from oxidative stress</p> <p>Contributes to the reduction of tiredness and fatigue</p> <p>Contributes to tissue formation</p> <p>A factor in the maintenance of good health</p>					
<p>Vitamin B3 (Nicotinic Acid, Niacin and derivatives)</p> <p>To be calculated as niacin*</p> <p>i nicotinic acid</p> <p>ii nicotinamide / niacinamide</p>	<p>Helps to metabolise carbohydrates, fats and proteins</p> <p>Contributes to the maintenance of normal mucous membranes</p>	<p>Helps to metabolise carbohydrates, fats and proteins</p> <p>Contributes to normal growth and development</p>	<p>1 to 3 years 0,6 mg</p>	10 mg	1 mg	≤ 35 mg
			<p>4 to 8 years 0,6 mg</p>	15 mg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
iii nicotinamide ascorbate / niacinamide ascorbate	Contributes to the maintenance of normal skin Contributes to normal psychological function	A factor in the maintenance of good health	9 to 13 years 0,6 mg	20 mg		
iv inositol hexanicotinate (inositol hexaniacininate)	Contributes to the reduction of tiredness and fatigue Contributes to normal growth and development A factor in the maintenance of good health	Multi-vitamin supplement/ Multi-vitamin/mineral supplement	14 to 18 years 1 mg	30 mg		
<i>*1 mg niacin equivalents (NE) = 1 mg niacin = 60 mg tryptophan</i>						
Vitamin B3 - Nicotinamide (niacinamide)	Helps to metabolise carbohydrates, fats and proteins	Helps to metabolise carbohydrates, fats and proteins	1 to 3 years 0,6 mg	10 mg	2,4 mg	≤ 500 mg
	Contributes to normal growth and development	Contributes to normal growth and development	4 to 8 years 0,6 mg	15 mg		
	A factor in the maintenance of good health	A factor in the maintenance of good health	9 to 13 years 0,6 mg	20 mg		
	A factor in the maintenance of good health	Multi- Vitamin supplement/ Multi-vitamin/mineral supplement	14 to 18 years 1 mg	30 mg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin B5 (Pantothenic Acid) To be calculated as d-pantothenic acid* i Calcium-d-pantothenate ii Calcium-dl-pantothenate iii Pantethine iv d-Panthenol/ Dexpanthenol v dl-Panthenol vi d-Pantothenic acid vii dl-Pantothenic acid	Helps to metabolise carbohydrates, fats and proteins Contributes to normal energy-yielding metabolism Contributes to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters Contributes to the reduction of tiredness and fatigue Contributes to normal mental performance Contributes to tissue formation A factor in the maintenance of good health	Helps to metabolise carbohydrates, fats and proteins	1 to 13 years 0,2 mg	≤ 200 mg	0,4 mg	≤ 200 mg
		Contributes to tissue formation	14 to 18 years 0,4 mg	≤ 200 mg		
		A factor in the maintenance of good health				
		Multi-vitamin supplement/ Multi-vitamin/mineral supplement				

1 mg d-pantothenic acid = 1,07 mg d-panthenol
1 mg d-pantothenic acid = 0,92 mg calcium-d-panthotenate
1 mg d-pantothenic acid = 0,5 mg dl-pantothenic acid
1 mg d-pantothenic acid = 0,54 mg dl-panthenol
1 mg d-pantothenic acid = 0,46 mg calcium-dl-panthotenate

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin B6 (pyridoxine) To be calculated as pyridoxine i Pyridoxal ii Pyridoxal hydrochloride iii Pyridoxal-5-phosphate (calcium salt) iv Pyridoxamine v Pyridoxamine-5-phosphate vi Pyridoxine vii Pyridoxine hydrochloride viii Pyridoxine-5-phosphate	Helps to metabolise carbohydrates, fats and proteins Contributes to normal cysteine synthesis Contributes to normal energy-yielding metabolism Contributes to normal functioning of the nervous system Contributes to normal homocysteine metabolism Contributes to normal protein and glycogen metabolism Contributes to normal psychological function Contributes to normal red blood cell formation Contributes to the normal function of the immune function Contributes to the reduction of tiredness and fatigue Contributes to the regulation of hormonal activity Contributes to tissue formation A factor in the maintenance of good health	Helps to metabolise carbohydrates, fats and proteins Contributes to tissue formation A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 3 years 0,05 mg	30 mg	0,1 mg	≤ 100 mg
			4 to 8 years 0,05 mg	40 mg		
			9 to 13 years 0,05 mg	60 mg		
			14 to 18 years 0,1 mg	80 mg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin B12 (cyanocobalamin) To be calculated as cyanocobalamin i cyanocobalamin ii hydroxocobalamin iii 5'-deoxy-adenosylcobalamin iv methylcobalamin	Helps to metabolise carbohydrates, fats and proteins Plays a role in the process of cell division Contributes to normal red blood cell formation Contributes to normal energy-yielding metabolism Contributes to normal functioning of the nervous system Contributes to normal homocysteine metabolism Contributes to normal psychological function Contributes to the normal function of the immune system Contributes to the reduction of tiredness and fatigue A factor in the maintenance of good health	Helps to metabolise carbohydrates, fats and proteins Contributes to normal red blood cell formation A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 13 years 0,09 µg	≤ 100 µg	0,14 µg	≤ 100 µg
			14 to 18 years 0,14 µg	≤ 100 µg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p>Vitamin C (Ascorbic Acid)</p> <p>To be calculated as vitamin C</p> <ul style="list-style-type: none"> i Ascorbic acid/Vitamin C ii Ascorbyl palmitate iii Calcium ascorbate iv Magnesium ascorbate v Niacinamide ascorbate/Nicotinamide ascorbate vi Potassium ascorbate vii Sodium ascorbate viii Zinc ascorbate 	Contributes to iron absorption from food	Helps to metabolise fats and proteins	1 to 3 years 2,2 mg	400 mg		
	Helps to metabolise fats and proteins	Helps in the development and maintenance of bones, cartilage, teeth and gums	4 to 8 years 2,2 mg	650 mg		
	Contributes to cell protection from free radical damage	Helps in connective tissue formation	9 to 13 years 2,2 mg	≤ 1 000 mg		
	Contributes to maintain the normal function of the immune system during and after intense physical stress (the claim may be used for a daily intake of 200 mg in addition to recommended daily intake).	Helps in wound healing	14 to 18 years 6 mg	≤ 1 000 mg		
	Contributes to normal collagen formation for the normal function of blood vessels	An antioxidant for the maintenance of good health			6 mg	≤ 1 000 mg
	Contributes to normal collagen formation for the normal function of bones	A factor in the maintenance of good health				
	Contributes to normal collagen formation for the normal function of cartilage	Multi-vitamin supplement/ Multi-vitamin/mineral supplement				
	Contributes to normal collagen formation for the normal function of gums					

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin C (Ascorbic Acid) cont.	<p>Contributes to normal collagen formation for the normal function of skin</p> <p>Contributes to normal collagen formation for the normal function of teeth</p> <p>Contributes to normal energy-yielding metabolism</p> <p>Contributes to normal functioning of the nervous system</p> <p>Contributes to normal psychological function</p> <p>Contributes to the normal function of the immune system</p> <p>Contributes to the protection of cells from oxidative stress</p> <p>Contributes to the reduction of tiredness and fatigue</p> <p>Contributes to the regeneration of the reduced form of Vitamin E</p> <p>Helps in connective tissue formation</p> <p>Contributes to wound healing</p>					

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin C (Ascorbic Acid) cont.	An antioxidant for the maintenance of good health A factor in the maintenance of good health					
Vitamin D To be calculated as ergocalciferol (D2) or cholecalciferol (D3) i Ergocalciferol* ii Cholecalciferol* *1 µg Cholecalciferol (Vitamin D3) and Ergocalciferol (Vitamin D2) = 40 I.U. (international units) vitamin D	Helps in the absorption and use of calcium and phosphorous Contributes to normal cell division Contributes to normal blood calcium levels Contributes to the development and maintenance of strong bones and teeth Contributes to the maintenance of normal muscle function Contributes to the normal function of the immune system Has a role in the process of cell division	Helps in the development and maintenance of bones and teeth Helps in the absorption and use of calcium and phosphorous A factor in the maintenance of good health Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 13 years 0,2 µg	≤ 25 µg	0,8 µg	≤ 1 000 I.U. (25 µg)
			14 to 18 years 0,8 µg	≤ 25 µg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin D cont.	Calcium intake, when combined with sufficient vitamin D, a healthy diet and regular exercise, may reduce the risk of developing osteoporosis. A factor in the maintenance of good health					
Vitamin E To be calculated as d-alpha-tocopherol i D-alpha-tocopherol ⁽¹⁾ ii DL-alpha-tocopherol iii D-alpha-tocopheryl acetate iv DL-alpha-tocopheryl acetate v D-alpha-tocopheryl acid succinate vi mixed tocopherols ⁽²⁾ vii tocotrienol tocopherol ⁽³⁾	Contributes to the protection of cells from oxidative stress A factor in the maintenance of good health	An antioxidant for the maintenance of good health A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 3 years 0,6 mg	100 mg	1 mg	≤ 400 I.U. (273,3 mg)
			4 to 8 years 0,6 mg	150 mg		
			9 to 13 years 0,6 mg	≤ 273,3 mg		
			14 to 18 years 1 mg	≤ 273,3 mg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p>(1) As d-alpha-tocopherol: $mg = TE \ 1 \ mg \ (d \ alpha \ tocopherol) = 1,49 \ I.U. \ (international \ units) \ of \ vitamin \ E$</p> <p>(2) alpha-tocopherol < 20 %, beta-tocopherol < 10 %, gamma-tocopherol 50-70 % and delta-tocopherol 10-30 %</p> <p>(3) Typical levels of individual tocopherols and tocotrienols:</p> <ul style="list-style-type: none"> • 115 mg/g alpha-tocopherol (101 mg/g minimum), • 5 mg/g beta-tocopherol (< 1 mg/g minimum), • 45 mg/g gamma-tocopherol (25 mg/g minimum), • 12 mg/g delta-tocopherol (3 mg/g minimum), • 67 mg/g alpha-tocotrienol (30 mg/g minimum), • < 1 mg/g beta-tocotrienol (< 1 mg/g minimum), • 82 mg/g gamma-tocotrienol (45 mg/g minimum), • 5 mg/g delta-tocotrienol (< 1 mg/g minimum) <p>OR</p> <p><i>D-alpha tocopherol equivalent on the basis that 3,3 mg alpha-tocotrienol or 10 mg gamma-tocopherol are equivalent to 1 mg D-alpha tocopherol.</i></p>						
Vitamin K i Vitamin K1 / phylloquinone / phytomenadione / phytonadione ii Vitamin K2 / menaquinone / menatetrenone	Contributes to the maintenance of normal bones	Contributes to the maintenance of normal bones	1 to 3 years 3 ug	30 ug	6 ug	≤ 120 ug
			4 to 8 years 3 ug	55 ug		
	A factor in the maintenance of good health	A factor in the maintenance of good health	9 to 13 years 3 ug	60 ug		
			14 to 18 years 6 ug	60 ug		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Vitamin H (Biotin) i D-biotin ii Biocytin	Helps the body to metabolise carbohydrates, fats and proteins Contributes to normal energy-yielding metabolism Contributes to normal functioning of the nervous system Contributes to normal psychological function Contributes to the maintenance of normal hair Contributes to the maintenance of normal mucous membranes Contributes to the maintenance of normal skin A factor in the maintenance of good health	Helps the body to metabolise carbohydrates, fats and proteins A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 13 years 1 ug	≤ 500 ug	1,8 ug	≤ 500 ug
			14 to 18 years 1,8 ug	≤ 500 ug		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Folic Acid To be calculated as folic acid* i pteroylmonoglutamic acid ii calcium-L-methylfolate Accepted source: 5-Methyltetrahydrofolic acid	Contributes to maternal tissue growth during pregnancy Helps the body to metabolise proteins Helps to form red blood cells Helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy A factor in the maintenance of good health	Helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy Helps the body to metabolise proteins Helps to form red blood cells A factor in the maintenance of good health Multi-vitamin supplement/ Multi-vitamin/mineral supplement	1 to 13 years 15 µg	≤ 200 µg	30 ug	≤ 500 ug
			14 to 18 years 30 µg	≤ 500 µg		
*1 µg dietary folate equivalents (DFE) = 1 µg food folate 1 µg dietary folate equivalents (DFE) = 0,6 µg as supplement consumed with food 1 µg dietary folate equivalents (DFE) = 0,5 µg as supplement taken on an empty stomach						

ANNEXURE F

Allowable Levels and claims: Minerals

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

Amino acid chelates as acceptable sources of minerals:

Due to the non-specific description of the ligand in the amino acid chelate, it is theoretically possible that an amino acid chelate may contain amino acids which are separately listed as health supplements in Annexure G of Guideline 7.04, with specified dosage ranges and may contribute to the total values of more than one substance per dosage unit. Different amino acids may be used in different chelation formulations (e.g. Glycine, Methionine, Lysine, Aspartate) already identified as source materials for various minerals. In order to safeguard the rights of consumers and where the intake of substances may impact their health or disease status, not only should these be specifically identified, but the amount of amino acid delivered from the source materials identified must therefore be determined as these may constitute active ingredients to a product formulation and should not exceed or contribute to exceeding the maximum daily value specified in Annexure G of Guideline 7.04.

Where the presence of these amino acids do not contribute to the indication of the complementary medicine, it shall be sufficient to identify their presence and level in the Professional Information (PI) and Patient Information Leaflet (PIL) only.

The subpopulation "Adults" is the only acceptable subpopulation for the following medicinal ingredients: Boron, Chromium, Manganese, Molybdenum, Potassium, Selenium, Vanadium, Zinc sourced from zinc picolinate

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Boron <i>Boracic acid/Orthoboric acid</i> <i>Borax/Disodium tetraborate / Sodium baborate / Sodium borate/ Sodium pyroborate / Sodium tetraborate</i> <i>Boron aspartate</i> <i>Boron citrate</i> <i>Boron glycinate</i> <i>Boron hydrolyzed animal protein (HAP) chelate</i> <i>Boron hydrolyzed vegetable protein (HVP) chelate</i> <i>Calcium borate / Calcium pyroborate / Calcium tetraborate</i> <i>Calcium borogluconate / Calcium diborogluconate</i> <i>Calcium fructoborate</i> <i>Magnesium borate</i>	A factor in the maintenance of good health. Helps maintain healthy calcium metabolism.	A factor in the maintenance of good health	<i>Not permitted.</i>	<i>Not permitted.</i>	0,7 mg	≤ 3 mg
		Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p>Calcium</p> <p><i>Including the following sources:</i></p> <p><i>Bone meal*</i></p> <p><i>Calcium acetate</i></p> <p><i>Calcium ascorbate</i></p> <p><i>Calcium bisglycinate</i></p> <p><i>Calcium carbonate</i></p> <p><i>Calcium chloride</i></p> <p><i>Calcium chloride, hexahydrate</i></p> <p><i>Calcium chloride dehydrate</i></p> <p><i>Calcium citrate</i></p> <p><i>Calcium citrate malate</i></p> <p><i>Calcium citrate tetrahydrate</i></p> <p><i>Calcium fumarate</i></p> <p><i>Calcium glubionate anhydrous</i></p> <p><i>Calcium glubionate monohydrate</i></p> <p><i>Calcium gluceptate</i></p> <p><i>Calcium gluconate</i></p> <p><i>Calcium gluconate monohydrate</i></p> <p><i>Calcium glutarate</i></p> <p><i>Calcium glycerophosphate</i></p> <p><i>Calcium hydrolyzed animal protein (HAP) chelate</i></p> <p><i>Calcium hydrolyzed vegetable protein (HVP) chelate</i></p> <p><i>Calcium hydroxide</i></p> <p><i>Calcium lactate</i></p>	<p>Contributes to the development and maintenance of bones and teeth</p> <p>Contributes to normal muscle function</p> <p>Contributes to normal blood clotting</p> <p>Contributes to normal energy-yielding metabolism</p> <p>Contributes to normal neurotransmission</p> <p>Contributes to normal function of digestive enzymes</p> <p>Has a role in the process of cell division and specialisation</p> <p>Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis</p> <p>A factor in the maintenance of good health</p>	<p>Contributes to the development and maintenance of bones and teeth</p> <p>A factor in the maintenance of good health</p> <p>Mineral supplement/ Vitamin/Mineral supplement/ Multi-mineral supplement</p> <p>Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis</p>	<p>1 to 18 years</p> <p>65 mg</p>	<p>≤ 1 300 mg</p>	<p>65 mg</p>	<p>≤ 1 300 mg</p>

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Calcium lactate gluconate Calcium lactate pentahydrate Calcium lactate trihydrate Calcium lactobionate dihydrate Calcium levulinate Calcium lactate pentahydrate Calcium lactate trihydrate Calcium lactobionate dihydrate Calcium levulinate dihydrate Calcium malate Calcium oxide Calcium phosphate, dibasic Calcium phosphate, monobasic Calcium pidolate Calcium pyrophosphate Calcium silicate Calcium sodium lactate Calcium succinate Calcium sulfate Calcium sulphate dihydrate Coral (Whole) Dolomite Oyster (Shell)						
*When bone meal is used as a source material for calcium or phosphorus, it must be sourced from a non-human animal that is not susceptible to Transmissible Spongiform Encephalopathy (TSE) diseases, including Bovine Spongiform Encephalopathy (BSE)						
Chromium Chromium (III) bisglycinate/Chromic bisglycinate Chromium (III) chloride/Chromic chloride Chromium (III) chloride hexahydrate/Chromic chloride hexahydrate	Contributes to normal macronutrient metabolism Contributes to the maintenance of normal blood glucose levels Helps the body to metabolise carbohydrates and fats	Provides support for healthy glucose metabolism Helps the body to metabolise carbohydrates and fats A factor in the maintenance of good health	Not permitted.	Not permitted.	2,2 µg	≤ 200 µg

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p><i>Chromium (III) citrate/Chromic citrate</i></p> <p><i>Chromium (III) dinicotinate/Chromic dinicotinate</i></p> <p><i>Chromium (III)-enriched yeast/Chromic-enriched yeast</i></p> <p><i>Chromium (III) fumarate/Chromic fumarate</i></p> <p><i>Chromium (III) glutarate/Chromic glutarate</i></p> <p><i>Chromium (III) HAP chelate/Chromic HAP chelate</i></p> <p><i>Chromium (III) HVP chelate/Chromic HVP chelate</i></p> <p><i>Chromium (III) malate/Chromic malate</i></p> <p><i>Chromium (III) nicotinate / Chromic nicotinate</i></p> <p><i>Chromium (III) pidolate / Chromic pidolate</i></p> <p><i>Chromium (III) polynicotinate / Chromic polynicotinate</i></p> <p><i>Chromium (III) potassium sulfate dodecahydrat / Chromic potassium sulfate dodecahydrate</i></p>	<p>A factor in the maintenance of good health</p>	<p>Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement</p>				
<p>Copper</p> <p><i>Calcium copper edetate</i></p> <p><i>Copper (II) acetate/Cupric acetate</i></p> <p><i>Copper (II) bisglycinate/Cupric bisglycinate</i></p>	<p>Contributes to normal iron transport and metabolism</p> <p>Contributes to the protection of cells from oxidative stress</p> <p>Contributes to normal energy-yielding metabolism</p>	<p>Helps to produce and repair connective tissue</p> <p>Helps to form red blood cells</p> <p>A factor in the maintenance of good health</p>	<p>1 to 3 years 35 µg</p> <p>4 to 8 years 35 µg</p> <p>9 to 18 years 35 µg</p>	<p>700 µg</p> <p>2 500 µg</p> <p>≤ 4 000 µg</p>	<p>65 µg</p>	<p>≤ 4 mg</p>

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p><i>Copper (II) carbonate/Cupric carbonate</i></p> <p><i>Copper (II) chloride/Cupric chloride</i></p> <p><i>Copper (II) chloride dihydrate/Cupric chloride dihydrate</i></p> <p><i>Copper (II) citrate/Cupric citrate</i></p> <p><i>Copper (II) fumarate/Cupric fumarate</i></p> <p><i>Copper (II) gluconate/Cupric gluconate</i></p> <p><i>Copper (II) glutarate/Cupric glutarate</i></p> <p><i>Copper (II) HAP chelate/Cupric HAP chelate</i></p> <p><i>Copper (II) HVP chelate/Cupric HVP chelate</i></p> <p><i>Copper (II) malate/Cupric malate</i></p> <p><i>Copper (II) succinate/Cupric succinate</i></p> <p><i>Copper (II) sulfate/Cupric sulfate</i></p> <p><i>Copper (II) sulfate pentahydrate/Cupric sulfate pentahydrate</i></p>	<p>Contributes to normal functioning of the nervous system</p> <p>Contributes to normal hair pigmentation</p> <p>Contributes to normal skin pigmentation</p> <p>Contributes to maintenance of normal connective tissues</p> <p>Contributes to the normal function of the immune system</p> <p>Helps to produce and repair connective tissue</p> <p>Helps to form red blood cells</p> <p>A factor in the maintenance of good health</p>	<p>Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement</p>				
<p>Iodine</p> <p><i>sodium iodide</i></p> <p><i>sodium iodate</i></p> <p><i>potassium iodide</i></p> <p><i>potassium iodate</i></p>	<p>Contributes to the normal production of the thyroid hormones and normal thyroid function</p>	<p>Contributes to the normal production of the thyroid hormones and normal thyroid function</p>	<p>1 to 3 years 6 µg</p>	<p>133 µg</p>	<p>14 µg</p>	<p>≤ 150 µg</p>
	<p>Contributes to normal cognitive function</p>	<p>A factor in the maintenance of good health</p>	<p>4 to 13 years 6 µg</p>	<p>≤ 150 µg</p>		
	<p>Contributes to normal energy-yielding metabolism</p>				<p>≤ 150 µg</p>	

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
	<p>Contributes to normal functioning of the nervous system</p> <p>Contributes to the maintenance of normal skin</p> <p>A factor in the maintenance of good health</p>	<p>Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement</p>	<p>> 14 years 14 µg</p>			
<p>Iron</p> <p><i>Ferritin</i></p> <p><i>Ferrocholate</i></p> <p><i>Iron, carbonyl (not pentacarbonyl)</i></p> <p><i>Iron, electrolytic</i></p> <p><i>Iron HAP chelate</i></p> <p><i>Iron HVP chelate</i></p> <p><i>Iron, reduced</i></p> <p><i>Iron (II) ascorbate/Ferrous ascorbate</i></p> <p><i>Iron (II) aspartate/Ferrous aspartate / Ferrous chloride</i></p> <p><i>Iron (II) aspartate tetrahydrate/ Ferrous aspartate tetrahydrate</i></p> <p><i>Iron (II) bisglycinate / Ferrous bisglycinate</i></p> <p><i>Iron (II) carbonate / Ferrous carbonate</i></p> <p><i>Iron (II) chloride</i></p> <p><i>Iron (II) chloride tetrahydrate/Ferrous chloride tetrahydrate</i></p> <p><i>Iron (II) citrate/Ferrous citrate</i></p> <p><i>Iron (II) fumarate/Ferrous fumarate</i></p> <p><i>Iron (II) gluceptate/Ferrous gluceptate</i></p> <p><i>Iron (II) gluconate/Ferrous gluconate</i></p>	<p>Contributes to normal energy - yielding metabolism</p> <p>Contributes to normal oxygen transport in the body</p> <p>Contributes to normal formation of red blood cells and haemoglobin and proper function</p> <p>Contributes to normal cognitive function</p> <p>Contributes to the reduction of tiredness and fatigue</p> <p>Contributes to the normal functioning of the immune system</p> <p>A factor in the maintenance of good health</p>	<p>Helps to form red blood cells and helps in their proper function</p> <p>A factor in the maintenance of good health</p> <p>Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement</p>	<p>0 to 18 years 0,6 mg</p>	<p>≤ 24 mg</p>	<p>1,4 mg</p>	<p>≤ 24 mg</p>

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Iron (II) gluconate dihydrate/Ferrous gluconate dihydrate Iron (II) glutarate/Ferrous glutarate Iron (II) glycine sulfate/Ferrous glycine sulfate Iron (II) lactate/Ferrous lactate Iron (II) lactate trihydrate/Ferrous lactate trihydrate Iron (II) malate/Ferrous malate Iron (II) oxalate/Ferrous oxalate Iron (II) oxalate dihydrate/Ferrous oxalate dihydrate Iron (II) succinate/Ferrous succinate Iron (II) sulfate/Ferrous sulfate Iron (II) sulfate dried (monohydrate)/Ferrous sulfate dried (monohydrate) Iron (II) sulfate heptahydrate/Ferrous sulfate heptahydrate Iron (II) tartrate/Ferrous tartrate Iron (III) ammonium citrate/Ferric ammonium citrate Iron (III) citrate/Ferric citrate Iron (III) glycerophosphate / Ferric glycerophosphate Iron (III) phosphate / Ferric phosphate Iron (III) pyrophosphate / Ferric pyrophosphate						

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults			
			Minimum	Maximum	Minimum	Maximum		
Magnesium <i>Magnesium acetate</i> <i>Magnesium acetate tetrahydrate</i> <i>Magnesium ascorbate</i> <i>Magnesium aspartate</i> <i>Magnesium bisglycinate</i> <i>Magnesium carbonate</i> <i>Magnesium chloride</i> <i>Magnesium chloride hexahydrate</i> <i>Magnesium citrate</i> <i>Magnesium fumarate</i> <i>Magnesium gluceptate</i> <i>Magnesium gluconate</i> <i>Magnesium gluconate dihydrate</i> <i>Magnesium glutarate</i> <i>Magnesium glycerophosphate</i> <i>Magnesium HAP chelate</i> <i>Magnesium HVP chelate</i> <i>Magnesium hydroxide</i> <i>Magnesium lactate</i> <i>Magnesium malate</i> <i>Magnesium oxide</i> <i>Magnesium phosphate dibasic trihydrate / Magnesium hydrogen phosphate trihydrate /</i>	Contributes to normal energy - yielding metabolism	Helps to metabolise carbohydrates, fats and proteins	1 to 3 years 12 mg	65 mg	20 mg	≤ 250 mg		
	Contributes to normal functioning of the nervous system	Contributes to the development and maintenance of bones and teeth	4 to 8 years 12 mg	≤ 100 mg				
	Contributes to normal electrolyte balance	Contributes to tissue formation	9 to 13 years 12 mg	≤ 250 mg				
	Contributes to a reduction of tiredness and fatigue	Contributes to the maintenance of normal muscle function	14 to 18 years 20 mg	≤ 250 mg				
	Contributes to the maintenance of normal muscle function	A factor in the maintenance of good health						
	Contributes to normal protein synthesis	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement						
	Contributes to normal psychological function							
	Has a role in the process of cell division							
	Contributes to the maintenance of normal bones							
	Contributes to the maintenance of normal teeth.							

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p><i>Dimagnesium phosphate trihydrate</i></p> <p><i>Magnesium phosphate tribasic tetra-, penta-, or octahydrate / Trimagnesium phosphate tetra-, penta-, or octahydrate</i></p> <p><i>Magnesium pidolate</i></p> <p><i>Magnesium succinate</i></p> <p><i>Magnesium sulfate</i></p> <p><i>Magnesium sulfate heptahydrate</i></p>	<p>Helps to metabolise carbohydrates, fats and proteins</p> <p>Contributes to tissue formation</p> <p>A factor in the maintenance of good health</p>					
<p>Manganese</p> <p><i>Manganese (II) bisglycinate / Manganous bisglycinate</i></p> <p><i>Manganese (II) chloride / Manganous chloride</i></p> <p><i>Manganese (II) chloride tetrahydrate / Manganous chloride tetrahydrate</i></p> <p><i>Manganese (II) citrate / Manganous citrate</i></p> <p><i>Manganese (II) gluconate / Manganous gluconate</i></p> <p><i>Manganese (II) glycerophosphate / Manganous glycerophosphate</i></p> <p><i>Manganese (II) HAP chelate / Manganous HAP chelate</i></p> <p><i>Manganese (II) HVP chelate / Manganous HVP chelate</i></p> <p><i>Manganese (II) sulfate / Manganous sulfate</i></p> <p><i>Manganese (II) sulfate monohydrate / Manganous sulfate monohydrate</i></p> <p><i>Manganese (II) sulfate tetrahydrate / Manganous sulfate tetrahydrate</i></p>	<p>Helps the body to metabolise carbohydrates, fats and protein</p> <p>Contributes to the development and maintenance of normal bones</p> <p>Contributes to the protection of cells from oxidative stress</p> <p>Contributes to normal energy-yielding metabolism</p> <p>Contributes to the normal formation of connective tissue</p> <p>A factor in the maintenance of good health</p>	<p>Helps the body to metabolise carbohydrates, fats and protein</p> <p>Contributes to the development and maintenance of normal bones</p> <p>A factor in the maintenance of good health</p> <p>Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement</p> <p>Contributes to the maintenance of normal electrolyte balance in anticipation of extended</p>	<i>Not permitted.</i>	<i>Not permitted.</i>	0,13 mg	4 mg

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Manganese (IV) dioxide		(greater than 60 min), high intensity exercise.				
Molybdenum Ammonium molybdate (VI) Ammonium molybdate (VI) tetrahydrate Molybdenum bisglycinate Molybdenum citrate Molybdenum fumarate Molybdenum glutarate Molybdenum HAP chelate Molybdenum HVP chelate Molybdenum malate Molybdenum succinate Sodium molybdate (VI) Sodium molybdate (VI) dihydrate	Contributes to normal sulphur amino acid metabolism Helps the body to metabolise proteins A factor in the maintenance of good health	Helps the body to metabolise proteins A factor in the maintenance of good health Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement	Not permitted.	Not permitted.	2,5 µg	≤ 230 µg
Phosphorus Bone meal* Calcium glycerophosphate Calcium phosphate dibasic Calcium phosphate monobasic Calcium phosphate tribasic Potassium phosphate dibasic	Helps to metabolise carbohydrates, fats and proteins Contributes to the development and maintenance of normal bones Contributes to normal function of the cell membranes	Helps to metabolise carbohydrates, fats and proteins Contributes to the development and maintenance of normal bones and teeth A factor in the maintenance of good health	1 to 18 years 62 mg	≤ 250 mg	62 mg	≤ 250 mg

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<i>Potassium phosphate monobasic</i> <i>Sodium phosphate dibasic</i> <i>Sodium phosphate dibasic dihydrate</i> <i>Sodium phosphate dibasic dodecahydrate</i> <i>Sodium phosphate dibasic heptahydrate</i> <i>Sodium phosphate monobasic</i> <i>Sodium phosphate monobasic dihydrate</i> <i>Sodium phosphate monobasic monohydrate</i>	Contributes to energy-yielding metabolism Contributes to the development and maintenance of normal teeth Helps to metabolise carbohydrates, fats and proteins A factor in the maintenance of good health	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				
<p><i>*When bone meal is used as a source material for calcium or phosphorus, it must be sourced from a non-human animal that is not susceptible to Transmissible Spongiform Encephalopathy (TSE) diseases, including Bovine Spongiform Encephalopathy (BSE)</i></p>						
Potassium <i>Potassium acetate</i> <i>Potassium aspartate</i> <i>Potassium bicarbonate</i> <i>Potassium carbonate</i> <i>Potassium chloride</i> <i>Potassium citrate</i> <i>Potassium citrate monohydrate</i> <i>Potassium gluconate</i> <i>Potassium glycerophosphate</i> <i>Potassium glycerophosphate trihydrate</i> <i>Potassium sulphate</i>	Contributes to normal functioning of the nervous system Contributes to normal muscle function Contributes to the maintenance of normal blood pressure A factor in the maintenance of good health	A factor in the maintenance of good health Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement	Not permitted.	Not permitted.	75 mg	≤1 500 mg
		Contributes to the maintenance of normal electrolyte balance in anticipation of extended (greater than 60 min), high intensity exercise.			98 mg	600 mg

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Selenium <i>Monohydrated selenium dioxide</i> <i>Selenium citrate</i> <i>Selenium HAP chelate</i> <i>Selenium HVP chelate</i> <i>Selenium yeast</i> <i>Selenocysteine</i> <i>Selenomethionine</i> <i>Sodium selenate</i> <i>Sodium selenite</i>	Contributes to the protection of cells from oxidative stress Contributes to normal spermatogenesis Contributes to the maintenance of normal hair Contributes to the maintenance of normal nails Contributes to the normal function of the immune system Contributes to normal thyroid function An antioxidant for the maintenance of good health A factor in the maintenance of good health	An antioxidant for the maintenance of good health A factor in the maintenance of good health Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement	<i>Not permitted.</i>	<i>Not permitted.</i>	3,5 µg	≤ 200 µg
Silicon <i>Calcium silicate;</i> <i>Choline-stabilised orthosilicic acid;</i> <i>Orthosilicic acid;</i> <i>Silicic acid;</i> <i>Silicon dioxide;</i> <i>Silicon hydrolyzed animal protein (HAP) chelate;</i> <i>Silicon hydrolyzed vegetable protein (HVP) chelate,</i> <i>Sodium metasilicate</i>	Helps to maintain healthy hair, nails and/or skin.	Mineral supplement.	<i>Not permitted.</i>	<i>Not permitted.</i>	10 mg	84 mg
	Silicon from <i>Equisetum arvense</i>: Data (or certification) must be available upon request to show that thiaminase has been inactivated. If silicon is sourced from <i>Equisetum arvense</i> herb top, it should be isolated and purified.					
Vanadium <i>Sodium metavanadate</i> <i>Vanadium citrate</i> <i>Vanadium HAP chelate</i> <i>Vanadium HVP chelate</i> <i>Vanadyl sulfate (IV)</i>	A factor in the maintenance of good health Mineral supplement	A factor in the maintenance of good health Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement	<i>Not permitted.</i>	<i>Not permitted.</i>	9,1 µg	≤ 182 µg

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Zinc (and derivatives) Including: <i>Zinc acetate</i> <i>Zinc acetate dihydrate</i> <i>Zinc bisglycinate</i> <i>Zinc chloride</i> <i>Zinc citrate</i> <i>Zinc fumarate</i> <i>Zinc gluconate</i> <i>Zinc glutarate</i> <i>Zinc glycerate</i> <i>Zinc HAP chelate</i> <i>Zinc HVP chelate</i> <i>Zinc malate</i> <i>Zinc monomethionine</i> <i>Zinc oxide</i> <i>Zinc phosphate</i> <i>Zinc succinate</i> <i>Zinc sulphate</i> <i>Zinc sulphate heptahydrate</i>	Contributes to the maintenance of immune function	Helps in connective tissue formation	0 to 12 months 0,2 mg	2 mg	0,7 mg	≤ 25 mg
	Contributes to the maintenance of normal skin	Helps to maintain healthy skin	1 to 3 years 0,4 mg	7 mg		
	Contributes to normal acid-base metabolism	Helps the body to metabolise carbohydrates, fats and proteins	4 to 8 years 0,4 mg	12 mg		
	Contributes to normal cognitive function	Helps to maintain immune function	9 to 13 years 0,4 mg	23 mg		
	Contributes to normal DNA synthesis	A factor in the maintenance of good health	14 to 18 years 0,7 mg	≤ 25 mg		
Contributes to normal fertility and reproduction	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement					
If <i>Zinc picolinate</i> is used as a source: <ul style="list-style-type: none"> • <i>Not suitable for children</i> • <i>Label: Consult a relevant health care provider for use beyond 3 months</i> • <i>Label: Do not use this product if you are pregnant or breastfeeding</i> 	Contributes to normal macronutrient metabolism Contributes to normal metabolism of Vitamin A Contributes to the maintenance of normal nails Contributes to the maintenance of normal bones Contributes to the maintenance of normal hair Contributes to the maintenance of normal testosterone levels in the blood Contributes to the maintenance of normal vision					

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
Zinc (and derivatives) cont.	<p>Contributes to the protection of cells from oxidative stress</p> <p>Has a role in the process of cell division</p> <p>Contributes to connective tissue formation</p> <p>Helps the body to metabolise carbohydrates, fats and proteins</p> <p>A factor in the maintenance of good health</p>					

Allowable Levels and claims: Minerals: Electrolytes

Substances such as sodium, chloride and phosphate in the form of supplements do not contribute to the maintenance of good health since there is likely to be an excess of such substances (particularly sodium) from the diet, not a deficiency. Despite this, the use of such substances in high-intensity exercise to supplement the loss of electrolytes and reduce the risk of dehydration may take place.

These entries are therefore provided for products which may be classifiable as Health Supplements on the basis of their combination but are not intended to be applicable to foodstuffs supplied in terms of their permissible use. Such products are not intended to be used as oral rehydration solutions which are classifiable as Category A medicine.

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children	Adults
<p>Electrolytes <i>Including:</i> Sodium Chloride Phosphate</p>	<p><i>Not permitted.</i></p>	<p>Contributes to the maintenance of normal electrolyte balance in anticipation of extended (greater than 60 min), high intensity exercise.</p> <p>Supports hydration before during and after exercise and to maintain performance.</p> <p>When combined with carbohydrates contributes to the maintenance of exercise performance or endurance.</p>	<p><i>Not permitted.</i></p>	<p>Claims would be permitted on electrolyte drinks with an average osmolality of 200-340 mOsm/kg.</p> <p><i>When combined with carbohydrates:</i> Metabolisable carbohydrates: = 75% of total energy. 250kJ/l (60kcal/l) = Energy = 1488kJ/l (350kcal/l). 15 mmol/l (345 mg/l) = Sodium (Na+) = 20 mmol/l (460 mg/l)</p> <p>Include warning: not to be used in cases of dehydration as a substitute of an oral rehydration solution.</p>

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

SSF: Single substance formulation

MSF: Multiple substance formulation

Unless otherwise stated the dosage form is oral.

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:

Action:

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

Warning:

All products:

Sufficient protein is provided in normal well-balanced daily meals.

Do not exceed daily dosage level without consulting a relevant health care provider.

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

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

Products related to Group 2 indications (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 relevant health care provider.

Use or purpose:

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

Consume no later than 90 minutes after exercising.

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 required on the labelling.

Protein	Source Material	Health Supplement Claim (Single and Multiple Substance Products)	Children		Adults	
			Minimum ^a	Maximum ^b	Minimum	Maximum
Acid casein	Extract - <i>Bos taurus</i> - milk	<p>Group 1:</p> <p>Source of: - protein for the maintenance of good health.</p> <p>- protein which helps build and repair body tissues.</p> <p>- amino acids involved in muscle protein synthesis.</p> <p>Protein contributes to the maintenance of muscle mass.</p> <p>Group 2:</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>	<i>Combined dose for all ingredients from proteins in the product.</i>			
Alfalfa protein concentrate	Extract - <i>Medicago sativa</i> – herb top		Age 1 to 3		2,6 g	90 g
Calcium caseinate	Isolate – <i>Bos taurus</i> - milk		650 mg	13 g		
Calcium sodium caseinate	<i>Bos taurus</i> - milk		Age 4 to 8			
Hydrolyzed casein	<i>Bos taurus</i> - milk		950 mg	19 g		
Defatted wheat germ protein	<i>Triticum aestivum</i> – seed germ		Age 9 to 13			
Flaxseed protein	<i>Linum usitatissimum</i> - seed		1 700 mg	34 g		
Hemp protein concentrate	<i>Cannabis sativa</i> seed extract where it consists of a processed product made from cannabis seeds containing not more than: <ol style="list-style-type: none"> a. 10 mg/kg (0,001 percent) of tetrahydrocannabinol and does not contain whole cannabis seeds; and b. 75 mg/kg (0,0075 percent) of cannabidiol (CBD); 		Age 14 to 17			
Hemp protein isolate			2 450 mg	49 g		
Hemp seed protein						
Casein Micelles	Extract - <i>Bos taurus</i> - milk		<p>^aMinimum required for label claim = 5 % of the maximum safe level per day.</p> <p>^bMaximum based on the Recommended Dietary Allowance (average between boys and girls) as specified in Dietary Reference Intakes, Institute of Medicine, National Academies Press, Washington DC, 2002/2005, Chapter 10, p. 632 to 649.</p>			
Milk protein concentrate	Extract - <i>Bos taurus</i> - milk					
Milk protein isolate	Extract - <i>Bos taurus</i> - milk					
Pea protein	<i>Pisum sativum</i> seed isolate					
Potato protein	<i>Solanum tuberosum</i> – tuber - Extract dry, Extract dry standardised					
Rice protein	Rice protein concentrate isolate					
Rice protein concentrate	<i>Oryza sativa</i> - seed					
Sodium caseinate	Isolate – <i>Bos taurus</i> - milk					

Protein	Source Material	Health Supplement Claim (Single and Multiple Substance Products)	Children		Adults	
			Minimum ^a	Maximum ^b	Minimum	Maximum
Soy protein	Isolated from the bean of <i>soy/Glycine max</i> (L.) Merr.					
Wheat protein isolate	Extract - <i>Triticum aestivum</i> - seed germ					
Whey protein isolate	<i>Bos taurus</i> - milk or <i>Capra hircus</i> - milk					
Whey protein concentrate	<i>Bos taurus</i> - milk or <i>Capra hircus</i> - milk					
Whey protein hydrolysate	<i>Bos taurus</i> - milk or <i>Capra hircus</i> - milk					
Sesame seed protein Avocado protein Collagen protein	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>					
Hydrolysed Collagen	See Annexure H - Animal Extracts, Products and Derivatives					

2. AMINO ACIDS

NOTES:

1. 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.
2. 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:

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 non-essential 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 β -alanine):

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

All products:

The indicated daily dose should not be exceeded.

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

Sufficient protein is provided in normal well-balanced daily meals.

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

Not suitable for children under the age of 18.

Ensure to drink enough fluid before, during, and after exercise.

All other products:

Use in children under the guidance of a relevant health care provider.

Permitted indications as Workout Supplements (adults only):

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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.

Use or Purpose:

Standardised Indication:

Supplementation of the dietary supply of amino acids used for the synthesis of body protein and other nitrogen-containing compounds.

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
1. ESSENTIAL AMINO ACIDS				
L- Isoleucine Sources: 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 Source of (an) (essential) amino acid(s) involved in muscle protein synthesis	Must not be consumed by pregnant women, children, or for extended lengths of time without medical advice.	66,5 mg	1 065 mg
L- Leucine Sources 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	Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet. Products containing all three of L-leucine, L-isoleucine and L-valine, at or above the respective minimum doses indicated in the Dose section: Source of branched chain amino acids, which are involved in protein synthesis		147 mg	1 824 mg
L-Valine Sources: 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	Workout supplement Athletic support		84 mg	1 194 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
1. ESSENTIAL AMINO ACIDS				
L- Histidine Sources: Calcium Sodium Caseinate Hydrolyzed collagen L-Histidine hydrochloride Whey protein concentrate Whey protein isolate	Source of (an) essential amino acid(s) for the maintenance of good health 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.		49 mg	220 mg
L-Threonine Sources: Calcium Sodium Caseinate dl-Threonine Hydrolyzed collagen Whey protein concentrate Whey protein isolate	Assists in the building of lean muscle [tissue/mass] when combined with regular [weight/resistance] training and a healthy balanced diet. Must contain at least one ingredient at or above the minimum dose: Workout supplement Athletic support		70 mg	301 mg
L-Phenylalanine Sources: Calcium Sodium Caseinate DL-Phenylalanine Hydrolyzed collagen L-Phenylalanine methyl ester N-Acetyl-L-phenylalanine Whey protein concentrate Whey protein isolate	Source of (an) essential amino acid(s) for the maintenance of good health 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.	Products for oral use: <ul style="list-style-type: none"> • Phenylketonurics: Contains phenylalanine. • Oral products containing more than 5 mg per MDD: <ul style="list-style-type: none"> ○ Do not use if pregnant or breastfeeding or intending to become pregnant. 	115,5 mg	339 mg
L-Lysine Sources: Brown Rice Protein Calcium Sodium Caseinate Hydrolyzed collagen L-Lysine-L-aspartate L-Lysine monohydrochloride L-Lysine hydrochloride	Source of (an) essential amino acid(s) for the maintenance of good health Source of (an) (essential) amino acid(s) involved in muscle protein synthesis		133 mg	3 000 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
1. ESSENTIAL AMINO ACIDS				
<p><i>Lysine acetate</i> <i>Lysine dihydrochloride</i> <i>Milk protein isolate</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i></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>L-Methionine Sources: <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>	<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 relevant health care provider before use if you have acidosis, atherosclerosis, or methylenetetrahydrofolate reductase deficiency.</p>	66,5 mg	210 mg
<p>L-Tryptophan Sources: <i>Calcium Sodium Caseinate</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>Consult a relevant health care provider before use if you have eosinophilia myalgia syndrome or liver disease or have depression.</p>	17,5 mg	220 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
2. NON-ESSENTIAL AMINO ACIDS				
L- Alanine Sources: 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.		> 0 mg	363 mg
beta-Alanine Sources: Elymus repens subsp. repens Humulus lupulus Malus domestica Prunus cerasus Ribes nigrum Solanum lycopersicum	May improve physical performance and exercise capacity. May help to delay muscle fatigue during physical activity.	May cause a flushing, tingling and/or prickling sensation of the skin, in which case, reduce the dose.	> 0 mg	3 g Maximum single dose: 1 g
L- Arginine Sources: 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 L-Arginine hydrochloride L-Arginine ketoisocaproic acid L-Arginine L-aspartate L-Arginine monohydrochloride L-Arginine taurinate Whey protein concentrate Whey protein isolate	Source of (an) amino acid(s) involved in muscle protein synthesis.	Consult a relevant health care provider prior to use if you are pregnant or breastfeeding	> 0 mg	9 000 mg
	May help support a modest improvement in exercise capacity in individuals with stable cardiovascular diseases. Supports sperm count and motility. Supports reproductive health in men and women.	Consult a relevant health care provider prior to use if you are pregnant or breastfeeding <u>For products providing 0,42 to 9 g per day:</u> Consult a relevant health care provider: <ul style="list-style-type: none"> • if your cardiovascular condition worsens. • prior to use if you have a renal/kidney disease or if you are following a low protein diet • to use if you suffer from a cardiovascular disease and are attempting an increase in physical activity • prior to use if you are taking medication for cardiovascular diseases, erectile dysfunction, and/or blood thinners 		

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
2. NON-ESSENTIAL AMINO ACIDS				
		<p>Contraindication(s): <u>For products providing 0,42 to 9 g per day:</u></p> <ul style="list-style-type: none"> Do not use if you have had a heart attack/myocardial infarction <p>Known Adverse Reaction(s): <u>For products providing 0,42 to 9 g per day:</u></p> <ul style="list-style-type: none"> Some people may experience gastrointestinal discomfort (such as diarrhoea) 		
<p>L- Asparagine Sources: <i>L-Asparagine</i> <i>L-Asparagine monohydrate</i></p>	Source of (an) amino acid(s) involved in muscle protein synthesis.		> 0 mg	93,5 mg
<p>L- Aspartic Acid Sources: <i>Calcium Sodium Caseinate</i> <i>Hydrolyzed collagen</i> <i>Potassium aspartate</i> <i>Potassium magnesium aspartate</i> <i>Whey protein concentrate</i> <i>Whey protein isolate</i></p>	Source of (an) amino acid(s) involved in muscle protein synthesis.		> 0 mg	1 000 mg
<p>L- Carnitine <i>(L-3-Carboxy-2-hydroxypropyl) trimethylammonium hydroxide, inner salt</i> <i>Carnitine</i> Also for:</p>	<p>Antioxidant</p> <p>Workout support/supplement</p> <p>L-Carnitine from L-Carnitine tartrate:</p>	<p>Consult a relevant health care provider prior to use if you:</p> <ul style="list-style-type: none"> are pregnant or breastfeeding; or have a liver disease, a kidney disease, or a seizure disorder. 	> 0 g	<p>4 g</p> <p><i>(not more than 2 g per single dose)</i></p>

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
2. NON-ESSENTIAL AMINO ACIDS				
<p><i>L-Carnitine Fumarate</i> <i>L-Carnitine Hydrochloride</i> <i>L-Carnitine Magnesium Citrate</i></p> <p>Sources: <i>L-Carnitine tartrate</i> <i>L-Carnitine fumarate</i></p>	<p>Aids in the muscle recovery process by reducing muscle tissue damage associated with a resistance training regimen</p> <p>Helps:</p> <ul style="list-style-type: none"> - support muscle tissue repair in individuals involved in resistance training - improve physical performance when used in conjunction with a training regimen - delay fatigue during physical activity - support fat metabolism - support fat oxidation 	<p>Directions for use: Take 2 – 4 hours prior to exercise.</p>	<p>1 g <i>if related to muscle recovery</i></p>	
			<p>2 g <i>if related to physical performance.</i></p>	
<p>L-Citrulline</p> <p><i>(S)-N5-Carbamoylornithine</i> <i>N5-(aminocarbonyl)-L-Ornithine</i></p>	Source of a non-essential amino acid.		> 0 mg	3 000 mg
<p>L-Cystine</p> <p><i>(R-(R*,R*))</i>-3,3'-Dithiobis (2-aminopropanoic acid), <i>L-Cystine</i></p>	Source of a non-essential amino acid.		> 0 mg	1 000 mg
<p>L-Cysteine</p> <p>Sources: <i>Cysteine hydrochloride</i> <i>Cysteine hydrochloride monohydrate</i> <i>D-Ribose-L-cysteine</i> <i>N-Acetyl-L-cysteine</i></p>	Source of (an) amino acid(s) involved in muscle protein synthesis.		> 0 mg	1 000 mg
<p>L- Glutamic Acid</p> <p>Sources: <i>Calcium Sodium Caseinate</i> <i>Glutamic acid hydrochloride</i> <i>Hydrolyzed collagen</i> <i>Monosodium glutamate</i> <i>Whey protein concentrate</i></p>	Source of (an) amino acid(s) involved in muscle protein synthesis.		> 0 mg	1 500 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
2. NON-ESSENTIAL AMINO ACIDS				
<i>Whey protein isolate</i>				
L- Glutamine Sources: Alanylglutamine Glutamic acid L-Glutamine ethyl ester L-Glutamine methyl ester Magnesium glycyl glutamine chelate N-Acetyl-L-glutamine Pea Protein	Source of (an) amino acid(s) involved in muscle protein synthesis. Products containing L-Glutamine above 5 g per day: Helps : - restore plasma glutamine levels depleted after periods of physical stress (e.g. prolonged exhaustive exercise) - support immune system health after periods of physical stress - support digestive system health after periods of physical stress - to assist in muscle cell repair after exercise	Consult a relevant health care provider prior to use: - if you are following a low protein diet - if you are pregnant or breastfeeding.	> 0 mg	9 000 mg
Glycine Aminoacetic Acid 2-aminoacetic acid E640 Sources: Calcium Sodium Caseinate Glycine hydrochloride Hydrolyzed collagen N-Glycyl-L-leucine Whey protein concentrate Whey protein isolate.	Source of (an) amino acid(s) involved in muscle protein synthesis.		> 0 mg	1 800 mg
L-Proline Sources: Calcium Sodium Caseinate Glycine hydrochloride Hydrolyzed collagen N-Glycyl-L-leucine Whey protein concentrate			> 0 mg	519 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
2. NON-ESSENTIAL AMINO ACIDS				
<i>Whey protein isolate</i>				
L-Serine Sources: Calcium Sodium Caseinate Hydrolyzed collagen Whey protein concentrate Whey protein isolate			> 0 mg	351 mg
L-Tyrosine Sources: Brown Rice Protein Calcium Sodium Caseinate Casein Hydrolyzed collagen L-Tyrosine ethyl ester N-Acetyl tyrosine Whey protein concentrate Whey protein isolate	Source of (an) amino acid(s) involved in muscle protein synthesis.	Consult a relevant health care provider prior to use if you are: <ul style="list-style-type: none"> • following a low protein diet; or • pregnant or breastfeeding. 	> 0 mg	3 600 mg
	Products containing 10 g L-Tyrosine taken 1-2 times per day: Helps to decrease cognitive fatigue due to physically stressful situations (e.g. extended wakefulness, exposure to cold, excessive noise)	For products providing more than 3 600 mg L-Tyrosine per day: Some people may experience gastrointestinal discomfort (nausea, diarrhoea, vomiting), nervousness or palpitations, in which case, reduce the dose.		10 g <i>(max twice daily)</i>

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
3. OTHER AMINO ACIDS				
Acetyl L-Carnitine <i>Acetyllevocarnitine hydrochloride</i> <i>1-Propanaminium, 2-(acetyloxy)-3-carboxy-N,N,N-trimethyl-, chloride, (R)-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.	If you are pregnant or breastfeeding, consult a relevant health care provider prior to use. If you have liver disease, kidney disease and/or a seizure disorder, consult a relevant health care provider prior to use. May cause digestive problems.	1,5 g	4 g
N-Acetyl-L-Methionine	<i>See L-methionine.</i>			
(s)-s-adenosyl methionine Including: <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> <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>	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 relevant health care provider. - if you have bipolar depression, except under the supervision of a relevant health care provider.	400 mg	1 600 mg
Creatine <i>(a-Methylguanido)acetic acid</i> <i>Glycine, N-(aminoiminomethyl)-N-methyl-</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>	Consult a relevant health care provider before long-term use.	<i>See claim.</i>	<i>See claim.</i>

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
3. OTHER AMINO ACIDS				
<i>Kre-Alkalyn</i> <i>N-Amidinosarcosine</i>				
Creatine hydrochloride <i>Creatine HCl</i> <i>Glycine, N-(aminoiminomethyl)-N-methyl-, monohydrochloride</i> <i>N-(aminoiminomethyl)-N-methyl-Glycine monohydrochloride</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>	Consult a relevant health care provider before long-term use.	<i>See claim.</i>	3 g
Creatine Monohydrate <i>Creatine hydrate</i> <i>Glycine, N-(aminoiminomethyl)-N-methyl-, monohydrate</i>	Increases [body/muscle/lean] [mass/size] when used in conjunction with a resistance training regimen Improves [strength/power/performance] in repetitive bouts of brief, highly-intense physical activity (e.g. sprints, jumping, resistance training) (by increasing [muscle/intramuscular] [creatine/phosphocreatine/energy] levels)	Consult a relevant health care provider: - before long-term use. - prior to use if you have a kidney disorder - prior to use if you are pregnant or breastfeeding. May result in weight gain.	2 g	Maintenance: 5 g Maximum: 20 g not to exceed 5 g per dose
Creatine Phosphate <i>Glycine, N-(imino(phosphonoamino)methyl)-N-methyl-N-(Phosphonoamidino)sarcosine</i> <i>Phosphocreatine</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>	Consult a relevant health care provider before long-term use.	<u>Annexure B submission required.</u>	20 g
Glucose Glutamate	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>	Permitted only in products for external use. Glucose is a mandatory component of this ingredient.	<i>See claim.</i>	6,8 g
Glutathione <i>Glycine, L-gamma-glutamyl-L-cysteinyl-</i>	Source of antioxidant(s)/Provides antioxidant(s).	Consult a relevant health care provider before use if pregnant, intending to become pregnant, or breastfeeding.	> 0 mg	743 mg

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
3. OTHER AMINO ACIDS				
<i>L-glutathione</i> <i>N-(N-L-gamma-Glutamyl-L-cysteinyl)glycine</i>	<u>SSF and MSF: Annexure B submission required for external use.</u>	Permitted in products for external use.	See claim.	4,5 g
Hydroxylysine <i>5-Hydroxylysine</i> <i>delta-Hydroxylysine</i> <i>erythro-5-Hydroxy-L-lysine</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>		2 g	5,6 g
I-Hydroxyproline <i>4-Hydroxy-2-pyrrolidinecarboxylic acid</i> <i>4-Hydroxy-L-proline</i> <i>L-4-Hydroxyproline</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>		See claim.	10 g if used alone or 16 g of the combination with other branch chain amino acids <i>i.e. leucine or valine</i>
L-Ornithine <i>Ornithine</i> <i>(S)-2,5-Diaminopentanoic acid</i> <i>2,5-diaminopentanoic acid</i>	Ornithine helps to support liver function.		4,8 g	6 g
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>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>		See claim.	See claim.
Ornicetil <i>L-Ornithine alpha-ketoglutarate</i> <i>(L)-Ornithine 2-oxoglutarate</i>	Support wound healing and the reduction of wound healing time.	For daily doses 10 g or more: Use longer than 30 days under the direction of a relevant health care provider.	10 g	20 g

Amino Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Adults	
			Minimum	Maximum
3. OTHER AMINO ACIDS				
<i>L(+)-Ornithine alpha-ketoglutarate</i> <i>L-Ornithine, mixt. With 2-oxopentanedioic acid</i> <i>OKG</i> <i>Ornithine alpha-ketoglutarate</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u>		See claim.	6 g
I-Selenomethionine <i>Butanoic acid, 2-amino-4-(methylseleno)-, (S)-</i> <i>L-Selenomethionine</i> <i>Selenium-L-methionine</i>	<u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</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 (Annexure F).	
Taurine <i>2-Aminoethane sulfonic acid</i> <i>2-Aminoethylsulfonic acid</i> <i>beta-Aminoethylsulfonic acid</i> <i>L-taurine</i>	Amino acid that plays a role in the support of the immune system. Antioxidant. Taurine is important for energy metabolism / the transformation of food into energy.	Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.	> 0 g	3 g
	Helps to support cardiovascular function.		1,5 g	
L-Theanine <i>(2S)-2-amino-5-(ethylamino)-5-oxopentanoic acid</i> <i>N-Ethyl-L-glutamine</i> <i>suntheanine</i> <i>theanin</i>	Supports maintenance of healthy sleep.		Annexure B submission required.	250 mg
	Helps to support relaxation.		200 mg	
	Helps to temporarily promote relaxation.			

ANNEXURE H

Allowable Levels and claims: Animal Extracts Products and Derivatives

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

As per MCC Guideline – Complementary Medicines – REGISTRATION APPLICATION ZA-CTD – QUALITY (7.05_CMs_Quality_Jun16_v1)

With regard to origin or source of ingredients/materials unless from a licensed cultivated, legal source, no animal or plant source should be included that are included in the lists of the following:

IUCN Red Data List, (<http://www.iucnredlist.org/technical-documents/categories-and-criteria>) or

South African National Biodiversity Red List of South African Plants (<http://redlist.sanbi.org/redcat.php>) as Near Threatened (NT), Vulnerable (V), Endangered (EN), Critically Endangered (CE) or Extinct in the Wild (EW),

The principles of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) of which South Africa is a member, must be adhered to.

Applicants may require a Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) import permit if making use of substances (e.g. Hoodia, etc) listed under the National Environmental Management: Biodiversity Act, 2004 (Act 10 of 2004).

Any complementary medicine that is of animal origin must comply with the requirements of the Animal Diseases Act, 1984 (Act 35 of 1984). Animal sources should not be susceptible to Transmissible Spongiform Encephalopathy (TSE) diseases, including Bovine Spongiform Encephalopathy (BSE).

Any complementary medicine which contains any genetically modified ingredients must comply with the provisions of the Consumer Protection Act, 2008 (Act 68 of 2008).

General Statements:

Warning:

If symptoms worsen or if you are pregnant or breastfeeding, consult a relevant health care provider.

Where applicable:

Derived from 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 required on the labelling.

For example, a product citing use or purpose statements for chondroitin sulfate and glucosamine hydrochloride need only include the following duration of use statement on the product label: "Use for a minimum of 1 month to see beneficial effects."

Ingredient	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage
<p>Cartilage Sources: <i>Bovine, Chicken</i></p>	<p>For joint health. For connective tissue health.</p>	<p>Do not use in children Do not use if pregnant or intending to become pregnant. Do not use if breastfeeding. Consult a relevant health care provider before use if you have recently had a heart attack, surgery or a major accident.</p>	<p><i>Annexure B submission required.</i></p>
<p>Chondroitin Sulphate <i>Avian Porcine Bovine Bovine calcium Bovine potassium Bovine sodium</i></p>	<p>For joint health Helps to supports the mobility of the joints Chondroitin (and glucosamine) may help to support healthy knees.</p>	<p>Use for a minimum of 3 months for beneficial effects. Do not use together with Warfarin or other anticoagulant therapy.</p>	<p>Minimum: 800 mg Maximum: 1 200 mg</p>
<p>Chitosan <i>Poliglusam (1-4)-2-Amino-2-deoxy-beta-D-glucan beta-1,4-D-glucosamine, deacetylated deacetyl chitin deacetylated chitin poly-(d)glucosamine Poly-beta-(1,4)-2-amino-2-deoxy-d-glucose</i> Sources: <i>Exoskeleton: Chitin from clam Chitin from crab Chitin from krill Chitin from oyster Chitin from shrimp</i></p>	<p>May help to maintain healthy cholesterol levels. May assist with weight management when used with increased physical activity and an energy reduced diet in healthy individuals.</p>	<p>May cause abdominal pain, bloating, constipation, indigestion and/or diarrhoea. If you are taking blood thinners, consult a relevant health care provider prior to use. If you have an allergy to seafood, do not use this product. Directions: Take with meals. Take two hours before or after taking other medications or natural health products since the absorption of these products may be delayed. Powdered dose forms: Do not take powder alone.</p>	<p>Minimum: 1 g Maximum: 6 g in 2 / 3 divided doses</p>

Ingredient	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage
<p>Collagen – hydrolysed <i>Hydrolysed collagen:</i> <i>Type I, Type II</i></p> <p>Sources: <i>Porcine skin</i> <i>Porcine bones</i> <i>Fish skin</i> <i>Fish bones</i> <i>Bovine skin/hide split</i> <i>Gallus gallus cartilage</i></p>	<p>Claim 1: Source of the essential amino acids histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, valine for the maintenance of good health and involved in protein synthesis.</p>	<p>Mix with food or fluid.</p> <p>Doses above 2,8 g hydrolysed collagen, per day:</p> <ul style="list-style-type: none"> If you have liver or kidney disease or if you have been instructed to follow a low protein diet, consult a relevant health care provider prior to use. <p>May cause mild gastrointestinal disturbances.</p> <p>Joint health / inflammation: Use of this substance for 5 (five) months has been shown to be beneficial and therefore its use should be undertaken in consultation with a relevant health care provider.</p>	<p>Claim 1: Minimum 5 % Quantity of each specific amino acid Nutrient Reference Values (NRVs) to a maximum of 10 g hydrolysed collagen, per day.</p>
	<p>Claim 2: Source of the non-essential amino acids alanine, arginine, aspartic acid, glutamic acid, glycine, proline, serine, tyrosine involved in protein synthesis.</p>		<p>Claim 2: Minimum 5 % of each specific amino acid Mean Intake to a maximum of 10 g hydrolysed collagen, per day.</p>
	<p>Claim 3: Source of the essential amino acid lysine to help in collagen formation.</p>		<p>Claim 3: Minimum 5 % of the Nutrient Reference Values (NRVs) to a maximum of 10 g hydrolysed collagen, per day.</p>
	<p>Claim 4: Helps to assist joint health or joint inflammation.</p>		<p>Joint health / inflammation: 1,2 – 10 g hydrolysed collagen per day.</p>

Ingredient	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage
<p>(Bovine) Colostrum Foremilk</p> <p>Sources: Colostrum - <i>Bos taurus</i></p> <p>Note: Sources of colostrum should not be from hyperimmunized cattle.</p>	<p>Helps to support immune function within the upper respiratory tract.</p> <p>Assistance with the maintenance of a healthy immune system.</p>	<p>This is not a breast milk substitute.</p> <p>Contains lactose and cow's milk proteins. If you have a known allergy/hypersensitivity to cow's milk, do not use this product.</p> <p>Do not use in children under 12 months old except on professional health advice.</p> <p>For prolonged use, consult a relevant health care provider.</p> <p>Consult a relevant health care provider prior to use if you:</p> <ul style="list-style-type: none"> • have diabetes or a history of cancer; • have liver or kidney disease or if you have been instructed to follow a low protein diet; or • suffer from an immune system disorder (e.g. Crohn's disease, myasthenia gravis, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, HIV/AIDS, etc.) or if you are taking immunosuppressants. 	<p>Minimum: 0,4 g Maximum: 10 g dried powder</p>
<p>Coturnix coturnix Quail egg</p>	<p>Contributes to maintaining normal immune responses to seasonal and environmental allergens.</p>	<p>Consult a relevant health care provider prior to use if:</p> <ul style="list-style-type: none"> • you are pregnant or breastfeeding, or • your symptoms persist or worsen. <p><i>Contraindication(s):</i></p>	<p>Minimum: 26,88 mg dried powder</p> <p>Maximum: 134,4 mg dried powder in 5 divided doses</p>

Ingredient	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage
		<p>Do not use if you have a (quail) egg allergy.</p> <p><i>Known adverse reaction(s)</i></p> <p>Stop use immediately if hypersensitivity/allergy occurs or if you experience irritation or swelling of the mouth or throat occurs.</p>	
<p>Green Lipped Mussel <i>New Zealand green lipped mussel</i> <i>Perna canalicula</i> Dried</p>	<p>For joint health. Promotes joint functioning.</p>		<p>1 150 mg daily</p>
<p>Royal jelly Sources: <i>Apis mellifera - secretion</i> (Dry, Powder, Non-Standardised Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)</p>	<p>Antioxidant. Nutritive tonic.</p>	<p>Consult a relevant health care provider prior to use if you are-</p> <ul style="list-style-type: none"> • pregnant or breastfeeding; or • allergic to bee products, poplar tree products, or balsam of Peru. <p><i>Contraindication(s):</i></p> <p>Do not use this product if you have a history of asthma or allergies.</p> <p><i>Known adverse reaction(s)</i></p> <p>Stop use immediately if hypersensitivity/allergy occurs or if you experience irritation or swelling of the mouth or throat occurs.</p>	<p><i>Antioxidant:</i></p> <p>Not to exceed 6 g fresh royal jelly or the equivalent thereof per day.</p> <p><i>Nutritive tonic:</i></p> <p>0,8 to 6 g fresh royal jelly, or the equivalent thereof per day.</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

SSF: Single substance formulation

MSF: Multiple substance formulation

Unless otherwise stated the minimum and maximum dosage applies to adults (> 18 years).

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 relevant health care provider.

Consult a relevant health care provider 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.
- **Children 3 to 5 years:** The acceptable dosage forms are limited to chewables, emulsion/ suspension, powders and solution/drops.
- **Children 6 to 12 years, Adolescent Children 13 to 17 years, and Adults ≥ 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

7.04_CM_SE_Health_Supplements_Mar22_v4_3

All plant oils may refer to Essential Fatty Acid Constituents for additional guidance on claims, statements, warnings and dosage values.

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.

Pertinent to all fish/marine oils:

Maximum levels for certain heavy metals in oils from marine sources:

All oils from marine sources must comply with the limits set for heavy metals by Commission Regulation (EC) No 1881/2006 of 19 December 2006, setting the maximum levels for certain contaminants in foodstuff, as amended.

Maximum values of oxidative stability parameters for oils:

Oxidative stability parameter	Maximum value
Peroxide value (PV)	5 mEq/kg
<i>p</i> -Anisidine value (AV)	20
Totox value	26 (calculated as (2 x PV) + AV)
<i>These oxidative stability requirements apply to all oil ingredients used in the manufacturing of health supplements.</i>	

Maximum levels of dioxins, dioxin-like polychlorinated biphenyls (DL PCB) and polychlorinated biphenyls (PCB) in oils from marine sources:

Dioxin, DL PCB, and PCB contaminants	Maximum level	
	EU 1259/2011	USP 35
Dioxins (sum of PCDDs + PCDFs) ^{1, 2}	1,75 pg/g	1,0 pg/g
Sum of dioxins and DL PCBs ^{1, 3}	6 pg/g	
PCBs ⁴	200 ng/g	0,5 ppm ⁵
<p><i>These contaminant requirements apply to all marine oil ingredients used in the manufacturing of health supplements.</i></p> <p>Footnotes:</p> <p><i>1: Expressed in World Health Organization (WHO) toxic equivalents using WHO-toxic equivalent factors (TEFs). Analytical results relating to 17 individual dioxin congeners of toxicological concern are expressed in a single quantifiable unit: 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) toxic equivalent concentration (TEQ) (USP 35; EU 2011).</i></p> <p><i>2: Sum of dioxins: WHO-PCDD/F-TEQ (USP 35; EU 2011)</i></p> <p><i>3: Sum of dioxins and dioxin-like PCBs: WHO-PCDD/F-PCB-TEQ (EU 2011)</i></p> <p><i>4: Sum of PCB congeners 28, 52, 101, 118, 138, 153 and 180 (USP 35; EU 2011)</i></p> <p><i>5: Equivalence: 0,5 ppm = 500 ng/g</i></p>		

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
1. Plant Oils					
Argania spinosa kernel oil <i>Lipofructyl argan</i> <i>Argan Seed Oil</i>	Source of antioxidant(s)/Provides antioxidant(s). <u>Annexure B submission required.</u>		Restrictions on manufacturing: The concentration must be no more than 5 % in the product.	<i>See claim.</i>	15 g
Blackcurrant seed oil <i>Blackcurrant esters</i> <i>Ribes nigrum esters</i> <i>Ribes nigrum</i> (Parts: Seed)	Dependent on required Fatty Acid Constituents. <u>Annexure B submission required.</u>	If you are pregnant or breastfeeding, consult a relevant health care provider prior to use. Products not encapsulated: Refrigerate after opening.		<i>See claim.</i>	10,5 g
Borage Oil <i>Borago officinalis L.</i> (Boraginaceae) (Parts: Seed)	Source of essential fatty acids/omega-6 fatty acids/ 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).	<i>According to EFA constituents.</i>	5,0 g
				Oil Fixed	
				3,7 g	5,0 g
				Oil Fixed Standardised	
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> <i>Copra oil</i> <i>Unhydrogenated coconut oil</i> <i>Coconut oil - fractionated</i> <i>Copra oil, fractionated</i> <i>Coconut oil - hydrogenated</i> <i>Copra oil, hydrogenated</i> <i>Medium chain triglycerides</i>	Provides/source of antioxidants. Assists in the maintenance of skin health when applied topically.			<i>See claim.</i>	15 g

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
1. Plant Oils					
Echium oil <i>Echium plantagineum oil</i> <i>Echium vulgare seed oil</i> Source Material(s): <i>Echium plantagineum</i> (Parts: Seed)	<u>Annexure B submission required.</u>		Must be derived only from <i>Echium vulgare</i> seed.	<i>See claim.</i>	Must not contain more than 1 mg of the equivalent dry material.
Evening Primrose Oil <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"> • 7 to 14 % gamma-Linolenic acid • 65 to 85 % Linoleic acid 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
False flax oil <i>Big-seed false flax</i> <i>False flax</i> <i>Myragrum sativum</i> <i>Camelina sativa</i> (Parts: Seed)	Dependent on required Fatty Acid Constituents. <u>Annexure B submission required.</u>	Products not encapsulated: Refrigerate after opening.		<i>See claim.</i>	15 g
Flaxseed Oil	Group 1:	Products not encapsulated:		<u>Group 1 Claim:</u>	

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
1. Plant Oils					
<p><i>Linseed oil</i> <i>Linum usitatissimum seed oil</i> (<i>Linaceae</i>) – seed</p>	<p>Source of essential fatty acids for the maintenance of good health.</p> <p>Source of omega-3 fatty acids for the maintenance of good health.</p> <p>Source of alpha-linolenic acid (ALA) for the maintenance of good health.</p>	<p>Refrigerate after opening.</p>	<p>Doses indicated relate to seed oil.</p>	<p>2 to 4 years: 0,04 g / 0,17 ml</p>	<p>2 to 4 years: 5,33 g / 5,67 ml</p>
	<p>Group 2: Source of omega-6 fatty acids for the maintenance of good health.</p> <p>Source of linoleic acid (LA) for the maintenance of good health.</p>			<p>5 to 9 years: 0,06 g / 0,25 ml</p>	<p>5 to 9 years: 8 g / 8,5 ml</p>
				<p>10 to 14 years: 0,12 g / 0,5 ml</p>	<p>10 to 14 years: 16 g / 17 ml</p>
				<p>15 and over: 0,23 g / 1 ml</p>	<p>15 and over: 32 g / 34 ml</p>
				<i>Group 2 Claim:</i>	
				<p>2 to 4 years: 1,28 g / 1,33 ml</p>	<p>2 to 4 years: 5,33 g / 5,67 ml</p>
				<p>5 to 9 years: 1,93 g / 2 ml</p>	<p>5 to 9 years: 8 g / 8,5 ml</p>
	<p>10 to 14 years: 3,85 g / 4 ml</p>			<p>10 to 14 years: 16 g / 17 ml</p>	
<p>15 and over: 7,7 g / 8 ml</p>	<p>15 and over: 32 g / 34 ml</p>				
<p>Hemp Seed Oil <i>Cannabis sativa Seed Oil</i></p>	<p>Source of antioxidant(s)/Provides antioxidant(s).</p>	<p>If you are pregnant or breastfeeding, consult a</p>	<p>Processed product made from cannabis</p>	<p>See claim.</p>	<p>15 g</p>

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
1. Plant Oils					
<i>(Parts: Seed)</i>	<i>Refer to Fatty Acid Constituents.</i>	relevant health care provider prior to use. Products not encapsulated: Refrigerate after opening.	seeds containing not more than: a. 10 mg/kg (0,001 %) of tetrahydrocannabinol and does not contain whole cannabis seeds; and b. 75 mg/kg (0,0075 percent) of cannabidiol (CBD).		
Olive oil <i>Olea europaea (Parts: Fruit)</i>	Source of antioxidant(s)/Provides antioxidant(s). <i>Refer to Fatty Acid Constituents.</i>				15 g
Pumpkin Seed Oil <i>Pumpkin seed oil</i> <i>Cucurbita pepo seed oil</i> <i>(Parts: Seed)</i>	Source of antioxidant(s)/Provides antioxidant(s). Contributes to prostate gland health. Source of phytosterols. <i>Dependent on required Fatty Acid Constituents.</i>		Only <i>Cucurbita pepo</i> seed oil fixed is permitted.	<i>See claim.</i>	15 g
Safflower Oil <i>Carthamus tinctorius oil</i> <i>(Parts: Seed)</i>	<i>Dependent on required Fatty Acid Constituents.</i> <u><i>Annexure B submission required.</i></u>			<i>See claim.</i>	15 g
Sea buckthorn oil (omega-7)	<i>Dependent on required Fatty Acid Constituents.</i>	If you are pregnant or breastfeeding, consult a		<i>See claim.</i>	5 g

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
1. Plant Oils					
<p><i>Hippophae rhamnoides</i> var. <i>procera</i></p> <ul style="list-style-type: none"> • Sallowthorn • Sea buckthorn • Sea-buckthorn • Shaji <p>(Parts:Seed)</p>	<p><u>Annexure B submission required.</u></p>	<p>relevant health care provider prior to use.</p> <p>Products not encapsulated: Refrigerate after opening.</p>			
<p>Wheat Germ Oil Oil of wheat germ <i>Triticum aestivum</i> seed (grain) embryo (germ) oil fixed Wheat oils (Parts: Seed germ)</p>	<p>Source of antioxidant(s)/Provides antioxidant(s).</p> <p><i>Dependent on required Fatty Acid Constituents.</i></p> <p><u>Annexure B submission required.</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>	<p>See claim.</p>	<p>15 g</p>

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum												
2. Marine Oils																	
<p>Algal oil <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>Crypthecodinium 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>Products not encapsulated: Refrigerate after opening.</p>	<p>For DHA/EPA rich Schizochytrium algal oil: 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>Cod Liver Oil <i>Oleum morrhuae</i> <i>Lecoris Aselli Oleum</i> Source: <i>Liver of Atlantic cod, Gadus morhua L. (Gadidae)</i> <i>Liver of Greenland cod, Gadus ogac Richardson (Gadidae)</i> <i>Liver of Pacific cod, Gadus macrocephalus Tilesius (Gadidae)</i> <i>Liver from Arctic cod, Arctogadus glacialis Peters (1872) (Gadidae)</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>For products providing daily doses of vitamin A at or above the RDA or AI (adjusted for the life stage groups): Source of vitamin A, a factor in the maintenance of good health.</p> <p>For products providing daily doses of vitamin D at or above the RDA or AI (adjusted for the life stage groups): Source of vitamin D, a factor in the maintenance of good health.</p> <p>For products providing 138 to 1 500 µg retinol activity</p>	<p>Products not encapsulated: 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>	<table border="1"> <tr> <td colspan="2" data-bbox="1680 676 2016 804">Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</td> </tr> <tr> <td data-bbox="1680 804 1850 909">0 to 3 years 0,83 ml / 0,77 g</td> <td data-bbox="1850 804 2016 909">0 to 3 years 0,87 ml / 0,80 g</td> </tr> <tr> <td data-bbox="1680 909 1850 1015">4 to 8 years 0,83 ml / 0,77 g</td> <td data-bbox="1850 909 2016 1015">4 to 8 years 1,3 ml / 1,2 g</td> </tr> <tr> <td data-bbox="1680 1015 1850 1120">9 to 13 years 0,83 ml / 0,77 g</td> <td data-bbox="1850 1015 2016 1120">9 to 13 years 2,4 ml / 2,2 g</td> </tr> <tr> <td data-bbox="1680 1120 1850 1225">14 to 18 years 0,83 ml / 0,77 g</td> <td data-bbox="1850 1120 2016 1225">14 to 18 years 4,0 ml / 3,7 g</td> </tr> <tr> <td data-bbox="1680 1225 1850 1331">> 18 years 0,83 ml / 0,77 g</td> <td data-bbox="1850 1225 2016 1331">> 18 years 4,3 ml / 4,0 g</td> </tr> </table>		Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.		0 to 3 years 0,83 ml / 0,77 g	0 to 3 years 0,87 ml / 0,80 g	4 to 8 years 0,83 ml / 0,77 g	4 to 8 years 1,3 ml / 1,2 g	9 to 13 years 0,83 ml / 0,77 g	9 to 13 years 2,4 ml / 2,2 g	14 to 18 years 0,83 ml / 0,77 g	14 to 18 years 4,0 ml / 3,7 g	> 18 years 0,83 ml / 0,77 g	> 18 years 4,3 ml / 4,0 g
Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.																	
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9 to 13 years 0,83 ml / 0,77 g	9 to 13 years 2,4 ml / 2,2 g																
14 to 18 years 0,83 ml / 0,77 g	14 to 18 years 4,0 ml / 3,7 g																
> 18 years 0,83 ml / 0,77 g	> 18 years 4,3 ml / 4,0 g																

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
2. Marine Oils					
	<p>equivalents (RAE) (µg vitamin A/all-trans retinol (palmitate)), per day: Refer to Annexure E for Vitamin A related claims.</p> <p>For products providing 1,15 to 25 µg vitamin D3 (cholecalciferol), per day: 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>For products providing 100 to 1 360 mg eicosapentaenoic acid (EPA) + docosahexaenoic acid (DHA), per day: 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>For products providing 100 to 1 360 mg EPA + DHA including at least 100 mg DHA, per day: Helps support cognitive health and/or brain function.</p>				

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum				
2. Marine Oils									
	<p>For products providing 150 to 1 360 mg EPA + DHA including at least 150 mg DHA, per day + DHA:</p> <p>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></p> <p>Note: The above corresponds to oil from the body of one or more of the stated species in its natural triglyceride/triacylglycerol form and/or its concentrated esterified form.</p>	<p>For products providing 100 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, per day:</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>For products providing 200 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:</p> <p>Helps maintain/support cardiovascular health</p> <p>For products providing 1 000 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid and containing a ratio of Eicosapentaenoic acid:</p>	<p>Active: Concentrated omega-3 triglycerides-fish (only for oral use).</p> <p>Products not encapsulated: Refrigerate after opening.</p>	<p>The potencies of vitamin A, vitamin D and/or EPA+DHA, in addition to the level of Fish liver oil, must be indicated on the product registration application and label.</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 relevant health care provider before use if you suffer from a bleeding disorder, take blood-thinning medicines or are asthmatic with sensitivity to aspirin.</p>	<p><i>If health claims are made for vitamin A or colestiferol (vitamin D), refer to the restrictions for vitamin A or colestiferol.</i></p> <p><i>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</i></p>	<table border="1" data-bbox="1680 970 2018 1098"> <tr> <td colspan="2" data-bbox="1680 970 2018 1018" style="text-align: center;">Oil fixed standardised</td> </tr> <tr> <td data-bbox="1680 1018 1850 1098" style="text-align: center;">100 mg</td> <td data-bbox="1850 1018 2018 1098" style="text-align: center;">3 000 mg</td> </tr> </table> <p>of Eicosapentaenoic acid + Docosahexaenoic acid per day.</p>	Oil fixed standardised		100 mg	3 000 mg
Oil fixed standardised									
100 mg	3 000 mg								

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
2. Marine Oils					
	<p>Docosahexaenoic acid between 0,5:1 and 2:1, per day: Helps to reduce serum triglycerides/triacylglycerols</p> <p>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: In conjunction with conventional therapy, helps to reduce the pain of rheumatoid arthritis in adults</p> <p>For products providing 100 to 3 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, including at least 100 mg Docosahexaenoic acid, per day: Helps support cognitive health and/or brain function</p> <p>For products providing 150 to 2 000 mg Eicosapentaenoic acid + Docosahexaenoic acid, including at least 150 mg Docosahexaenoic acid, per day: Helps support the development of the brain, eyes and nerves in children up to 12 years of age</p>				

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
2. Marine Oils					
	<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: Helps to promote healthy mood balance</p>				

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
2. Marine Oils					
<p>Fish Liver Oil Sources: Ammodytidae Carangidae Clupeidae Engraulidae Osmeridae Salmonidae Scombridae</p>	<p><i>See also Cod Liver Oil.</i></p> <p><u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>	<p><i>See also Cod Liver Oil.</i></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><i>See also Cod Liver Oil.</i></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><i>See also Cod Liver Oil.</i></p> <p>If health claims are made for vitamin A or colecalciferol (vitamin D), refer to the restrictions for vitamin A or colecalciferol.</p> <p>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p>	
<p>Halibut Liver Oil Hippoglossus hippoglossus Atlantic halibut</p>	<p><i>See Fish Liver Oil / Cod Liver Oil.</i></p>			<p>If health claims are made for vitamin A or cholecalciferol (vitamin D), refer to the restrictions for vitamin A or cholecalciferol.</p> <p>Vitamin A and D levels not to exceed stipulated</p>	

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
2. Marine Oils					
				doses as indicated in the Vitamin Annexures.	
<p>Krill oil <i>Euphausia pacifica</i> (north pacific krill) (Parts: Whole) <i>Euphausia superba oil</i> (Antartica krill) <i>Euphausia superba</i> (Parts: Whole)</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>Contains crustacean shellfish. [OR] Derived from seafood.</p> <p>Hypersensitivity/allergy has been known to occur (with shellfish); if this occurs, discontinue.</p> <p>If you are pregnant or breastfeeding, consult a relevant health care provider prior to use.</p> <p>Products not encapsulated: Refrigerate after opening.</p>		-	4,1 g
<p>Pollack-liver oil <i>Theragra chalcogramma</i> Alaska pollock Pacific pollock wall-eye pollock whiting (Parts: Whole) Pollack-liver oil (cont...)</p>	See Fish Oil.	Derived from seafood.		<p>If health claims are made for vitamin A or cholecalciferol (vitamin D), refer to the restrictions for vitamin A or cholecalciferol.</p> <p>Vitamin A and D levels not to exceed stipulated doses as indicated in the Vitamin Annexures.</p>	
<p>Salmon Oil <i>Oncorhynchus gobuscha</i> <i>Oncorhynchus nerka</i> <i>Oncorhynchus tshawytscha</i> <i>Salmo salar</i></p>	See Fish Oil.			See Fish Oil.	

Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
2. Marine Oils					
<p>Squid oil <i>Todarodes pacificus</i> - whole <i>Docidicus gigas</i> - whole <i>Illex argentinus</i> - whole <i>Illex illecebrosus</i> - whole</p>	<p><i>Dependent on required Fatty Acid Constituents.</i></p> <p><u>SSF: Annexure B submission required.</u> <u>MSF: See 3.2.2 of Guideline 7.04.</u></p>	<p>Derived from seafood.</p> <p>If you are pregnant or breastfeeding, consult a relevant health care provider prior to use.</p> <p>Hypersensitivity/allergy has been known to occur (with shellfish); if this occurs, discontinue use.</p> <p>Products not encapsulated: Refrigerate after opening.</p>	<p>Must be derived only from species of the order Teuthida of the class Cephalopoda AND be in combination with other ingredients in the product.</p>	<p><i>See claim.</i></p>	<p>5 g</p>
<p>Tuna fish oil/Skipjack liver oil</p>	<p><i>See Fish Oil.</i></p>		<p>The ingredient must conform to the BP monograph for fish oils.</p>		<p>If health claims are made for vitamin A or cholecalciferol (vitamin D), refer to the restrictions for vitamin A or cholecalciferol. 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
3. Other Fats or Oils					
Emu oil <i>Dromiceius oil</i> <i>Dromaius novaehollandiae</i> (Parts: Fat)	A source of polyunsaturated and monounsaturated fatty acids.		Must be derived only from <i>Dromaius ovaehollandiae</i> .	See claim.	
Lecithin <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-Diacylglycero-3-phosphocholine</i> Sub-ingredients: Choline; Phosphatidic acids, Phosphatidylethanolamin, Phosphatidylinositol Source Material: <i>Brassica napus</i> (Parts: Seed); <i>Glycine max</i> (Parts: Seed); <i>Helianthus annuus</i> (Parts: Seed); <i>Salmo salar</i> (Parts: Egg) Source Ingredients: Soya Oil	Helps to support liver function.		The concentration must not exceed 5 % (hydrogenated lecithin). The concentration of soy phosphatidylserine must not exceed 15 %.	1 g	6 g
Phospholipids <i>Pending relevant scheduling amendment.</i>	<u>Annexure B submission required.</u>		Omega-3 phospholipids: <i>See claim.</i> Phospholipids (egg, milk and soy): Permitted only in products for external use. The concentration must not exceed 20%.	See claim.	
Source Material: <i>Clupea harengus</i> (Parts: Egg); <i>Euphausia superba</i> (Parts: Whole); <i>Helianthus annuus</i> (Parts: Seed); <i>Pandalus borealis</i> (Parts: Internal shell); <i>Squid oil Squid</i> (Parts: Whole)					
Phosphatidylcholine	See Lecithin.			See claim.	

Fat / Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
3. Other Fats or Oils					
Phosphatidylserine <i>1,2-diacyl-sn-glycerol-(3)-L-phosphoserine</i> <i>phosphatidyl serine</i> <i>phosphotidylserine</i>	Helps to support cognitive health and/or brain function.			Claim applies to a minimum daily level of 300 mg.	600 mg
Soy phosphatidylserine <i>Soy phosphatidylserine</i> <i>-enriched soy lecithin</i> <i>liquid/powder</i>	Helps to support cognitive health and/or brain function.	Products for internal use from soya origin: Contains soya.	The concentration of soy phosphatidylserine must not exceed 15%.		
Phytosterols <i>Including:</i> <i>Plant sterols</i> <i>Plant sterol esters</i> <i>Plant stanol esters</i>	Plant sterols/stanols contribute to the maintenance of healthy blood cholesterol levels.		This product is not intended for people who do not need to control their blood cholesterol level	In order to bear the claim for contribution 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 at least 0,8 g of plant sterols/stanols. "Phytosterols" must be standardized to one or more of these specific sub-ingredients in order to support the claim.	
Sub-ingredients: <i>Free plant stanols , Plant stanol esters , Plant sterol esters</i>					
Source material: <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); Pinus pinaster (Parts:Trunk); Prunus africana (Parts: Stem bark); Prunus africana (Parts: Trunk bark); Secale cereale (Parts: Pollen); Zea mays (Parts: Pollen)</i>					
Plant sterols <i>Free plant sterols</i> <i>Phytosterols</i>	Helps maintain healthy cholesterol levels.	Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.	This product is not intended for people who do not need to control	Adult dose(s):	
				0,74 g	3 g
				including at least 80 % Combined beta-Sitosterol,	

Fat / Oil	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
3. Other Fats or Oils					
	Plant sterols support the functioning of the immune system.	Directions For Use: With food	their blood cholesterol level	campesterol and Stigmasterol per day 20 mg	3 g
<i>Source Material: 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>					
<i>Sub-ingredients: beta-Sitosterol , Campesterol , Combined beta-Sitosterol, Campesterol and Stigmasterol , Stigmasterol</i>					
Plant sterol esters	Helps maintain healthy cholesterol levels.	Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.	This product is not intended for people who do not need to control their blood cholesterol level.	Adult dose(s):	
	Plant sterols support the functioning of the immune system.	Directions For Use: With food		0,8 g	4,8 g
including at least 80 % Combined beta-Sitosterol, Campesterol and Stigmasterol per day					
				20 mg	4,8 g
<i>Source Material: As for plant sterols.</i>					
Plant stanol esters	Helps maintain healthy cholesterol levels.	Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.	This product is not intended for people who do not need to control their blood cholesterol level.	Adult dose(s):	
	Plant stanols support the functioning of the immune system.	Directions For Use: With food		1,8 g	5,1 g
including at least 80 % combined Sitostanol and campestanol per day					
				20 mg	5,1 g
<i>Source Material: As for plant sterols.</i>					

Fatty Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
<p>4. Fatty Acid Constituents Included to guide recommended use for oils and fats based on FA content. Levels, if not stated, must be determined by source material otherwise Annex. B submission required.</p>					
<p>Alpha-Linolenic Acid (ALA) Linolenic acid (9Z,12Z,15Z)-9,12,15-octadecatrienoic acid cis,cis,cis-9,12,15-octadecatrienoic acid</p>	<p>Source of alpha-linolenic acid (ALA) for the maintenance of good health. Source of omega-3 fatty acid for the maintenance of good health. Source of an essential fatty acid for the maintenance of good health.</p>			80 mg	As for source.
	<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.
<p>Source ingredients: <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>Linoleic acid (LA) (Z,Z,)-9,12-Octadecadienoic acid 9,12-Linoleic acid alpha-Linoleic acid cis,cis-9,12-Octadecadienoic acid Linolic acid</p>	<p>Source of linoleic acid (LA) for the maintenance of good health. Source of omega-6 fatty acid for the maintenance of good health. Source of an essential fatty acid for the maintenance of good health.</p>			850 mg	As for source.
	<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	

Fatty Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
<p>4. Fatty Acid Constituents Included to guide recommended use for oils and fats based on FA content. Levels, if not stated, must be determined by source material otherwise Annex. B submission required.</p>					
				obtained with a daily intake of 2 g of -linolenic acid (ALA) and a daily intake of 10 g of linoleic acid (LA).	
<p>Source Material: <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.
<p>Alpha-lipoic acid <i>R-alpha lipoic acid</i> (+)-1,2-Dithiolane-3-pentanoic acid 1,2-Dithiolane-3-valeric acid Lipoic acid Thioctic acid, d form 2 forms: (±)-1,2-Dithiolane-3-pentanoic acid DL-alpha-Lipoic acid AND (+)-alpha-Lipoic acid R-alpha-Lipoic acid</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 relevant health care provider prior to use.</p> <p>Consumers should discontinue use and consult a relevant health care 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 relevant health care provider prior to use</p>	As for source.	600 mg
<p>Arachidonic Acid <i>Arachidonic acid</i> 5,8,11,14-Eicosatetraenoic acid Icosa-5,8,11,14-tetraenoic acid</p>	<u>Annexure B submission required.</u>		Permitted only in products for external use.	See claim.	
<p>Caprylic Acid Caprylic/capric triglyceride Capric acid, triglyceride Glycerin/caprylic/capric triester Miglyol</p>	<u>Annexure B submission required.</u>		Permitted only in products for external use.	See claim.	

Fatty Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
<p>4. Fatty Acid Constituents Included to guide recommended use for oils and fats based on FA content. Levels, if not stated, must be determined by source material otherwise Annex. B submission required.</p>					
<p>Octanoic/decanoic acid triglyceride Octanoic acid Source materials: <i>Cocos nucifera</i> (Parts: Seed endosperm) Source ingredients: <i>Calcium caprylate; Magnesium caprylate; Zinc caprylate</i></p>			The concentration must not exceed 2 %.		
<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 relevant health care provider 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 relevant health care provider prior to use if you are pregnant or breastfeeding</p> <p>Consult a relevant health care provider prior to use if your goal is to achieve weight loss.</p>	<p>Contraindication(s): Do not use if you have cardiovascular disease, diabetes, metabolic syndrome or insulin resistance.</p> <p>Known Adverse Reaction(s): Some people may experience gastrointestinal upset.</p>	<p><i>Annexure B submission</i></p>	<p>5 g</p>
				<p>Pertinent to the claim: 3 g</p>	
<p>Dihomo-gamma-linolenic acid <i>all-cis-8,11,14-Eicosatrienoic acid</i> DGLA</p>	<p><u><i>Annexure B submission required.</i></u></p>			<p><i>See claim.</i></p>	
<p>Docosahexaenoic Acid (DHA) <i>(4Z,7Z,10Z,13Z,16Z,19Z)-4,7,10,13,16,19-Docosahexaenoic acid</i></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>	

Fatty Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
<p>4. Fatty Acid Constituents Included to guide recommended use for oils and fats based on FA content. Levels, if not stated, must be determined by source material otherwise Annex. B submission required.</p>					
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.
	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.
	DHA maternal intake contributes to the normal development of the eye of the foetus and breastfed infants.				Minimum: EPA + DHA = 250 mg DHA = 200 mg
<p>Source Material: <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>Cryptocodinium 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 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); <i>Ulkenia amoeboidea</i> (Parts: Whole); <i>Ulkenia spp.</i> (Parts: Whole)</p> <p>Source Ingredients: 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.

Fatty Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
<p>4. Fatty Acid Constituents <i>Included to guide recommended use for oils and fats based on FA content. Levels, if not stated, must be determined by source material otherwise Annex. B submission required.</i></p>					
<p>Source material: <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></p>					
<p>Eicosapentaenoic Acid (EPA) <i>Icosapent (ethyl ester)</i> <i>(all-Z)-5,8,11,14,17-</i> <i>Eicosapentaenoic acid</i> EPA <i>Fish oil fatty acid</i> <i>Icosapentaenoic acid</i> <i>Timnodonic acid</i></p>	<p>Source of eicosapentaenoic acid (EPA) for the maintenance of good health.</p>	<p>Products not encapsulated: Refrigerate after opening.</p> <p>Consult a relevant health care provider before use if you have a sensitivity to aspirin or high blood pressure</p>		<p>100 mg</p>	<p><i>As for source.</i></p>
<p>DHA + DPA + EPA</p>	<p>Source of omega-3 fatty acids for the maintenance of good health.</p>	<p>As for any constituent contained therein.</p>	<p>As for any constituent contained therein.</p>	<p>100 mg of the combination thereof.</p>	<p><i>As for source.</i></p>
<p>DHA + EPA</p>	<p>Helps support/maintain (normal) heart/cardiovascular health/function.</p>	<p>As for any constituent contained therein.</p>	<p>As for any constituent contained therein.</p>	<p>250 mg of the combination thereof.</p>	<p><i>As for source.</i></p>
	<p>Helps to support/maintain normal serum/blood triglyceride/triacylglycerol levels.</p>			<p>2 g of the combination thereof.</p>	<p><i>As for source.</i></p>
<p>gamma-Linolenic acid (GLA) <i>Gamolenic acid</i> <i>(6Z,9Z,12Z)-6,9,12-</i> <i>Octadecatrienoic acid</i> <i>cis-6,cis-9,cis-12-</i> <i>Octadecatrienoic acid</i></p>	<p>Source of gamma-linoleic acid.</p>			<p>100 mg</p>	<p><i>As for source.</i></p>
<p>Source materials: <i>Arthrospira platensis (Parts: Whole); Borago officinalis (Parts: Seed); Carthamus tinctorius (Parts: Seed); Echium plantagineum (Parts: Seed); Oenothera biennis (Parts: Seed); Ribes nigrum (Parts: Seed)</i></p>					

Fatty Acid	Health Supplement Claim	SPECIFIED WARNING(S)	Other Instructions/ Directives	Minimum	Maximum
4. Fatty Acid Constituents					
<i>Included to guide recommended use for oils and fats based on FA content. Levels, if not stated, must be determined by source material otherwise Annex. B submission required.</i>					
Oleic acid (OA) <i>(Z)-octadec-9-enoic acid 9-octadecenoic acid butter acids cis-oleic acid medium chain fatty acids omega-9 Fatty Acids</i>	Source of oleic acid.			100 mg	As for source.
Omega-3 fatty acids without EPA/DHA	For the maintenance of good health. <i>As per source.</i>			<i>See claim. As per source.</i>	
<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	<i>As per source.</i>			<i>See claim. As per source.</i>	
<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 (Parts: Fruit)</i>	<i>As per source.</i>			<i>See claim. As per source.</i>	
Omega-9 fatty acids	<i>As per source.</i>			<i>See claim. As per source.</i>	
<i>Buglossoides arvensis (Parts: Seed); Hippophae rhamnoides (Parts: Fruit); Persea americana (Parts: Fruit); Vitis vinifera (Parts: Seed)</i>					

ANNEXURE J

Allowable levels and claims: Carotenoids

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.

Carotenoids are divided into the following categories:

- A. Carotenoids with **Pro-Vitamin A activity**.
- B. Carotenoids mainly used as **Anti-oxidants**.

The maximum daily dose for these Carotenoids in combination with other vitamin A source materials must not exceed the maximum daily dose for vitamin A indicated in Annexure E.

Carotenoids may be derived from the listed source materials but must be substantially pure extracts from the source material and not simply the inclusion of the source material as a whole.

Action: Source of Pro-vitamin A OR antioxidants.

General Statements:

Requirement for labelling:

If you are pregnant or breast feeding your baby please consult your doctor, pharmacist or other relevant health care provider for advice before taking this medicine.

Store in airtight container, protected from light.

Do not exceed daily dosage level without consulting a relevant health care provider.

Long term users (3-month continuous use) should be evaluated and practiced under the care of a relevant health care provider.

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 required on the labelling.

Carotenoid	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage <i>RE: Retinol Equivalents</i>	
			Minimum	Maximum
A. Carotenoids with Pro-Vitamin A activity				
β-Carotene (all-E)-1,1'-(3,7,12,16-Tetramethyl-1,3,5,7,9,11,13,15,17-octadecanonaene-1,18-diyl)bis[2,6,6-trimethylcyclohexen. All-trans beta carotene Beta carotene Sources: All-trans-beta-carotene Beta-carotene	Provitamin A; - for the maintenance of good health. - to help maintain eyesight, skin, membranes and immune function. - to help in the development and maintenance of night vision. - to help in the development and maintenance of bones and teeth. - Maintain / Support healthy vitamin A levels.	Consult a relevant health care provider prior to use if you are a tobacco smoker, have cardiovascular disease, or use statins to lower cholesterol.	Calculated to yield Retinal Activity Equivalents not exceeding dosages as stipulated in Annexure E, Vitamin A.	
α-Carotene (all-E)-1,3,3-Trimethyl-2-(3,7,12,1-tetramethyl-18-(2,6,6-trimethyl-2-cyclohexen-1-yl)-1,3,5,7,9,11,13,15,17-octadecanonaenyl)cyclohexene Sources: Citrus sinensis (Fruit); Dunaliella salina (Whole); Elaeis guineensis (Branch); Elaeis guineensis (Fruit); Persea americana (Fruit); Rubus idaeus (Fruit); Solanum lycopersicum (Fruit); Zea mays (Seed)	As per Annexure E, Vitamin A. Source of antioxidant(s)/Provides antioxidant(s).		Calculated to yield Retinal Activity Equivalents (RAE) not exceeding dosages as stipulated in Annexure E, Vitamin A.	
Cryptoxanthin (3R)-beta,beta-Caroten-3-ol beta-Caroten-3-ol Cryptoxanthine Kryptoxanthin Sources: Capsicum annuum (Fruit); Capsicum annuum (Petal); Carica papaya (Fruit); Citrus aurantium (Fruit peel); Citrus limon (Fruit peel); Citrus paradisi (Fruit); Citrus paradisi (Fruit peel); Citrus sinensis (Fruit peel); Dunaliella salina (Whole); Persea americana (Fruit); Prunus persica (Whole plant); Tagetes erecta (Flower); Zea mays (Seed)	As per Annexure E, Vitamin A. Source of antioxidant(s)/Provides antioxidant(s).		Calculated to yield Retinal Activity Equivalents not exceeding dosages as stipulated in Annexure E, Vitamin A.	

Carotenoid	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage	
			Minimum	Maximum
B. Carotenoids mainly used as Anti-oxidants				
<p>Astaxanthin 3,3'-dihydroxy-4,4'-diketo-beta-carotene. 3,3'-Dihydroxy-beta,beta-carotene-4,4'-dione Sources: Haematococcus pluvialis (Whole); Pandalus borealis (Internal shell)</p>	<p>Source of antioxidant(s)/Provides antioxidant(s). Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.</p>	<p>Not suitable for children. Use should be avoided when taking immunosuppressants, by patients with bleeding disorders, and by patients on 5-α-reductase inhibitors. Astaxanthin > 4 mg per day: For use beyond 3 months, consult a relevant health care provider.</p>	4 mg	8 mg
<p>Lycopene All-trans-lycopene Lycopene psi,psi-Carotene CI 75125 E160(d) Natural yellow 27</p>	<p>Source of antioxidant(s)/Provides antioxidant(s). Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals. For products providing at least 6,5 mg per day: Helps to support prostate health.</p>	<p>Not suitable for children. Consult a relevant health care provider prior to use if diagnosed or suspected to suffer from prostate cancer.</p>	Annexure B submission required.	20 mg
<p>Sources: Tomato extract; Blakeslea trispora (Whole); Citrullus lanatus var. lanatus (Fruit); Citrus aurantium (Fruit); Citrus limon (Fruit); Citrus paradisi (Fruit); Citrus sinensis (Fruit); Elaeis guineensis (Fruit); Rosa canina (Fruit); Solanum lycopersicum (Fruit); Solanum lycopersicum (Fruit flesh)</p>				

Carotenoid	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage	
			Minimum	Maximum
B. Carotenoids mainly used as Anti-oxidants				
Lutein (3R,3'R,6'R)-beta,epsilon-Carotene-3,3'-diol (3R,3'R,6'R)-beta,epsilon-Carotene-3,3'-diol CI 75125 E161(b) Mixed carotenoids (comprising xanthophylls and zeaxanthin) Vegetable lutein Vegetable luteol Xanthophylls	Antioxidant for the maintenance of good health/eye health.		Annexure B submission required.	20 mg
	Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.			
	For products providing at least 6 mg per day: Helps to maintain/support eyesight in certain conditions (associated with sunlight damage). Helps to improve macular pigment optical density.		6 mg	
Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae)); <i>Arnica montana</i> (Flower); <i>Capsicum annuum</i> (Fruit); <i>Cucurbita pepo</i> (Flower); <i>Fucus vesiculosus</i> (Whole); <i>Oryza sativa</i> (Whole plant); <i>Pisum sativum</i> (Whole plant); <i>Solanum lycopersicum</i> (Fruit); <i>Tagetes erecta</i> (Flower); <i>Tagetes erecta</i> (Herb flowering oleoresin); <i>Tagetes erecta</i> (Petal); <i>Taraxacum officinale</i> (Flower); <i>Tussilago farfara</i> (Flower); <i>Viscum album</i> (Leaf)				
Lutein Esters Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae))	Antioxidant for the maintenance of good health/eye health.		Annexure B submission required.	40 mg
	Antioxidant that helps fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals.			
	For products providing at least 12 mg per day: Helps to maintain/support eyesight in certain conditions (associated with sunlight damage). Helps to improve macular pigment optical density.		12 mg	

Carotenoid	Health Supplement Claim	SPECIFIED WARNING(S)	Dosage	
			Minimum	Maximum
B. Carotenoids mainly used as Anti-oxidants				
<p>Zeaxanthin (3R,3'R)-beta,beta-Carotene-3,3'-diol All-trans-beta-Carotene-3,3'-diol Anchovyxanthin beta-Carotene-3,3'-diol meso-zeaxanthin Zeaxanthol</p>	<p>Antioxidant for the maintenance of good health / eye health.</p> <p><i>For products providing at least 0,7 mg per day:</i> Helps to maintain eyesight in conditions (associated with sunlight damage).</p> <p>Helps to improve macular pigment optical density.</p>		Annexure B submission required.	2,5 mg (Total from all sources)
<p>Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i>L.(Asteraceae)); <i>Arnica montana</i> (Flower); <i>Asparagus officinalis</i> (Whole plant); <i>Berberis vulgaris</i> (Whole plant); <i>Camellia sinensis</i> (Leaf); <i>Capsicum annuum</i> (Fruit); <i>Capsicum frutescens</i> (Fruit); <i>Carica papaya</i> (Fruit); <i>Citrus aurantiifolia</i> (Fruit); <i>Citrus aurantium</i> (Fruit); <i>Citrus bergamia</i> (Fruit); <i>Citrus limon</i> (Leaf); <i>Citrus medica</i> var. <i>sarcodactylis</i> (Fruit); <i>Citrus paradisi</i> (Fruit); <i>Citrus reticulata</i> (Fruit); <i>Citrus sinensis</i> (Fruit); <i>Crocus sativus</i> (Peta); <i>Crocus sativus</i> (Stigma and style); <i>Cucurbita pepo</i> (Flower); <i>Dunaliella salina</i> (Whole); <i>Eschscholzia californica</i> (Whole plant); <i>Fucus vesiculosus</i> (Whole); <i>Hippophae rhamnoides</i> (Fruit); <i>Lycium chinense</i> (Fruit); <i>Medicago sativa</i> (Whole plant); <i>Momordica charantia</i> (Fruit); <i>Nannochloropsis gaditana</i> (Broken cell); <i>Palmaria palmata</i> (Whole plant); <i>Prunus persica</i> (Fruit); <i>Rosa canina</i> (Fruit); <i>Solanum lycopersicum</i> (Fruit); <i>Tagetes erecta</i> (Flower); <i>Tagetes erecta</i> (Herb flowering oleoresin); <i>Zea mays</i> (Seed); <i>Zea mays</i> (Whole plant)</p>				
<p>Zeaxanthin Esters Sources: Oleoresin from the flower of marigold (<i>Tagetes erecta</i> L.(Asteraceae))</p>	<p>Antioxidant for the maintenance of good health / eye health.</p> <p><i>For products providing at least 1,5 mg per day:</i> Helps to maintain eyesight in conditions (associated with sunlight damage).</p> <p>Helps to improve macular pigment optical density.</p>		Annexure B submission required.	5 mg (Total from all sources)

ANNEXURE K

Allowable levels and claims: Polyphenols (including Bioflavonoids)

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 a Health Supplement

General Statements:

Action: Source of [type of polyphenol] e.g. source of isoflavones

Warning:

If symptoms worsen, consult a relevant health care provider.

Not suitable for children.

Safety in pregnancy and when breastfeeding has not been established.

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 required on the labelling.

Dosage:

For products providing citrus bioflavonoids, quercetin, hesperidin or rutin, the total daily dose of all bioflavonoids must not exceed 1 000 mg per day.

Appendix 1 - Definitions and Conversion Factors

Definitions

- **Dried Fruit Equivalent**

Also known as the **Quantity Crude Equivalent (QCE)**, is the amount of raw, dried fruit used to make a particular extract, e.g. if 1 g of a 20:1 extract is used, 1 g of the extract provides 20 g of dried fruit equivalent.

- **Aglycone Isoflavone Equivalents (AIE)**

The maximum amount of bioavailable isoflavone upon ingestion. The glycoside forms of the isoflavones must first be cleaved to the aglycone form before they can be absorbed. As such, simple addition of aglycone and glycoside forms of isoflavone quantities, without taking into consideration the biochemical transformation of the isoflavones, will overestimate bioavailable quantities by almost a factor of two.

Conversion factors

The quantity of isoflavones must always be determined in terms of AIE quantities (i.e. in terms of genistein, daidzein, biochanin A and formononetin) for each of the glycoside, malonyl glycoside and/or aglycone forms present in the product.

Table 1 - Conversion of specific isoflavone quantities into aglycone isoflavone equivalent (AIE) quantities

Isoflavone (1 mg)	Aglycone Isoflavone Equivalents (AIE) (mg)
Biochanin A	1,0
Biochanin A -7-O-glucoside	0,64
Formononetin	1,0
Formononetin-7-O-glucoside	0,62
Genistein	1,0
Genistin	0,625
Malonyl genistin	0,521
Daidzein	1,0
Daidzin	0,611
Malonyl daidzin	0,506
Glycitein	1,0

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.1 Anthocyanins			
<p>Anthocyanins Anthocyanosides Grapeskin extract (comprising Cyanidin, Peonidin, Malvidin, Delphinidin, Petunidin, Pelargonidin) Anthocyanosides from cherries, berries, red cabbage, red wine etc.</p> <p>Source: <i>Aristotelia chilensis</i> (Parts: Fruit), <i>Brassica oleracea</i> var. <i>capitata</i> (Parts: Leaf), <i>Daucus carota</i> subsp. <i>sativus</i> var. <i>atrorubens</i> (Parts: Root), <i>Fruit Anthocyanins</i> (Parts: Fruit), <i>Ipomoea batatas</i> cv. <i>ayamurasaki</i> (Parts: Root), <i>Prunus cerasus</i> (Parts: Fruit skin), <i>Raphanus sativus</i> (Parts: Root), <i>Raphanus sativus</i> var. <i>sativus</i> (Parts: Root), <i>Ribes nigrum</i> (Parts: Fruit), <i>Sambucus nigra</i> subsp. <i>nigra</i> (Parts: Fruit), <i>Vaccinium angustifolium</i> (Parts: Fruit), <i>Vaccinium corymbosum</i> (Parts: Fruit), <i>Vaccinium myrtillus</i> (Parts: Fruit), <i>Vaccinium myrtillus</i> (Parts: Leaf), <i>Vaccinium uliginosum</i> (Parts: Fruit), <i>Vegetable Anthocyanins</i> (Parts: Leaf), <i>Vegetable Anthocyanins</i> (Parts: Root)</p>	<p><u>Annexure B submission required.</u></p>		<p>Maximum: 50 mg</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.2 Isoflavones			
<p>Red Clover Isoflavone Extract <i>Trifolium pratense</i> L. Leaf <i>Trifolium pratense</i> L. Herb Top <i>Trifolium pratense</i> L. Flower</p>	<p>Source of antioxidants.</p> <p>Menopausal and postmenopausal women For use in reducing symptoms associated with menopause such as hot flashes and/or night sweats.</p> <p>Postmenopausal women When combined with sufficient vitamin D, calcium, a healthy diet and regular exercise, may contribute to the reduced loss of bone mineral density (BMD).</p>	<p>Pre-menopausal Women If you are pregnant or breastfeeding, consult a relevant health care provider prior to use.</p> <p>Postmenopausal women Ensure that you are up-to-date on appointed clinical tests such as mammograms and endometrial ultrasounds or biopsies before using this product.</p> <p>Consult a relevant health care provider prior to use if you:</p> <ul style="list-style-type: none"> • are taking thyroid hormone replacement therapy; or you have a liver disorder or develop liver-related symptoms (e.g. abdominal pain, jaundice, dark urine); • have a history of hormonal or gynaecological disease including ovarian cancer, endometriosis and/or uterine fibroids; • are taking hormone replacement therapy; or <p>Discontinue use if you experience breast pain, discomfort, soreness and/or tenderness, abnormal uterine bleeding including spotting and/or recurrence of menstruation and consult a relevant health care provider.</p> <p><u>Hot flushes and/or night sweats</u> If symptoms worsen, consult a relevant health care provider.</p>	<p>Preparations equivalent to 40-100 mg total AIE, per day.</p> <p>Use for a minimum of 2 weeks to see beneficial effects.</p> <p>For all products: The total isoflavones content must be expressed in mg total AIE on the product label and in the potency section of the PLA.</p> <p>Optional: Potencies may be indicated for specific isoflavones (biochanin A, genistein, formononetin, daidzein). Their content must also be expressed in mg AIE on the product label and in the potency section of the PLA.</p> <p>Refer to Appendix 1 of this Annexure for the definition and derivation of AIE.</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.2 Isoflavones			
		<p>Contraindication(s)</p> <p><i>Postmenopausal women</i> <i>≥ 30 mg AIE, per day</i></p> <p>If you currently have or previously had breast cancer or if you have a predisposition to breast cancer, as indicated by an abnormal mammogram and/or biopsy, or if you have a family member with breast cancer, do not use this product.</p>	
<p>Soy Isoflavone Extract <i>Glycine max</i> (L.) Merr. <i>Glycine max</i> (Parts: Hypocotyl) <i>Glycine max</i> (Parts: Leaf cotyledon) <i>Glycine max</i> (Parts: Seed) <i>Glycine max</i> (Parts: Seed coat)</p>	<p>When combined with sufficient vitamin D, calcium, a healthy diet and regular exercise, may contribute to the reduced loss of bone mineral density (BMD).</p> <p>For use in reducing symptoms associated with menopause such as hot flashes and/or night sweats.</p>	<p>Ensure you are up-to-date on mammograms and gynaecological evaluations prior to use.</p> <p>Consult a relevant health care provider if symptoms worsen and prior to use if you:</p> <ul style="list-style-type: none"> • are taking blood thinners; • have a history of hormonal or gynaecological disease, including ovarian cancer, endometriosis, and/or uterine fibroids; • have a liver disorder or develop liver-related symptoms (e.g. abdominal pain, jaundice, dark urine); or • are taking hormone replacement therapy (HRT), including thyroid hormone replacement therapy. <p>Discontinue use and consult a relevant health care provider if you experience breast pain, discomfort and/or</p>	<p>Reduced loss of BMD: <i>Post-menopausal women</i> Total isoflavones: Preparations equivalent to 75-125 mg AIE, per day. Use for a minimum of 6 months to see beneficial effects.</p> <p>Reduced Menopausal symptoms: <i>Menopausal and post-menopausal women</i> Total isoflavones: Preparations equivalent to 30-100 mg AIE with a minimum of 15 mg AIE from genistein/genistin compounds, per day. Use for a minimum of 2 weeks to see beneficial effects.</p> <p>For all products: <i>Total isoflavones content must be expressed in aglycone isoflavone equivalents (AIE) on the product label and</i></p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.2 Isoflavones			
		tenderness, or a recurrence of menstruation and/or uterine spotting. Contraindication(s): Do not use if you currently have or previously had breast cancer and/or breast tumours or if you have a predisposition to breast cancer, as indicated by an abnormal mammogram and/or biopsy, or a family member with breast cancer.	in the potency section of the registration application. Additionally, genistein/genistin compounds (including genistein, genistin, acetyl genistin, and malonyl genistin) content must also be expressed in AIE on the product label and in the potency section of the registration application for products with reduction of menopausal symptom claims. Refer to Appendix 1 of this Annexure for the definition and derivation of AIE.
Biochanin A 4,5-dihydroxy-3-(4-methoxyphenyl)-chromen-7-one 4H-1-Benzopyran-4-one, 5,7-dihydroxy-3-(4-methoxyphenyl)- 5,7-Dihydroxy-3-p-methoxyphenyl-4H-chromen-4-one 5,7-Dihydroxy-4'-methoxyisoflavone Isoflavone, 5,7-dihydroxy-4'-methoxy-Pratensol Red Clover Isoflavone Extract	Permitted only as a component of Red Clover Isoflavone extract, unless subject to a successful Annexure B application.		
Source: <i>Trifolium pratense (Parts: Flower), Trifolium pratense (Parts: Herb top), Trifolium pratense (Parts: Leaf), Trifolium pratense (Parts: Whole plant)</i>			
Daidzein 4',7-Dihydroxyisoflavone 4H-1-Benzopyran-4-one, 7-hydroxy-3-(4-hydroxyphenyl)- 7,4'-Dihydroxyisoflavone Daidzeol soy isoflavone Red Clover isoflavone extract	Permitted only as a component of: 1. Red Clover Isoflavone extract; and 2. Soy isoflavone extract.	Do not use if: <ul style="list-style-type: none"> • pregnant or intending to become pregnant; • breastfeeding; or • you are taking oestrogen supplements or anticoagulant therapy such as warfarin. 	
Source: <i>Glycine max (Parts: Hypocotyl), Glycine max (Parts: Leaf cotyledon), Glycine max (Parts: Seed), Glycine max (Parts: Seed coat), Trifolium pratense (Parts: Flower), Trifolium pratense (Parts: Herb top), Trifolium pratense (Parts: Leaf), Trifolium pratense (Parts: Whole plant)</i>			
Daidzin	Permitted only as a component of:	Do not use if:	

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.2 Isoflavones			
<p>Daidzein 7-glucoside Daidzein 7-O-glucoside Daidzoside H-1-Benzopyran-4-one, 7-(beta-D-glucopyranosyloxy)-3-(4-hydroxyphenyl)- soy isoflavone</p> <p>Source: <i>Glycine max</i> (Parts: Hypocotyl, Leaf cotyledon, Seed, Seed coat), <i>Pueraria montana - var. lobata</i> (Parts: Root) - var. <i>thomsonii</i> (Parts: Root), <i>Trifolium pratense</i> (Parts: Whole plant)</p>	<p>1. Red Clover Isoflavone extract; or 2. Soy isoflavone extract.</p>	<ul style="list-style-type: none"> • pregnant or intending to become pregnant; • breastfeeding; or • you are taking oestrogen supplements or anticoagulant therapy, such as warfarin. 	
<p>Formononetin 7-Hydroxy-4'-methoxyisoflavone 4H-1-Benzopyran-4-one, 7-hydroxy-3-(4-methoxyphenyl)- Formononetol Red Clover Isoflavone Extract</p> <p>Source: <i>Trifolium pratense</i> (Parts: Flower), <i>Trifolium pratense</i> (Parts: Herb top), <i>Trifolium pratense</i> (Parts: Leaf), <i>Trifolium pratense</i> (Parts: Whole plant)</p>	<p>Permitted only as a component of: Red Clover Isoflavone extract.</p>		
<p>Genistein 4',5,7-Trihydroxyisoflavone 5,7-Dihydroxy-3-(4-hydroxyphenyl)-4H-1-benzopyran-4-one 4',5,7-Trihydroxyisoflavone 4H-1-Benzopyran-4-one, 5,7-dihydroxy-3-(4-hydroxyphenyl)- Genisteol Genisterin</p> <p>Source: <i>Glycine max</i> (Parts: Hypocotyl, Leaf cotyledon, Seed, Seed coat, Seed endosperm), <i>Trifolium pratense</i> (Parts: Flower, Herb top, Leaf, Whole plant)</p>	<p>Permitted only as a component of:</p> <p>1. Red Clover Isoflavone extract; or 2. Soy isoflavone extract.</p>	<p>Do not use if:</p> <ul style="list-style-type: none"> • pregnant or intending to become pregnant; • breastfeeding; or • you are taking oestrogen supplements or anticoagulant therapy, such as warfarin. 	
<p>Genistin 4H-1-Benzopyran-4-one, 7-(beta-D-glucopyranosyloxy)-3-(4-hydroxyphenyl)- 7-beta-D-glucopyranoside Genistein 7-glucoside soy isoflavone 7-(beta-D-glucopyranosyloxy)-3-(4-hydroxyphenyl)-4H-1-Benzopyran-4-one</p> <p>Source: <i>Glycine max</i> (Parts: Hypocotyl), <i>Glycine max</i> (Parts: Leaf cotyledon), <i>Glycine max</i> (Parts: Seed), <i>Glycine max</i> (Parts: Seed coat)</p>	<p>Permitted only as a component of:</p> <p>1. Soy isoflavone extract.</p>	<p>Do not use if:</p> <ul style="list-style-type: none"> • pregnant or intending to become pregnant; • breastfeeding; or • you are taking oestrogen supplements or anticoagulant therapy, such as warfarin. 	

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.3 Flavonols			
<p>Quercetin <i>Quercetin</i> <i>Quercetin dihydrate</i> <i>2-(3,4-dihydroxyphenyl)-3,5,7-trihydroxychromen-4-one</i> <i>3,3',4',5,7-Pentahydroxyflavone</i> <i>Quercitin</i> <i>Sophoretin</i></p>	<p>An antioxidant.</p> <p>Used as a capillary/blood vessel protectant.</p> <p>Contributes to maintaining normal immune response to seasonal allergens.</p>	<p>Not for use in children.</p> <p>Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.</p> <p>For products providing 40 – 1 200 mg per day: For use beyond 12 weeks, consult a relevant health care provider.</p> <p>For products providing doses that are 40 - 1 200 mg per day, the following statement is required: Take in 2 or 3 divided doses with food/meals.</p>	<p>Adults: Maximum: 1 200 mg</p> <p>Capillary/blood vessel protectant Dose(s): 600 – 1 200 mg per day</p> <p>Normal immune response to seasonal allergens: Dose(s): 200 – 1 200 mg per day</p>
<p>Sources: <i>Allium cepa</i> (Parts: Bulb); <i>Allium sativum</i> (Parts: Bulb); <i>Allium schoenoprasum</i> (Parts: Leaf); <i>Apis mellifera</i> (Parts: Gum from beehive); <i>Avena sativa</i> (Parts: Herb); <i>Azadirachta indica</i> (Parts: Flower); <i>Azadirachta indica</i> (Parts: Leaf); <i>Brassica oleracea</i> var. <i>botrytis</i> (Parts: Flower); <i>Brassica oleracea</i> var. <i>botrytis</i> (Parts: Leaf); <i>Brassica oleracea</i> var. <i>capitata</i> (Parts: Leaf); <i>Brassica oleracea</i> var. <i>gemmifera</i> (Parts: Sprout); <i>Brassica oleracea</i> var. <i>gongylodes</i> (Parts: Shoot); <i>Brassica oleracea</i> var. <i>sabellica</i> (Parts: Leaf); <i>Camellia sinensis</i> (Parts: Leaf); <i>Camellia sinensis</i> (Parts: Whole plant); <i>Capsicum frutescens</i> (Parts: Fruit); <i>Dimorphandra mollis</i> (Parts: Leaf); <i>Dimorphandra mollis</i> (Parts: Seed); <i>Empetrum nigrum</i> (Parts: Fruit); <i>Empetrum nigrum</i> var. <i>hermaphroditum</i> (Parts: Fruit); <i>Helianthus annuus</i> (Parts: Flower); <i>Helianthus annuus</i> (Parts: Leaf); <i>Hippophae rhamnoides</i> (Parts: Fruit); <i>Malus domestica</i> (Parts: Fruit pericarp); <i>Oenothera biennis</i> (Parts: Herb); <i>Oenothera biennis</i> (Parts: Leaf); <i>Olea europaea</i> (Parts: Fruit); <i>Olea europaea</i> (Parts: Fruit flesh); <i>Podophyllum hexandrum</i> (Parts: Rhizome); <i>Podophyllum peltatum</i> (Parts: Rhizome Resin); <i>Prunus virginiana</i> (Parts: Fruit); <i>Pyrus communis</i> (Parts: Fruit pericarp); <i>Ribes nigrum</i> (Parts: Fruit); <i>Sorbus aucuparia</i> (Parts: Fruit); <i>Spinacia oleracea</i> (Parts: Leaf); <i>Styphnolobium japonicum</i> (Parts: Flower); <i>Styphnolobium japonicum</i> (Parts: Flower bud); <i>Styphnolobium japonicum</i> (Parts: Whole plant); <i>Vaccinium angustifolium</i> (Parts: Fruit); <i>Vaccinium macrocarpon</i> (Parts: Fruit); <i>Vaccinium myrtillus</i> (Parts: Fruit); <i>Vaccinium vitis-idaea</i> (Parts: Fruit)</p>			

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.3 Flavonols			
<p>Rutoside (Rutin) <i>Rutin</i> <i>Rutinoside</i> 3-[[6-O-(6-Deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl]oxy]-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4H-1-benzopyran-4-one <i>quercetin-3-O-rutinoside</i> <i>Sophorin</i> 3,3',4',5,7-Pentahydroxyflavone-3-rutinoside 3-(O-6-deoxy-alpha-l-mannopyranosyl-(1-6)-beta-d-glucopyranosyloxy)-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4H-chromen-4-one</p>	<p>An antioxidant. Used as a capillary/blood vessel protectant.</p>	<p>If pregnant or breastfeeding, consult a relevant health care provider prior to use. For products providing doses greater than or equal to 250 mg per day: For use beyond 6 weeks, consult a relevant health care provider.</p>	<p>Maximum: 1 000 mg Capillary/blood vessel protectant Dose(s): 400 – 1 000 mg per day <i>NOTE: A single dose should not exceed 500 mg.</i></p>
<p>Source: <i>Apium graveolens var. dulce</i> (Parts: Whole plant), <i>Artemisia dracunculus</i> (Parts: Shoot), <i>Brassica oleracea var. gemmifera</i> (Parts: Shoot), <i>Camellia sinensis</i> (Parts: Leaf), <i>Citrus limon</i> (Parts: Fruit), <i>Citrus limon</i> (Parts: Leaf), <i>Citrus sinensis</i> (Parts: Fruit pericarp), <i>Citrus sinensis</i> (Parts: Leaf), <i>Dimorphandra gardneriana</i> (Parts: Seed), <i>Dimorphandra gardneriana</i> (Parts: Seed pod), <i>Dimorphandra mollis</i> (Parts: Fruit), <i>Dimorphandra mollis</i> (Parts: Husk), <i>Dimorphandra mollis</i> (Parts: Seed pod), <i>Eschscholzia californica</i> (Parts: Flower), <i>Fagopyrum esculentum</i> (Parts: Flower), <i>Fagopyrum esculentum</i> (Parts: Herb top), <i>Fagopyrum esculentum</i> (Parts: Leaf), <i>Fagopyrum esculentum</i> (Parts: Stem), <i>Fagopyrum esculentum</i> (Parts: Whole plant), <i>Ficus carica</i> (Parts: Leaf), <i>Forsythia suspensa</i> (Parts: Flower), <i>Forsythia suspensa</i> (Parts: Fruit), <i>Humulus lupulus</i> (Parts: Leaf), <i>Humulus lupulus</i> (Parts: Strobile), <i>Hydrangea paniculata</i> (Parts: Flower), <i>Lespedeza capitata</i> (Parts: Leaf), <i>Magnolia kobus</i> (Parts: Flower), <i>Morus alba</i> (Parts: Leaf), <i>Nicotiana glauca</i> (Parts: Leaf), <i>Nicotiana tabacum</i> (Parts: Leaf), <i>Persicaria hydropiper</i> (Parts: Leaf), <i>Petroselinum crispum</i> (Parts: Leaf), <i>Prunus armeniaca</i> (Parts: Leaf), <i>Reynoutria japonica</i> (Parts: Whole plant), <i>Reynoutria multiflora</i> (Parts: Whole plant), <i>Rheum officinale</i> (Parts: Leaf), <i>Rheum officinale</i> (Parts: Rootlet), <i>Rheum officinale</i> (Parts: Stem), <i>Rheum undulatum</i> (Parts: Leaf), <i>Rheum undulatum</i> (Parts: Stem), <i>Ricinus communis</i> (Parts: Leaf), <i>Rumex acetosa</i> (Parts: Leaf), <i>Rumex acetosella</i> (Parts: Shoot), <i>Ruscus aculeatus</i> (Parts: Whole plant), <i>Ruta graveolens</i> (Parts: Leaf), <i>Ruta graveolens</i> (Parts: Whole plant), <i>Sambucus nigra subsp. canadensis</i> (Parts: Flower), <i>Sambucus nigra subsp. canadensis</i> (Parts: Leaf), <i>Sambucus nigra subsp. nigra</i> (Parts: Flower), <i>Sambucus nigra subsp. nigra</i> (Parts: Leaf), <i>Solanum lycopersicum</i> (Parts: Fruit), <i>Solanum lycopersicum</i> (Parts: Leaf), <i>Solidago virgaurea</i> (Parts: Herb), <i>Spinacia oleracea</i> (Parts: Leaf), <i>Styphnolobium japonicum</i> (Parts: Flower), <i>Styphnolobium japonicum</i> (Parts: Flower bud), <i>Styphnolobium japonicum</i> (Parts: Fruit), <i>Styphnolobium japonicum</i> (Parts: Leaf), <i>Tussilago farfara</i> (Parts: Flower), <i>Uncaria elliptica</i> (Parts: Leaf), <i>Viola odorata</i> (Parts: Flower), <i>Viola tricolor</i> (Parts: Flower), <i>Ziziphus jujuba</i> (Parts: Leaf)</p>			

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.4 Flavanols (flavan-3-ols)			
<p>Grape Seed extract <i>spp. Vitis vinifera (L.)</i> <i>Vitis vinifera Seed Extract</i> (source of oligomeric proanthocyanidins)</p>	<p>Source of antioxidants for the maintenance of good health.</p> <p>Contributes to the maintenance of venous health.</p>	<p>Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.</p> <p>Venous health: Use for a minimum of 1 month to see beneficial effects. Consult a relevant health care provider for use beyond 3 months or if symptoms worsen.</p>	<p>Antioxidant: Maximum: 475 mg containing 80 to 85 % oligomeric proanthocyanidins</p> <p>Venous health: 150 mg to 475 mg grape seed extract containing 80 to 85 % oligomeric proanthocyanidins</p>
<p>Green Tea Catechins – complex Sources: <i>Camellia sinensis</i> L. Kuntze <i>Camellia sinensis</i> (Parts: Leaf) <i>Camellia sinensis</i> (Parts: Leaf bud) <i>Camellia sinensis</i> (Parts: Leaf young)</p>	<p>Source of antioxidants for the maintenance of good health.</p> <p>To be used with a program of reduced intake of dietary calories and increased physical activity (if possible); to help in weight management.</p> <p>If containing caffeine refer to: Guideline 7.06, Annex 1: CAFFEINE.</p>	<p>Catechins (of <i>Camellia sinensis</i> L. Kuntze) if containing caffeine: CONTAINS CAFFEINE (refer to Guideline 7.06, Annex 1: CAFFEINE). Rare, unpredictable cases of liver injury associated with green tea extract-containing products have been reported. Stop use and consult a relevant health care provider if you develop symptoms of liver trouble such as yellowing of the skin/eyes (jaundice), stomach pain, dark urine, sweating, nausea, unusual tiredness and/or loss of appetite. Consult a relevant health care provider:</p> <ul style="list-style-type: none"> • for use beyond 12 weeks; • prior to use if you are pregnant or breastfeeding; or • if you have a liver disorder or an iron deficiency. 	<p>Antioxidant: Extracts providing up to 690 mg total catechins, and no more than 150 mg caffeine, per day.</p> <p>Weight management: Extracts providing 136 to 300 mg (-)-epigallocatechin-3-gallate (EGCG) and 75 to 150 mg caffeine, per day with an EGCG:caffeine ratio of 1.8:1 to 4:1.</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.4 Flavanols (flavan-3-ols)			
<p>Epigallocatechin gallate (EGCG) <i>Epigallocatechin-3-gallate</i> 3,4,5-Trihydroxybenzoic acid, (2R,3R)-3,4-dihydro-5,7-dihydroxy-2-(3,4,5-trihydroxyphenyl)-2H-1-benzopyran-3-yl ester</p> <p>Sources: <i>Camellia sinensis</i> (Parts: Leaf), <i>Camellia sinensis</i> (Parts: Leaf bud), <i>Camellia sinensis</i> (Parts: Leaf young), Green tea Polyphenols Phospholipid Group (Parts: Leaf)</p>	<p>Orally: Permitted only as a component of Green Tea extract.</p>		
<p>Proanthocyanidins <i>(4,8'-Bi-2H-1-benzopyran)-3,3',5,5',7,7'-hexol, 2'-(3,5-dihydroxy-4-methoxyphenyl)-3,3',4,4'-tetrahydro-2-(4-hydroxyphenyl)-, (2R,2'R,3R,3'R,4R)-</i> Grape seed extract</p> <p>Sources: Blend of Fruit (Parts: Fruit); <i>Ceratonia siliqua</i> (Parts: Fruit); <i>Hamamelis virginiana</i> (Parts: Leaf); <i>Pinus massoniana</i> (Parts: Stem bark); <i>Pinus pinaster</i> (Parts: Stem bark); <i>Pinus radiata</i> (Parts: Stem bark); <i>Pinus radiata</i> (Parts: Twig bark); <i>Vaccinium macrocarpon</i> (Parts: Fruit); <i>Vitis vinifera</i> 'Chardonnay' (Parts: Seed); <i>Vitis vinifera</i> (Parts: Fruit skin); <i>Vitis vinifera</i> (Parts: Seed)</p>	<p>An antioxidant.</p>		<p>Maximum: 50 mg For <i>Vaccinium macrocarpon</i>, proanthocyanidins calculated as: procyanidine B1</p>
<p>Oligomeric Proanthocyanidins</p> <p>Sources: Blend of Fruit (Parts: Fruit); <i>Crataegus laevigata</i> (Parts: Fruit); <i>Crataegus monogyna</i> (Parts: Fruit); Grape Seed Oligomeric proanthocyanidins Phospholipid Group (Parts: Seed); <i>Hamamelis virginiana</i> (Parts: Leaf); <i>Hamamelis virginiana</i> (Parts: Twig bark); <i>Pinus pinaster</i> (Parts: Whole plant); <i>Vitis vinifera</i> (Parts: Seed)</p>	<p>Source of antioxidants for the maintenance of good health.</p>	<p>Consult a relevant health care provider prior to use if you are pregnant or breastfeeding.</p>	<p>Maximum: 400 mg oligomeric proanthocyanidins</p>
<p>Tannins</p>		<p>For any containing-product: This product may adversely affect the absorption of Iron and Zinc.</p>	

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.5 Flavones			
<p>Diosmin <i>Diosmetin-7-O-rutinoside</i> <i>Diosmine</i> <i>Barosmin</i> <i>5-Hydroxy-2-(3-hydroxy-4-methoxyphenyl)-7-(O6-alpha-L-rhamnopyranosyl-beta-D-glucopyranosyloxy)chromen-4-one</i> <i>3',5-Dihydroxy-4'-methoxy-4-oxo-4H-chromen-7-ylrutosid</i> <i>7-[(6-O-(6-Deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl)oxy]-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4H-1-benzopyran-4-one</i></p> <p>Source: <i>Citrus sinensis</i> (L.); – fruit peel, <i>Buchu Resin</i></p>	<p><i>Pending scheduling amendment.</i> Permitted only as a component of Citrus polyphenol extract.</p>		
<p>Nobiletin <i>2-(3,4-Dimethoxyphenyl)-5,6,7,8-tetramethoxy-4H-1-benzopyran-4-one</i></p>	<p>Permitted only as a component of Citrus polyphenol extract.</p>		
<p>Polymethoxylated Flavones <i>methoxyflavones</i> <i>methoxylated flavones</i> Sub-ingredients: <i>5,6,7,8,4'-pentamethoxyflavone (Tangeretin)</i> <i>5,6,7,3',4'-pentamethoxyflavone (Sinensetin)</i> <i>5,6,7,8,3',4'-hexamethoxyflavone(nobiletin)</i> <i>3,5,6,7,8,3',4'-heptamethoxyflavone (heptamethoxyflavone)</i></p> <p>Sources: <i>Citrus aurantium</i> (Parts: Fruit peel); <i>Citrus reticulata</i> (Parts: Fruit peel); <i>Citrus sinensis</i> (Parts: Fruit peel)</p>	<p>Antioxidant.</p>	<p>Consult a relevant health care provider before use if you are:</p> <ul style="list-style-type: none"> • taking anticoagulants or antiplatelet medicines; or • at risk of bleeding problems. 	<p>Maximum: 270 mg</p>
<p>Tangeretin <i>5,6,7,8,4'-Pentamethoxyflavone</i> <i>5,6,7,8-Tetramethoxy-2-(4-methoxyphenyl)-4-benzopyrone</i></p> <p>Sources: <i>Citrus aurantium</i> (Parts: Fruit); <i>Citrus limon</i> (Parts: Fruit); <i>Citrus medica</i> (Parts: Fruit); <i>Citrus reticulata</i> (Parts: Fruit); <i>Citrus sinensis</i> (Parts: Fruit)</p>	<p>Permitted only as a component of a Citrus polyphenol extract.</p>		

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
1. FLAVONOIDS: 1.6 Flavanones			
Eriocitrin (S)-7-((6-O-(6-Deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl)oxy)-2-(3,4-dihydroxyphenyl)-2,3-dihydro-5-hydroxy-4H-benzopyran-4-one Citrus Bioflavonoid	Permitted only as a component of Citrus polyphenol extract.		
Hesperidin (2S)-7-[[[6-O-(6-Deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl]oxy]-2,3-dihydro-5-hydroxy-2-(3-hydroxy-4-methoxyphenyl)-4H-1-benzopyran-4-one Hesperetin 7-rutinoside Hesperitin-7-rhamnoglucoside	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.	For doses > 50 mg/day: Consult a relevant health care provider prior to use if you are: <ul style="list-style-type: none"> • pregnant or breastfeeding; and • taking any prescription medication. 	Maximum: 1 000 mg
Sources: Citrus aurantium (Parts: Fruit), Citrus limon (Parts: Fruit), Citrus medica (Parts: Fruit), Citrus paradisi (Parts: Fruit), Citrus reticulata (Parts: Fruit), Citrus sinensis (Parts: Fruit)			
Naringenin (S)-2,3-Dihydro-5,7-dihydroxy-2-(4-hydroxyphenyl)-4-benzopyrone	Permitted only as a component of Citrus polyphenol extract.		
Sources: Citrus maxima (Parts: Fruit), Citrus sinensis (Parts: Fruit pericarp)			
Naringin 4',5,7-Trihydroxyflavanone 7-rhamnoglucoside 7-[[[2-O-(6-Deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl]oxy]-2,3-dihydro-5-hydroxy-2-(4-hydroxyphenyl)-4H-1-benzopyran-4-one	Permitted only as a component of Citrus polyphenol extract.		
Sources: Citrus bergamia (Parts: Fruit), Citrus maxima (Parts: Fruit), Citrus maxima (Parts: Fruit peel), Citrus paradisi (Parts: Fruit), Citrus paradisi (Parts: Seed)			

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
2. STILBENOIDS			
<p>Resveratrol <i>(E)-5-(p-Hydroxystyryl)resorcinol</i> <i>1,3-Benzenediol, 5-(2-(4-hydroxyphenyl)ethenyl)-, (E)-3,4',5-Stilbenetriol</i> <i>3,4',5-Trihydroxystilbene</i> <i>5-[(1E)-2-(4-Hydroxyphenyl)ethenyl]-1,3-benzenediol</i> <i>trans-3,4',5-Trihydroxystilbene</i> <i>trans-Resveratrol</i></p> <p>Sources: <i>Reynoutria japonica (Parts: Root)</i> <i>Reynoutria multiflora (Parts: Root)</i> <i>Vitis vinifera 'Chardonnay' (Parts: Fruit)</i> <i>Vitis vinifera (Parts: Fruit)</i> <i>Vitis vinifera (Parts: Leaf)</i> <i>Yucca schidigera (Parts: Trunk bark)</i></p>	<p>An antioxidant.</p>	<p>Not suitable for children.</p> <p>Resveratrol may interact with anticoagulants or antiplatelet medicines.</p> <p>Consult a relevant health care provider prior to use, especially if you:</p> <ul style="list-style-type: none"> • are pregnant or breastfeeding; • are taking prescription medication, as resveratrol may alter the effectiveness of these medications; and • have hormone sensitive conditions. <p>Products providing more than 250 mg resveratrol per day: For prolonged use, consult a relevant health care provider.</p> <p>Known adverse reaction(s): Products providing ≥ 500 mg of resveratrol per day: May cause nausea, abdominal pain, and/or diarrhoea</p>	<p style="text-align: center;">Adults: Maximum: 1 000 mg per day</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
3. PHENOLIC ACIDS			
<i>None currently recognized as health supplements.</i>			

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
4. LIGNANS			
<p>Flaxseed 2,3-Bis(3-methoxy-4-hydroxybenzyl)butane-1,4-diol 1,4-diglucoside beta-D-Glucopyranose, diglycoside with 2,3-bis((4-hydroxy-3-methoxyphenyl)methyl-1,4-butanediol, (R-(R*,R*))-Secoisolariciresinol diglucoside</p> <p>Source: Linum usitatissimum seed (ripe seed only)</p>	<p><i>Reference to this entry is specific to the action of the lignans contained in Flaxseed:</i></p> <p>Contributes to the maintenance of normal blood glucose levels.</p> <p>Contributes to the maintenance of normal blood pressure.</p> <p><i>See also:</i></p> <p><i>Annexure G - Flaxseed protein</i></p> <p><i>Annexure I - Flaxseed oil</i></p> <p><i>Annexure O - Flaxseed</i></p>	<p>Consult a relevant health care provider if intended for use for longer than 3 months.</p>	<p>Maximum dose yielding 360 mg secoisolariciresinol diglucoside.</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
5. CURCUMINOIDS			
<p>Curcuminoids mixed <i>curcumin</i> <i>demethoxycurcumin</i> <i>bisdemethoxycurcumin</i></p> <p>Sources: <i>Curcuma longa</i> (Parts: Rhizome) <i>Curcuma longa</i> (Parts: Root) <i>Curcuma longa</i> (Parts: Whole plant) Turmeric Curcuminoids Phospholipid Group (Parts: Rhizome)</p>	<p>See 6. <i>Curcumin</i>.</p>		

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
6. CURCUMIN			
<p>Curcumin <i>(1E,6E)-1,7-Bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione</i> <i>Diferoyl Methane</i> <i>Turmeric yellow</i></p> <p>Sources: <i>Curcuma longa (Parts: Rhizome)</i> <i>Curcuma longa (Parts: Root)</i> <i>Curcuma picta (Parts: Rhizome)</i> <i>Turmeric Curcuminoids Phospholipid Group (Parts: Rhizome)</i></p>	<p>An antioxidant. Helps to relieve inflammation.</p>	<p>Consult a relevant health care provider prior to use if you:</p> <ul style="list-style-type: none"> • are pregnant; • are taking antiplatelet medication or blood thinners; • have gallstones or a bile duct obstruction; or • have stomach ulcers or excess stomach acid. <p>Relief of inflammation: Consult a relevant health care provider if symptoms persist or worsen.</p>	<p style="text-align: center;">Adults: Maximum: 400 mg, 3 times daily</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
7. MIXED EXTRACT POLYPHENOLS			
<p>Bilberry Extract <i>Vaccinium myrtillus</i> L. Common Name(s): Bilberry European blueberry Huckleberry Whortleberry</p>	<p>Provides antioxidants for the maintenance of good health.</p> <p>Use to maintain and promote eye health and healthy vision.</p> <p>Use to maintain and promote vascular health.</p>		<p>Maintain and promote: eye health and healthy vision / vascular health:</p> <p>160 to 480 mg of dried extract standardized to 36 % anthocyanins, per day; Not to exceed 160 mg per single dose</p> <p>Antioxidant: Minimum: 1,8 g QCE Maximum: 75 g QCE</p>
<p>Blueberry Extract Species: <i>Vaccinium corymbosum</i> L. <ul style="list-style-type: none"> • American blueberry • highbush blueberry • swamp blueberry • <i>Vaccinium atlanticum</i> • <i>Vaccinium constablaei</i>; <i>Vaccinium angustifolium</i> Aiton [accepted name] <ul style="list-style-type: none"> • Blueberry • Late sweet blueberry • Low sweet blueberry • Lowbush blueberry • Sweethurts • Upland lowbush blueberry • <i>Vaccinium brittonii</i> • <i>Vaccinium lamarckii</i> • <i>Vaccinium nigrum</i> • <i>Vaccinium pensylvanicum</i>; and/or • <i>Vaccinium pallidum</i> Aiton </p>	<p>Provides antioxidants.</p>	<p>Not suitable for children.</p> <p>Products providing ≥ 5 g dried fruit equivalent per day;</p> <p>If you are taking blood thinners, consult a relevant health care provider prior to use.</p>	<p>Adults:</p> <p>Dry, Non-Standardized extracts & Standardized extracts:</p> <p>Maximum: 20 g dried fruit equivalent per day</p>
<p>Citrus Bioflavonoids <i>Citrus bioflavonoids</i></p>	<p>Provides antioxidants.</p>	<p>Not suitable for children.</p>	<p>Adults:</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
7. MIXED EXTRACT POLYPHENOLS			
<p><i>Citrus extract</i> <i>Lemon bioflavonoids</i> <i>Orange bioflavonoids</i> Sub-ingredients: <i>Diosmin, Eriocitrin, Hesperidin, Naringenin, Naringin, Nobiletin, Quercetin, Rutin, Tangeretin</i></p> <p>Sources: <i>Citrus sinensis (L.), Citrus limon (L.), Citrus reticulata Blanco –; Peel, rind and/or fruit, Citrus aurantiifolia, Citrus paradisi Macfad. – Peel, rind and/or fruit, Citrus aurantiifolia (Parts: Fruit), Citrus aurantiifolia (Parts: Fruit peel), Citrus aurantium (Parts: Fruit), Citrus aurantium (Parts: Fruit peel), Citrus bergamia (Parts: Fruit), Citrus limon (Parts: Fruit), Citrus limon (Parts: Fruit peel), Citrus maxima (Parts: Fruit), Citrus paradisi (Parts: Fruit), Citrus paradisi (Parts: Fruit peel), Citrus reticulata (Parts: Fruit), Citrus reticulata (Parts: Fruit peel), Citrus sinensis (Parts: Fruit), Citrus sinensis (Parts: Fruit peel)</i></p>		<p>Products providing ≥ 50 mg per day:</p> <p>If you are taking prescription medication, consult a relevant health care provider prior to use, as citrus bioflavonoids may alter the effectiveness of these medications.</p>	<p>Maximum: 1 000 mg citrus bioflavonoids per day.</p>
<p>Green Tea Polyphenols Green Tea Catechins <i>Thea sinensis</i> See 1.4.7 – Green Tea Catechins</p>	<p>See Green Tea Catechins</p>		
<p>Lemon Bioflavonoids <i>Bioflavonoids</i></p>	<p>See Citrus Bioflavonoids.</p>		
<p>Pine Bark Extract <i>Pinus maritima</i> bark extract Source: <i>Pinus pinaster</i> (Parts: Whole plant) Preparations: Dry, Fresh</p>	<p>An antioxidant. 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>If you are taking blood thinners, diabetic medication or immune suppressant medication consult a relevant health care provider prior to use. Discontinue use at least 2 weeks before elective surgical procedures.</p>	<p>200 to 450 mg of extract standardised to 65-75 % procyanidins</p>

ANNEXURE L

Allowable levels and claims: Aminosaccharides

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

General Statements:

Warning:

If symptoms worsen, consult a relevant health care provider.

Not suitable for children unless under the care of a relevant health care provider.

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 required on the labelling.

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
Chitosan	<i>See Annexure H - Animal Extracts Products and Derivatives</i>		
Chondroitin sulphate	<i>See Annexure H - Animal Extracts Products and Derivatives</i>		
<p>Glucosamine Hydrochloride <i>2-Amino-2-deoxy-beta-D-glucopyranose hydrochloride</i> <i>◦2-Amino-2-deoxy-D-glucose hydrochloride</i></p> <p>Sources: <i>Crab (Exoskeleton)</i> <i>Lobster (Exoskeleton)</i> <i>Prawn (Exoskeleton)</i> <i>Shrimp (Exoskeleton)</i> <i>Decapoda (Exoskeleton)</i> <i>Monascus pilosus (Whole Cell) fermented</i> <i>Monascus purpureus (Whole Cell) fermented</i> <i>Aspergillus flavus var. oryzae (Whole) fermented</i> <i>Aspergillus melleus (Whole) fermented</i> <i>Aspergillus niger var. awamori (Whole) fermented</i> <i>Aspergillus niger (Whole) fermented</i> <i>Rhizopus oryzae (Whole) fermented</i></p>	<p>A factor in maintaining healthy cartilage. Helps to maintain healthy cartilage. A factor in maintaining joint health.</p>	<p>Consult a relevant health care provider prior to use if you are pregnant or breastfeeding. Not suitable for children. If obtained from marine sources: Derived from seafood.</p> <p>Duration of use Use for a minimum of 4 weeks to see beneficial effects.</p>	<p>1 500 to 2 000 mg</p>
<p>Glucosamine Sulphate <i>2-Amino-2-deoxy-D-glucose sulfate</i></p> <p>Sources: <i>Crab (Exoskeleton)</i> <i>Lobster (Exoskeleton)</i> <i>Prawn and/or Sergestoidea (Exoskeleton)</i> <i>Shrimp (Exoskeleton)</i> <i>Krill / Decapoda (Exoskeleton)</i> <i>Aspergillus niger (Whole)</i></p>	<p>Single and multi-substance formulation: Helps to relieve joint pain. Helps to protect against the deterioration of cartilage. A factor in maintaining good cartilage and/or joint health.</p>	<p>Consult a relevant health care provider prior to use if you are pregnant or breastfeeding. Not suitable for children. If obtained from marine sources: Derived from seafood.</p> <p>Duration of use Use for a minimum of 4 weeks to see beneficial effects.</p>	<p>1 500 mg</p> <p>Must not contain more than 600 mg of potassium chloride in glucosamine sulphate complexed products.</p>
Glucosamine Sulphate - Potassium Chloride Complex	<i>See Glucosamine Sulphate.</i>		

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p><i>Bis(2-Amino-2-deoxy-beta-D-glucopyranose) sulfate potassium chloride complex(-,-)</i> <i>Bis(D-Glucose, 2-amino-2-deoxy-), sulfate, potassium chloride complex</i> <i>D-Glucose, 2-amino-2-deoxy-, sulfate, compd. with potassium chloride (2:1:2)</i></p>			
<p>Glucosamine Sulphate - Sodium Chloride Complex <i>Bis(2-Amino-2-deoxy-beta-D-glucopyranose) sulfate sodium chloride complex(-,-)</i> <i>Bis(D-Glucose, 2-amino-2-deoxy-), sulfate sodium chloride complex</i></p>	<p><i>See Glucosamine Sulphate.</i></p>		

ANNEXURE M

Allowable levels and claims: Saccharides

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:

Warning:

If symptoms develop, worsen or persist consult a relevant health care provider.

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 required on the labelling.

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Inulin</p> <p><i>Alant starch</i> <i>β-(2-1) fructans</i></p> <p>Sources: <i>Agave tequilana (parts: stem and base leaves)</i> <i>Arctium lappa (parts root)</i> <i>Cichorium intybus (parts root)</i> <i>Helianthus tuberosus (parts tuber)</i> <i>Taraxacum officinale (parts root)</i></p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics <p>Helps support and maintain a healthy digestive system.</p> <p>Helps provide relief of irregular bowel movements.</p>	<p>If symptoms do not improve within seven days, consult a relevant health care provider.</p>	<p>Minimum: 2 g Maximum: 15 g</p> <p><i>Products providing ≥ 5 g inulin per dose</i></p> <ul style="list-style-type: none"> Take with 250 ml of water. Take two hours before or after taking other medications or natural health products since the absorption of these products may be affected.
<p>Fructooligosaccharides (FOS)</p> <p><i>Fructooligosochcharides</i> <i>Oligofructose</i></p> <p>Sources: <i>Beta vulgaris (Root)</i> <i>Cichorium intubus (Root)</i> <i>Helianthus tuberosus (Whole)</i> <i>Saccharum officinarum (Stem)</i> <i>Smallanthus sonchifolius (Root)</i></p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics 		
<p>Galactooligosaccharides (GOS)</p> <p><i>Alphagalactooligosaccharides</i> <i>Transgalactooligosaccharides</i></p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics 		

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Oligofructose</p> <p><i>Fructooligosochcharides</i></p> <p><i>Oligofructose</i></p> <p>Sources:</p> <p><i>Beta vulgaris (Root)</i></p> <p><i>Cichorium intubus (Root)</i></p> <p><i>Helianthus tuberosus (Whole)</i></p> <p><i>Saccharum officinarum (Stem)</i></p> <p><i>Smallanthus sonchifolius (Root)</i></p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics 		
<p>Polydextrose</p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics 		
<p>Trans-galactooligosaccharide</p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics 		
<p>Xylooligosaccharides (fXOS)</p> <p>Source</p> <p><i>Zea Mays (Cob)</i></p>	<ul style="list-style-type: none"> Refer to Annexure D: Prebiotics 		
<p>D-Fructose</p> <p><i>Fruit sugar</i></p> <p><i>Levulose</i></p> <p>Source:</p> <p><i>Malus domestica (fruit)</i></p> <p><i>Vitis Vinifera (fruit)</i></p>	<p>Source of carbohydrates to support energy production.</p> <p>Source of calories which contributes to weight gain.</p>	<p>Ensure sufficient fluid intake with use.</p> <p>For products intended for exercise performance or endurance based on carbohydrates:</p> <p>Not suitable for use in children under 18 years old.</p>	<p>Combined dose for all ingredients (carbohydrates) in the product: 6,5 to 180 g per day. (3 g per 100 ml intake)</p> <p>Not to exceed 45 g per single dose.</p>
<p>D-Galactose</p>			
<p>D-Glucose</p> <p><i>Dextrose</i></p> <p><i>Dextrose anhydrous</i></p> <p><i>D-Glucose</i></p> <p><i>Glucose</i></p>	<p>Helps to maintain performance in extended (greater than 60 min), high-intensity exercise.</p>		<p>Products for increasing exercise performance (optional):</p> <p>Consume 45 to 90 g minutes before exercising.</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Source: <i>Malus domestica</i> (fruit) <i>Oryza sativa</i> (seed) <i>Triticum aestivum</i> (flower stalk) <i>Triticum aestivum</i> (leaf) <i>Triticum aestivum</i> (stem) <i>Vitis vinifera</i> (fruit) <i>Zea mays</i> (fruit) Dextrates D-glucose monohydrate High fructose corn syrup Highly branched cyclic dextrin Highly branched modified starch</p>	<p>Helps to maintain endurance in extended (greater than 60 min), high-intensity exercise.</p> <p>Carbohydrates, such as simple sugars, can provide muscles with energy and assist in muscle recovery.</p>		<p>Products for endurance based on carbohydrates (optional): Consume 30 to 60 g carbohydrates per hour of high-intensity exercise.</p>
<p>D-Mannose Carubinose</p>	<p>For D-Glucose only when in a multiple substance formulation: Dextrose (sugar) can assist in the absorption of water and electrolytes.</p>		
<p>Lactose <u>Anhydrous lactose</u> <u>lactose anhydrous</u> <u>lactose monohydrate</u></p>			
<p>Maltodextrin</p>			
<p>Rice starch Source: <i>Oryza sativa</i></p>			
<p>D-Ribose Ribose D-Ribo-2,3,4,5-tetrahydroxyvaleraldehyde</p>			

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Sucrose <i>Cane sugar</i> <i>Beet sugar</i> <i>Saccharose</i> <i>Sugar</i> α-D-Glucopyranosyl- β -D-fructofuranoside β -D-Fructofuranosyl-α-D-glucopyranoside Sources: <i>Acer saccharum (sap)</i> <i>Beta vulgaris (Root)</i> <i>Borassus flabellifer (sap)</i> <i>Malus domestica (fruit)</i> <i>Oryza sativa (seed)</i> <i>Saccharum officinarum (leaf stalk)</i></p>			
<p>Corn starch <i>Maize Starch</i> <i>Topical starch</i> <i>Zea mays (Corn) starch</i> <i>Zea mays starch</i> <i>Waxy maize starch</i> Source: <i>Zea mays</i></p>			
<p>Potato starch Source: <i>Solanum tuberosum</i></p>			
<p>Wheat starch Source: <i>Triticum aestivum</i></p>			

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Glucomanan <i>(1-6)-alpha-D-gluco-D-mannan</i> <i>konjac</i> <i>manna</i> <i>mannoglucan</i></p> <p>Sources: <i>Amorphophallus bulbifer</i> <i>Amorphophallus konjac</i> <i>Amorphophallus muelleri</i> Other sources: <i>Aloe species</i></p>	<p>Promote(s) bowel movements by increasing bulk volume and water content.</p> <p>Provide(s) gentle relief of irregular bowel movements.</p>	<p>All: Not to be taken immediately before bedtime.</p> <p>Take with meals 2 hours before or after taking other medications</p> <p>Do not use if you have difficulty swallowing. Ensure sufficient fluid intake with use.</p> <p>Consult a relevant health care provider prior to use if you have diabetes.</p> <p>Promote bowel movement or relief of irregular bowel movement: Consult a relevant health care provider if:</p> <ul style="list-style-type: none"> • you have symptoms such as abdominal pain, nausea, vomiting or fever; or • symptoms worsen or if desired effect does not occur within 7 days. <p>Weight loss: Do not use continuously for more than two (2) months without consulting your relevant health care provider.</p>	<p>0,5 to 5 g 3 times per day</p> <p>The dosage form must not be a solid dosage form such as a capsule, pill or tablet.</p>
	<p>Contributes to the maintenance of normal blood cholesterol levels</p>		<p>Daily intake of 4 g of glucomanan.</p> <p>The claim may be used only for food which provides a daily intake of 4 g of glucomanan. In order to bear the claim, information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 4 g of glucomanan.</p>
	<p>May assist with weight loss when used with increased physical activity and an energy-reduced diet in healthy individuals.</p>		<p>Daily intake of 3 g of glucomanan in three doses of 1 g each, together with 1-2 glasses of water, before meals and in the context of an energy-restricted diet.</p> <p>The claim may be used only for food which contains 1 g of glucomanan per quantified portion. In order to bear the claim information shall be given to the consumer that the beneficial effect is obtained with a daily intake of 3 g of glucomanan in three doses of 1 g each, together with 1-2 glasses of water, before</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
		<p><i>As a boxed warning:</i> This product is not intended to prevent or treat obesity.</p> <p>Added to the PIL for all: Taking this product with insufficient liquid may result in choking and/or esophageal blockage/obstruction of the throat, oesophagus or intestine.</p>	<p>meals and in the context of an energy-restricted diet.</p>
<p>Beta-glucan <i>beta-D-glucan</i> Source: <i>Avena sativa (Parts: Seed bran, fibre)</i> <i>Hordeum vulgare (Parts: Seed, bran)</i></p>	<p>If taken with meals, may support healthy glucose metabolism for two hours after a meal.</p> <p>If taken with meals, may assist glucose metabolism for two hours after a meal.</p> <p>Source of fibre for the maintenance of good health.</p> <p>Helps support and maintain a healthy digestive system.</p> <p>Containing at least 750 mg of beta-glucans (from the stated sources only) per serving: Beta-glucan when consumed as part of a diet low in saturated fat and cholesterol, may reduce risk of coronary heart disease (CHD).</p>	<p>Not suitable for use in children under 18 years old.</p>	<p>2 to 10 grams of per day</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Pectin/s <i>Citrus fruit/peel</i></p> <p>Sources: May be derived from <i>Citrus aurantiifolia</i>, <i>Citrus limon</i>, <i>Citrus maxima</i>, <i>Citrus paradisi</i>, <i>Citrus reticulata</i>, <i>Citrus sinensis</i>, <i>Malus domestica</i>.</p>	<p>Demulcent. For the protection of an irritated throat.</p>	<p>Stop use and ask / consult a relevant health care provider if throat symptoms worsen or persist for more than two (2) days.</p> <p>Taking this product with insufficient liquid may result in choking and/or esophageal blockage/obstruction of the throat, oesophagus, or intestine.</p>	<p>Permitted in lozenges only.</p>

ANNEXURE N

Allowable levels and claims: Enzymes

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

Warning:

If symptoms develop, worsen or persist, consult a relevant health care provider.

Not suitable for children unless under the care of a relevant health care provider.

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 required on the labelling.

Statements for Digestive enzymes:

Take with meals unless otherwise instructed by a relevant health care provider.

Enteric-coated tablets: Swallow whole do not crush or chew.

Consult a health care provider for prolonged use.

For all enzymes except lactase: Not suitable for children under 18 years of age.

Cautions and warnings:

For all medicinal ingredients and ingredient combinations

Consult a relevant health care provider before use if you are pregnant or breastfeeding or for use beyond four (4) weeks.

For products containing one or more carbohydrases

Consult a relevant health care provider before use if you have diabetes.

For products containing one or more proteases

Consult a relevant health care provider before use if you

- have malabsorption or other GIT ailments or are having surgery; or
- are taking blood thinners, antibiotics or anti-inflammatory medication.

Note

The quantity must be expressed as the **enzymatic activity units** [Food Chemical Codex (FCC) unit]. The quantity of the **enzymatic preparation** must also be expressed in **mg or ml**.

Abbreviations:***Enzyme units per Food Chemical Codex (FCC)***

AGU	(Amyloglucosidase Unit)
ALU	(Acid Lactase Unit)
CU	(Cellulase Unit)
DP	(Diastase Power)
DU	(Dextrinising Unit)
Endo-PG	(Endo-polygalacturonase units)
FTU	(Phytase Unit)
FU	(Fibrinolytic Unit)
HCU	(Hemicellulase Unit)
HUT	(Hemoglobin Unit Tyrosine base)
INVU	(Invertase Activity Unit)
LU	(Lactase Unit)
PC	(Protease Unit)
PU	(Papain Unit)
SAP	(Spectrophotometric acid protease unit)
SU	(Sumner Unit)
TU	(Trypsin Unit)
XU	(Xylanase Unit)
BP	(British Pharmacopoeia)
USP	(United States Pharmacopoeia)

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)*	Dosage
1. CARBOHYDRASES				
<p>α-Amylase</p> <p>1,4-α--D-Glucan glucanohydrolase 4-α--D-glucan glucanohydrolase glucoamylase (amyloglucosidase), Amylase Diastase Endoamylase Glycogenase Taka-amylase A α-amylase E.C.3.2.1.1</p>	<p><i>Aspergillus flavus</i> (whole) <i>Aspergillus niger</i> (whole) <i>Aspergillus oryzae</i> (whole) <i>Bacillus licheniformis</i> (whole cell) <i>Bacillus stearothermophilus</i> (whole cell) <i>Bacillus subtilis</i> (whole cell) <i>Hordeum vulgare</i> (seed) <i>Rhizoptus niveus</i> <i>Rhizopus oryzae</i> (whole) <i>Bos taurus</i> (bovine pancreas) <i>Sus scrofa</i> (porcine/hog pancreas)</p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Maximum: 150 000 FCC DU of enzymatic activity; and 34 000 FCC DU per single dose.</p> <p>Glucoamylase Maximum: 300 FCC AGU.</p> <p>Diastase Maximum: 6 000 FCC DP.</p>
<p>α-Glucosidase</p> <p>Acid maltase α-1,4-glucosidase α-D-glucoside Glucohydrolase E.C. 3.2.1.20 Glucoinvertase Glucosidoinvertase Glucosidosucrase Maltase Maltase-glucoamylase Transglucosidase Amyloglucosidase Glucoamylase</p>	<p><i>Aspergillus niger</i> <i>Hordeum vulgare</i> <i>Aspergillus oryzae</i> <i>Rhizopus niveus</i> <i>Rhizopus oryzae</i></p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Products for oral use: Maximum: 6 000 FCC DP.</p>
<p>Cellulase</p> <p>1,4-β--D-endoglucanase 4-(1,3;1,4)-β--D-glucan 4-Glucanohydrolase 4-β--D-glucan 4-Glucanohydrolase Carboxymethyl cellulase Endoglucanase E.C. 3.2.1.4</p>	<p><i>Aspergillus flavus</i> <i>Aspergillus niger</i> <i>Trichoderma longibrachiatum</i> <i>Trichoderma reesei</i></p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Maximum: 110 000 FCC CU of enzymatic activity.</p>
<p>Hemicellulase</p> <p>1,3-β--D-xylan xylanohydrolase 1,4-β--D-mannan Mannanohydrolase</p>	<p><i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Trichoderma longibrachiatum</i> <i>Trichoderma reesei</i></p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Maximum: 45 000 FCC HCU.</p>

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)*	Dosage
1. CARBOHYDRASES				
<p>1,5-α-L-arabinan Arabinanohydrolase A-L-arabinofurano-side Arabinofurano-hydrolase E.C. 3.2.1.55 E.C. 3.2.1.78 E.C. 3.2.1.99</p>				
<p>Invertase / Sucrase Acid invertase Alkaline invertase B-D-fructofuranoside fructohydrolase B-fructofuranosidase B-fructosidase Fructosylinvertase Glucoinvertase Saccharase E.C. 3.2.1.26</p>	<p><i>Aspergillus niger</i> <i>Saccharomyces cerevisiae</i></p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Maximum: (activity unit/day) 3 000 FCC INVU or 4 200 FCC SU.</p>
<p>Lactase B-D-galactosidase B-D-galactoside Galactohydrolase B-D-lactosidase B-galactosidase Galantase Tilactase E.C. 3.2.1.23</p>	<p><i>Aspergillus flavus</i> <i>Aspergillus flavus var. oryzae</i> (Parts: Whole) <i>Aspergillus niger</i> (Parts: Whole) <i>Kluyveromyces marxianus var. lactis</i> (Parts: Whole) <i>Penicillium multicolor</i> (Parts: Whole) <i>Saccharomyces spp.</i> (Parts: Whole)</p>	<p>Digestive enzyme. To assist in the digestion of foods containing lactose (e.g. dairy foods, milk).</p>	<p>See General Statements – cautions and warning(s) for carbohydrases. Consult a relevant health care provider if symptoms such as abdominal cramps or pain, nausea, bloating, gas, and diarrhoea develop, persist or worsen.</p>	<p>Digestive enzyme: Maximum: 54 000 FCC ALU of enzymatic activity; and 18 000 FCC ALU per single dose. Lactose digestion: Maximum: 3 000 to 54 000 FCC ALU of enzymatic activity; not to exceed 18 000 FCC ALU per single dose.</p>
<p>Pectinase (1-4)-α-D-galacturonan GlycanohydrolaseD-galacturonase Endopectinase Endo-polygalcturonase</p>	<p><i>Aspergillus niger</i> <i>Aspergillus oryzae</i> <i>Trichoderma longibrachiatum</i> <i>Trichoderma reesei</i></p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Products for oral use: Maximum: 180 Endo-PG.</p>

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)*	Dosage
1. CARBOHYDRASES				
<p><i>Pectin depolymerase</i> <i>Pectin glycosidase</i> <i>Pectin hydrolase</i> <i>Poly(1-4-α-D-galacturonide) glycanohydrolase</i> <i>Polygalacturonase</i> E.C. 3.1.1.11 E.C. 3.2.1.15 E.C. 4.2.2.10 E.C. 4.2.2.2</p>				
<p>Xylanase 1,3-β-D-xylan xylanohydrolase 1,4-β-D-xylan xylanohydrolase β-1,3-xylanase β-1,4-endoxylanase β-1,4-xylanase Endo-1,3-β-xylanase Endo-1,4-β-xylanase E.C. 3.2.1.32 E.C. 3.2.1.8</p>	<p>Must be derived only from <i>Trichoderma longibrachiatum</i> (Parts: Whole) <i>Trichoderma reesei</i> (Parts: Whole)</p>	<p>Digestive enzyme.</p>	<p>See General Statements – cautions and warning(s) for carbohydrases.</p>	<p>Maximum: 3 300 XU.</p>

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)	Dosage
2. PROTEASES				
Bacterial Protease <i>Alcalase</i> <i>Bacillopeptidase</i> <i>Bacillus subtilis alkaline protease</i> <i>Neutral protease</i> <i>Subtilisin</i> <i>E.C. 3.4.21.62</i>	<i>Bacillus licheniformis</i> (whole cell) <i>Bacillus subtilis</i> (whole cell)	Digestive enzyme.	See General Statements – cautions and warning(s) for proteases.	Maximum: 490 000 FCC PC units.
Bromelain <i>Ananase</i> <i>Bromelase</i> <i>Bromelin</i> <i>Fruit bromelain</i> <i>Juice bromelain</i> <i>Pineapple fruit enzyme</i> <i>Pineapple protease</i> <i>Pineapple stem bromelain</i> <i>Pineapple stem enzyme</i> <i>Stem bromelain</i> <i>E.C. 3.4.22.32</i> <i>E.C. 3.4.22.33</i> <i>E.C. 3.4.4.24</i>	<i>Ananas comosus</i> <i>Ananas bracteatus</i>	Digestive enzyme. Assists in the relief of minor inflammation.	See General Statements – cautions and warning(s) for proteases. Hypersensitivity (e.g. allergy) has been known to occur. In such cases, discontinue use and consult a relevant health care provider. Products providing more than 20 000 000 FCC PU of enzymatic activity per day: For occasional use only.	Digestive enzyme: Maximum: 130 000 000 FCC PU of enzymatic activity and 45 000 000 FCC PU per single dose. Minor inflammation: Maximum: 480 000 to 20 000 000 FCC PU of enzymatic activity; and 10 000 000 FCC PU per single dose.
Chymotrypsin <i>α - Chymotrypsin</i>	<i>Bos taurus</i> (bovine pancreas) <i>Sus scrofa</i> (porcine/hog pancreas)	Digestive enzyme.	See General Statements – cautions and warning(s) for proteases.	Maximum: 480 000 USP chymotrypsin units of enzymatic activity; and 160 000 USP chymotrypsin units per single dose.
Fungal Protease <i>Acidic protease</i> <i>Acid protease</i> <i>Acid stable protease</i> <i>Aspergillus acid protease</i> <i>Fungal protease</i>	<i>Aspergillus flavus</i> <i>Aspergillus oryzae</i> <i>Aspergillus niger</i>	Digestive enzyme . Digestive aid. Helps digest proteins.	See General Statements – cautions and warning(s) for proteases.	Maximum: 680 000 FCC HUT and/or 6 800 FCC SAP of enzymatic activity.

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)	Dosage
2. PROTEASES				
Protease Protease 3.0 Protease 4.5 Protease 6.0		Digestive aid to help digest proteins. Digestive enzyme that helps digest proteins.		
Papain	<i>Carica papaya</i> fruit and leaf	Digestive enzyme	See General Statements – cautions and warning(s) for proteases. Consult a relevant health care provider before use if you have an allergy to latex or fruits (e.g. avocado, banana, chestnut, passion fruit, fig, melon, mango, kiwi, pineapple, peach, and tomato).	Single Substance Formulations Maximum: 7 200 000 FCC PU of enzymatic activity; and 2 400 000 FCC PU per single dose Multiple Substance Formulations Containing both papain and bromelain (fruit and/or stem), the combined proteolytic activity should not exceed the maximum proteolytic activity of 130 000 000 FCC PU.
Pepsin	<i>Sus scrofa</i> (porcine/hog stomach)	Digestive enzyme	See General Statements – cautions and warning(s) for proteases.	Maximum: 1 900 000 FCC Pepsin units of enzymatic activity.
Trypsin Trypsin Tryptic enzyme E.C. 3.4.21.4 E.C. 3.4.4.4	<i>Bos taurus</i> (bovine pancreas) <i>Sus scrofa</i> (porcine/hog pancreas)	Digestive enzyme	See General Statements – cautions and warning(s) for proteases.	Maximum: 1 200 000 USP Trypsin units of enzymatic activity; and 400 000 USP TU per single dose.

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)	Dosage
3. PANCREALYTIC ENZYMES				
<p>Pancreatin <i>Pancreatic enzymes</i> <i>Pancreatic extract</i> <i>Pancrelipase</i></p>	<p><i>Bos taurus</i> (bovine pancreas) <i>Sus scrofa</i> (porcine/hog pancreas)</p>	<p>Digestive enzyme. Digestive aid. May assist digestion and decrease bloating after high caloric, high fat meals.</p>	<p>See General Statements. Use the smallest effective dose.</p>	<p>Pancreatin is a combination of amylase, lipase and protease enzymes. Pancreatin contains in each mg not less than:</p> <ul style="list-style-type: none"> • Amylase: 17 000 to 149 000 USP amylase units per day, not to exceed 37 000 USP units per single dose • Lipase: 5 000 to 40 000 USP lipase units per day, not to exceed 20 000 USP units per single dose • Protease: 16 000 to 125 000 USP protease units per day, not to exceed 38 000 USP units per single dose

Ingredient	Sources	Health Supplement Claim	Specified Warning(s)	Dosage
4. OTHER ENZYMES				
Catalase Hydrogen-peroxide oxidoreductase Catalase-peroxidase E.C. 1.11.16	<i>Aspergillus flavus</i> (whole) <i>Aspergillus niger</i> (whole) <i>Penicillium simplicissimum</i> (whole cell) <i>Pisum sativum</i> (whole) <i>Saccharomyces cerevisiae</i> (whole)	Digestive enzyme	See General Statements.	Maximum: 3 200 FCC Baker units.
Lipase Triacylglycerol acylhydrolase Triacylglycerol lipase acid lipase adipose triglyceride lipase Aspergillus flavus var. oryzae lipase Aspergillus niger lipase Candida rugosa lipase Rhizopus oryzae lipase triacylglycerol acylhydrolase triacylglycerol lipase triglyceride lipase E.C. 3.1.1.3	<i>Aspergillus flavus</i> <i>Aspergillus niger</i> <i>Candida cylindrica</i> <i>Candida rugosa</i> <i>Rhizomucor miehei</i> <i>Rhizopus oryzae</i> <i>Ricinus communis</i> <i>Bos taurus</i> (bovine pancreas) <i>Sus scrofa</i> (porcine/hog pancreas)	Digestive enzyme	See General Statements.	Maximum: 110 000 FCC LU of enzymatic activity; and 30 000 FCC LU per single dose.
Phytase 1-phytase 3-phytase 4-phytase 6-Phytase Myo-inositol-hexakisphosphate 3-phosphohydrolase myo-inositol-hexakisphosphate 4-phosphohydrolase orthophosphoric-mono ester phosphohydrolase E.C. 3.1.3.2 E.C. 3.1.3.26 E.C. 3.1.3.8	<i>Aspergillus niger</i>	Digestive enzyme	See General Statements.	Maximum: 42 mg or 75 FCC FTU once a day, or 7 FCC Units three times a day.

ANNEXURE O

Allowable levels and claims: Other

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

General Statements:

Warning:

Consult a relevant health care provider:

- prior to use if you are pregnant or breastfeeding; or
- if symptoms worse.

Unless otherwise stated:

Not suitable for children unless under the care of a relevant health care provider.

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 required on the labelling.

Consult a relevant health care provider for prolonged use.

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>5-HTP</p> <p><i>5-Hydroxy-L-tryptophan</i> <i>L-5-Hydroxytryptophan</i> <i>5-hydroxy tryptamine</i></p> <p>Sources:</p> <p><i>Griffonia simplicifolia</i> (DC.) Baill. [seed]. Concentrated or standardised extracts of <i>G. simplicifolia</i> are considered discipline-specific medicines and not health supplements.</p> <p>For health supplement use, only the pure compound, isolated from <i>G. simplicifolia</i>, may be used.</p>	<p>Helps to promote healthy mood balance.</p> <p>Used as a sleep aid.</p>	<p>Consult a relevant health care provider prior to use if you are taking carbidopa or medicines/supplements with serotonergic activity. These may include, but are not limited to, L-tryptophan, S-Adenosylmethionine (SAME), St. John's wort, antidepressants, pain killers, over the counter cough and cold medication containing dextromethorphan, anti-nausea medication and anti-migraine medication.</p> <p>Stop use and consult a relevant health care provider if you show signs of weakness, oral ulcers, abdominal pain accompanied by severe muscle pain or if you experience skin changes.</p> <p>Avoid taking with alcohol or products that cause drowsiness.</p> <p><i>Sleep aid:</i></p> <p>Consult a relevant health care provider if sleeplessness persists continuously for more than 4 weeks (chronic insomnia).</p> <p><i>Refer to SAHPRA Guideline 2.14 for warning statement related to drowsiness and driving or operation of machinery.</i></p>	<p><i>Healthy mood balance</i></p> <p>150 to 220 mg of 5-HTP, per day;</p> <p>To minimise the risk of gastrointestinal side effects, start dosing at 100 mg, 2 - 3 times per day and slowly increase to effective dose over 2-week period.</p> <p><i>Sleep aid</i></p> <p>100 to 220 mg of 5-HTP, per day. Take 30 - 45 minutes before bedtime.</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Agar <i>Gelidium amansii extract</i> <i>Japanese isinglass</i> <i>Seaweed mucilage</i></p> <p>Sources: <i>Gelidium amansii</i> (Parts: Whole plant) <i>Gelidium amansii</i> and other red algae whole plant (thallus) of the families Gelidiaceae and Gracilariaceae and the relevant red algae of the class <i>Rhodophyceae</i></p>	<p>Assists with gastro-intestinal health.</p> <p>Enhances intestinal health.</p>	<p>Taking this product without adequate fluid may cause it to swell and block your throat or oesophagus and may cause choking. Do not take this product if you have difficulty in swallowing. If you experience chest pain, vomiting, or difficulty in swallowing or breathing after taking this product, seek immediate medical attention.</p> <p>Contraindication: Gastric bypass.</p>	<p><u>Maximum:</u> 16,5 g, divided into three doses of 2,75 to 5,5 g.</p> <p>Only for internal use when the medicine contains less than 150 µg of iodine per maximum daily dose.</p>
<p>Betaine hydrochloride <i>1-carboxy-N,N,N-trimethylmethanaminium, chloride</i> <i>glycine betaine hydrochloride</i> <i>trimethylglycine hydrochloride</i></p> <p>Sources: <i>Beta vulgaris</i> (Part: Root)</p>	<p>Helps to support liver function</p> <p>Helps to support digestion/digestive aid.</p>	<p>Consult a relevant health care provider prior to use if you have a peptic ulcer or excess stomach acid.</p> <p><i>Products providing 780 mg or more of Betaine hydrochloride as a medicinal ingredient or as a source ingredient, per day:</i> Consult a relevant health care provider prior to use if you have high cholesterol.</p>	<p>Adults 18 years and older only: <i>Liver function:</i> 500 mg to 1 500 mg per day</p> <p><i>Digestive aid:</i> 180 mg to 1 500 mg per day.</p> <p>Take with food/meal.</p>
<p>Brewer's Yeast <i>Torula yeast:</i> <i>Candida utilis</i></p> <p>Sources: Dried yeast of sources: <i>Saccharomyces cerevisiae</i> <i>Saccharomyces fragilis</i> <i>Saccharomyces boulardii</i></p>	<p>Helps support intestinal/gastrointestinal health.</p> <p>Assists to establish a favourable gut flora.</p> <p>Source of B vitamins and protein.</p>	<p>Consult a relevant health care provider prior to use if you have fever, vomiting, bloody diarrhoea or severe abdominal pain.</p> <p>Stop use and consult a relevant health care provider if symptoms of digestive upset (e.g. diarrhoea) occur, worsen and/or persists beyond 3 days.</p>	<p><i>Gastrointestinal health-related:</i> <u>Minimum:</u> 1,0 x 10⁷ CFU/day</p> <p><i>Source of B-vitamins, minerals or protein:</i> The specific claims for B-vitamins, protein and minerals may be used provided that the minimum Health Supplement dosage of the specific</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
	Source of minerals chromium, selenium, potassium, iron, zinc and magnesium. (see Annexures E and F).	Contraindication(s): Do not use this product if you have an immune-compromised condition (e.g. AIDS, lymphoma, patients undergoing long-term corticosteroid treatment).	substance is supplied by the Brewer's yeast. Dosage must meet the requirements for Minimum/ Maximum daily values of substances listed in other annexures (e.g., Vitamins, Proteins & Amino acids).
Caffeine	See Guideline 7.06 for guidance on use as a Health Supplement: Multiple Substance Formulation.		
Cannabidiol	See Guideline 7.06 for guidance on use as a Health Supplement.		
Charcoal activated <i>activated carbon</i> <i>medicinal carbon</i> <i>vegetable charcoal</i> Sources: <i>Common charcoal heated in the presence of a gas.</i>	Activated charcoal contributes to reducing excessive flatulence after eating. Digestion support.	When for internal use, the medicine requires the following warning statement on the medicine label: "Products containing activated charcoal should be used with caution in children or individuals with malabsorption conditions since it may interfere with absorption of nutrients." Activated charcoal may interact with other medicines. Activated charcoal is not recommended for long-term use.	Adults 18 years and older only: <i>Reducing excessive flatulence:</i> Take 1 g 30 minutes before and after a meal <i>Digestion support:</i> 200 mg capsules: 1 or 2 per day.
Chlorella Sources: <i>Chlorella vulgaris</i> <i>Chlorella pyrenoidosa</i> (source must be broken cells only)	Source of antioxidants. Source of vitamins and/or minerals (see permitted claims as per Annexure E and F). Source of protein.	As for Iodine and Potassium. <i>Products providing 250 mg or more of chlorella per day:</i> Take a few hours before or after taking other medicines.	<u>Maximum:</u> 6 g of broken cells Ensure that iodine and potassium levels as stated in the relevant annexures are not exceeded.

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
	<p>Source of (an) (essential) amino acid(s) (see permitted claims as per Annexure G)</p>	<p><i>Products providing 250 mg or more of chlorella per day or 6 µg or more vitamin K per day:</i> Consult a relevant health care provider prior to use if you are taking blood thinners.</p> <p><i>Products containing chlorella enriched with selenium and providing 70 µg or more of selenium per day:</i> Consult a relevant health care provider prior to use if you have a history of non-melanoma skin cancer.</p>	<p>Source of vitamins and/or minerals and Source of (an) (essential) amino acid(s): Dosage must meet the requirements for Minimum/ Maximum daily values of substances listed in other annexures (e.g., Vitamins, Minerals, Proteins & Amino acids).</p> <p><i>Iodine is a mandatory component of Chlorella:</i> Only for external use when the concentration of iodine in the medicine (excl. salts derivatives or iodophors) is 2,5 % or less. Only for internal use when the medicine contains less than 150 µg of iodine per maximum recommended daily dose.</p>
<p>Choline <i>(beta-hydroxyethyl)trimethylammonium</i> <i>2-Hydroxy-N,N,N-trimethylethanaminium</i> <i>Choline bitartrate</i> <i>Choline chloride</i> <i>Choline dihydrogen citrate</i> <i>Choline orotate</i> <i>Lecithin</i> <i>Phosphatidylcholine</i></p>	<p>Helps to support liver function.</p> <p>A factor in the maintenance of good health.</p>		<p>27,5 mg to 1 000 mg per day</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Co-enzyme Q10 2,5-Cyclohexadiene-1,4-dione, 2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl- Coenzyme Q10 CoQ10 Ubidecarenone Ubiquinone-1</p> <p>Sources: Agrobacterium rhizogenes Agrobacterium tumefaciens Aspergillus clavatus Escherichia coli Gluconobacter suboxydans Leucosporidium scottii Paracoccus denitrificans Rhodobacter sphaeroides Rhodospirillum rubrum Saccharomyces cerevisiae Schizosaccharomyces pombe</p>	<p>An antioxidant.</p> <p>Contributes to the protection of cells from oxidative stress</p> <p>Helps to maintain and / or support cardiovascular health.</p>	<p>Consult a relevant health care provider prior to use if you are taking blood pressure medication.</p> <p><i>Products providing more than 100 mg of Coenzyme Q10 per day</i></p> <p>Consult a health care practitioner prior to use if you are taking blood thinners.</p>	<p><i>Antioxidant:</i> <u>Maximum:</u> 300 mg</p> <p><i>Cardiovascular health:</i> 30 to 300 mg per day.</p>
<p>Inositol Inositol dihydrate Inositol hexanicotinate Inositol monophosphate Hexahydroxycyclohexane, synonyms 1,2,3,4,5,6-Cyclohexanehexol, cis-1,2,3,5-trans-4,6-Cyclohexanehexol Myo-Inositol D-Chiro-inositol (of Glycine max) D-inositol</p>	<p>The use of this substance for the treatment of disease/pathological states renders it a Category A medicine.</p> <p>Insufficient data is available indicating the use of this ingredient and its health benefits or promotion in healthy individuals.</p> <p>For its use as a health supplement, inositol must be combined with at least</p>	<p>Consult a relevant health care provider before use if you suspect that you may have insulin resistance, high blood glucose levels or diabetes.</p> <p>Warnings applicable to the ingredients with which Inositol is combined must apply.</p>	<p><u>Maximum:</u> 650 mg</p> <p><i>Note: Evidence available for the use of inositol in doses greater than 650 mg per day is generally only in the context of a clinical trial for the treatment of an identified pathological/disease state.</i></p> <p><i>Applications in terms of Annexure B may be undertaken demonstrating the</i></p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Sources: <i>Chlorella vulgaris</i> (Parts: Broken cell) <i>Glycine max</i> (Parts: Seed) <i>Oryza sativa</i> (Parts: Seed) <i>Zea mays</i> (Parts: Seed) <i>Zea mays</i> (Parts: Whole plant)</p>	<p>one other medicinal ingredient listed in Annexure E (Vitamins), Annexure F (Minerals) or the following specified ingredients: Beta-carotene, Choline, Lutein, Lycopene, or L-Methionine, from which the wording for the claim must be drawn.</p> <p>Inositol may also be combined with any other medicinal ingredient listed in the health supplement annexures and its use substantiated by the claim of the other substance.</p>		<p><i>benefit profile of supplementation to healthy individuals of doses greater than 650 mg daily.</i></p>
<p>Methylsulphonylmethane MSM Dimethyl sulfone Sulfonylbismethane</p>	<p>For joint health.</p> <p>A factor in maintaining joint health.</p> <p>Provides support for healthy joints, joint mobility and joint comfort</p>	<p>Not to be taken at bedtime.</p>	<p><u>Maximum:</u> 6 000 mg.</p> <p>1 500 to 6 000 mg per day for minimum of 4 weeks to see beneficial effects.</p> <p>Not to exceed 2 000 mg per single dose.</p>
<p>para-Aminobenzoic acid PABA 4-Aminobenzoic acid Para-Aminobenzoic acid, ethyl ester</p> <p>Sources: <i>Saccharomyces cerevisiae</i></p>	<p>No claim can be supported based on this medicinal ingredient.</p> <p>PABA must be combined with at least one other medicinal ingredient listed in Annexure E (Vitamins), Annexure F (Minerals), Beta-carotene, Choline, Lutein, Lycopene, or L-Methionine, from which the claim is drawn.</p>	<p>Stop use if hypersensitivity or allergy occurs and consult a relevant health care provider.</p> <p>Contact a relevant health care provider if you are taking sulphonamides.</p>	<p>18 years and older: 1 200 mg per day</p>
<p>Propolis</p>	<p>See Guideline 7.06 for guidance on use as a Health Supplement. <i>(To be published for comment)</i></p>		

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
<p>Spirulina <i>Spirulina represents a biomass of cyanobacteria (blue-green algae)</i> Sources: <i>Arthrospira platensis – whole cell</i> <i>Arthrospira maxima – whole cell</i></p>	<p>Source of/Provides antioxidants.</p> <p>Contributes to maintaining normal immune responses to seasonal and environmental allergens.</p> <p>Uses based on constituent potency at or above the minimum doses indicated in the dose section below:</p> <p>Source of beta-carotene (see permitted claims for beta-carotene).</p> <p>Source of iron (see permitted claims for iron).</p> <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 (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>Acceptable dosage forms by age group:</p> <p>Children 2 years: The acceptable dosage forms are limited to emulsion/suspension and solution/liquid preparations.</p> <p>Children 3-5 years: The acceptable dosage forms are limited to chewables, emulsion/suspension, powders and solution/liquid preparations.</p> <p>Children 6-11 years, Adolescents 12-17 years, and Adults 18 years and older:</p> <p>Consult a relevant health care provider prior to use if you have an autoimmune disease.</p>	<p>Maximum doses should not result in excess of maximum daily values of substances listed in other annexures (e.g. vitamins, minerals).</p> <p><i>Daily doses for symptoms associated with seasonal and environmental allergens:</i></p> <p>Children: 2-4 years: 0,3 g to 1 g 5-9 years: 0,5 g to 2 g 10-14 years: 1 g to 4 g</p> <p>Adolescents: 15 to 17 years: 2 g to 8g</p> <p>Adults: 18 years and older: 2 g to 8 g</p> <p><i>Daily doses as algal protein:</i></p> <p>Children: 2-4 years: 0, 6 g to 1 g 5-9 years: 0,9 g to 2 g 10-11 years: 1,5 g to 4 g</p> <p>Adolescents: 12 to 14 years: 1,5 g - 4g 15 to 17 years: 2,6 g - 8g</p> <p>Adults: 18 years and older: 2,6 g to 8 g</p> <p><i>Maximum dose of Spirulina as a source of beta-carotene:</i></p> <p>Children: 2 to 4 years: 1 g</p>

Ingredient	Health Supplement Claim	Specified Warning(s)	Dosage
			5 to 9 years: 2 g 10 to 14 years: 4 g Adolescents: 15 – 17 years: 8 g Adults: 18 years and older: 8 g <i>Maximum dose of Spirulina as a source of iron:</i> Children: 2 to 4 years: 1 g 5 to 9 years: 2 g 10 to 14 years: 4 g Adolescents: 15 – 17 years: 8 g Adults: 18 years and older: 8 g

The following substances have been identified for entries into Guideline 7.06 which will reference use of a Health Supplement:	
Glucuronolactone	See Guideline 7.06 for guidance on use as a Health Supplement. <i>(To be published for comment)</i>
Piperine	See Guideline 7.06 for guidance on use as a Health Supplement. <i>(To be published for comment)</i>
Propolis	See Guideline 7.06 for guidance on use as a Health Supplement. <i>(To be published for comment)</i>