

# MEDICINES CONTROL COUNCIL



## COMPLEMENTARY MEDICINES - HEALTH SUPPLEMENTS SAFETY AND EFFICACY

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

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

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

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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 guidelines, including those referred to therein:

- 7.01 Complementary Medicines - Discipline Specific: Safety and Efficacy
- 7.03 Complementary Medicines - Use of the ZA CTD format in the preparation of a registration application
- 7.05 Complementary Medicines - Quality
- 2.24 Guidance for the submission of the South African CTD/eCTD – General & Module 1
- 2.01 General Information
- 2.03 Alcohol content of medicines
- 2.04 Post-Importation testing
- 2.05 Stability
- 2.06 Biostudies
- 2.07 Dissolution
- 2.08 Amendments
- 2.14 Patient Information Leaflets (PILs)
- 2.15 Proprietary Names for Medicines
- 2.16 Package Inserts for Human Medicines
- 2.25 Pharmaceutical and Analytical – CTD/eCTD
- 2.36 Scheduling of Medicines
- 4.01 Guide to Good Manufacturing Practice for Medicines in South Africa
- 16.01 Guideline for Licence to Manufacture, Import or Export

and the forms:

- Application for Registration of a Medicine – South African Common Technical Document (ZACTD)
- 6.15 Screening Template for new application for registration
- 6.10 Licence Application to Manufacture, Import or Export Medicine

### 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 Medicines Control Council (MCC / Council) 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 MCC 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**

The definition of “health supplement” is provided as:

“**Health supplement**” means any substance, extract or mixture of substances that—

- a) may—
  - i) supplement the diet;
  - ii) have a nutritional physiological effect, or
  - iii) include pre- and probiotics classified as schedule 0, and
- b) are sold in pharmaceutical dosage forms not usually associated with a foodstuff and excludes injectables or substances schedule 1 or higher.

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.

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

Probiotics	<a href="#">ANNEXURE C</a>
Prebiotics	<a href="#">ANNEXURE D</a>
Vitamins	<a href="#">ANNEXURE E</a>
Minerals	<a href="#">ANNEXURE F</a>
Amino Acids	<i>To Follow</i>
Animal Extracts, Products and Derivatives	<i>To Follow</i>

Fats, Oils and Fatty Acids	<i>To Follow</i>
Carotenoids	<i>To Follow</i>
Bioflavonoids	<i>To Follow</i>
Aminosaccharides	<i>To Follow</i>
Saccharides	<i>To Follow</i>
Enzymes	<i>To Follow</i>
Other	<i>To Follow</i>

## 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 MCC'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 MCC.

## 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. Whilst 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.

Module	Heading	Comments/Notes
1.1	<b>Comprehensive Table of Contents (ToC) Modules 1 to 5</b>	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	<b>Application form</b>	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
1.2.2.3	<b>Dossier product batch information</b>	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	References listed that justify the medicine in terms of efficacy or safety claims (including traditional use and clinical evidence).
1.5	<b>Specific requirements for different types of applications</b>	
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 addressing the evidence of long standing use of the product (if relevant) 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	<b>CTD Table of Contents (ToC) Modules 2 to 5</b>	Ensure that the volume numbers indicated in the Table of Contents (ToC) correlate with the volume numbers of the final submission copies.
2.2	<b>Introduction</b>	Provide an introduction that would contextualise all presented information of the module including the relevance, necessity and appropriateness of Modules 2.4 and 2.5.

Module	Heading	Comments/Notes
2.4	<b>Non-clinical Overview</b>	<p>Any report on safety data should take into consideration the agreed format for the organisation of the non-clinical overview in the CTD.</p> <p>The list of relevant references for non-clinical data can be included at the end of module 2.4</p> <p>The applicant will need to demonstrate that the proposed product contains the CM substances which correspond to a CM substance listed in the monograph.</p> <p>For multiple substance formulations 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	<b>Clinical overview</b>	<p>For single substance formulations reference to the relevant MCC annexure will suffice provided that the indication used aligns with that annexure cited.</p> <p>For multiple substance formulations, reference to the relevant MCC annexure(s) will be required in addition to:</p> <ul style="list-style-type: none"> <li>• Justification of the selected indication;</li> <li>• The plausibility of the intended effects or efficacy of the medicinal product as well as information on the safety of use; and</li> <li>• The safety / efficacy assessments should not only focus on the single CM substances, but also an assessment of the combination is necessary.</li> </ul> <p>The safety report for the multiple substance formulation should ideally consider the following aspects of safety:</p> <ul style="list-style-type: none"> <li>• the nature of the patient population and the extent of patient exposure/world-wide marketing experience to date</li> <li>• common and non-serious adverse events</li> <li>• serious adverse events <ul style="list-style-type: none"> <li>methods to prevent, mitigate or manage adverse events</li> </ul> </li> <li>• reactions due to overdose</li> <li>• long-term safety if relevant data is available</li> <li>• special patient populations e.g. children and pregnant or lactating women</li> </ul> <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"> <li>a) citation of the relevant annexures</li> <li>b) indication wording</li> <li>c) strength/type of substance</li> <li>d) posology</li> <li>e) specific information on safe use and evidence of safety (multiple substance formulation only)</li> </ol>

**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 Council to be undesirable
- not contain scheduled substances (above S0)(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 Section 2.2.1.3.

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/IngredientspackagingLabeling/GRAS/>). Where required make reference to the relevant GRAS listing and ensure that the substance complies with specified requirements.

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, 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. Applicants are therefore required to ensure that the following disclaimer appears on the immediate (as appropriate) and outer container label: "Health supplements are intended only to complement health or supplement the diet."

Reference to the relative Nutritional Reference Value as a percentage may also be included on the label where relevant.

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

### 3.2.1 Single Substance Formulations

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** provided hereto 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.

### 3.2.2 Multiple Substance Formulation 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 a claim.

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 an acceptable health supplement claim that will adequately provide for the intended action 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 diseases<sup>1</sup>
- 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

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

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.

## 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**

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 MCC 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**

An investigation in respect of a medicine for use in humans and animals that involves human subjects or animals and that is intended to discover or verify the clinical, pharmacological or pharmacodynamic effects of the medicine, identify any adverse events, study the absorption, distribution, metabolism and excretion of the medicine or 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.

**Complementary medicine**

Any substance or mixture of substances that—

- (a) originates from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council, and
- (b) is used or purporting to be suitable for use or manufactured or sold for use—
  - (i) in maintaining, complementing, or assisting the innate healing power or 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 Council, or
- (d) is declared by the Minister, on recommendation by the Council, by notice in the Gazette to be a complementary medicine;

**Dosage form**

The pharmaceutical form in which a product is presented for therapeutic administration, e.g. tablet, cream. *See also General Information Guideline*

**Drug**

See **Medicine**. Note that legislative definitions apply in both singular and plural forms.

**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**

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 that—

- a) may—
  - i) supplement the diet;
  - ii) have a nutritional physiological effect, or
  - iii) include pre- and probiotics classified as schedule 0, and
- b) are sold in pharmaceutical dosage forms not usually associated with a foodstuff and excludes injectables or substances schedule 1 or higher.

**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**

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.

**Nutritional physiological effect**

A beneficial physiological effect brought about by substances originating from or associated with foodstuffs.

**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**

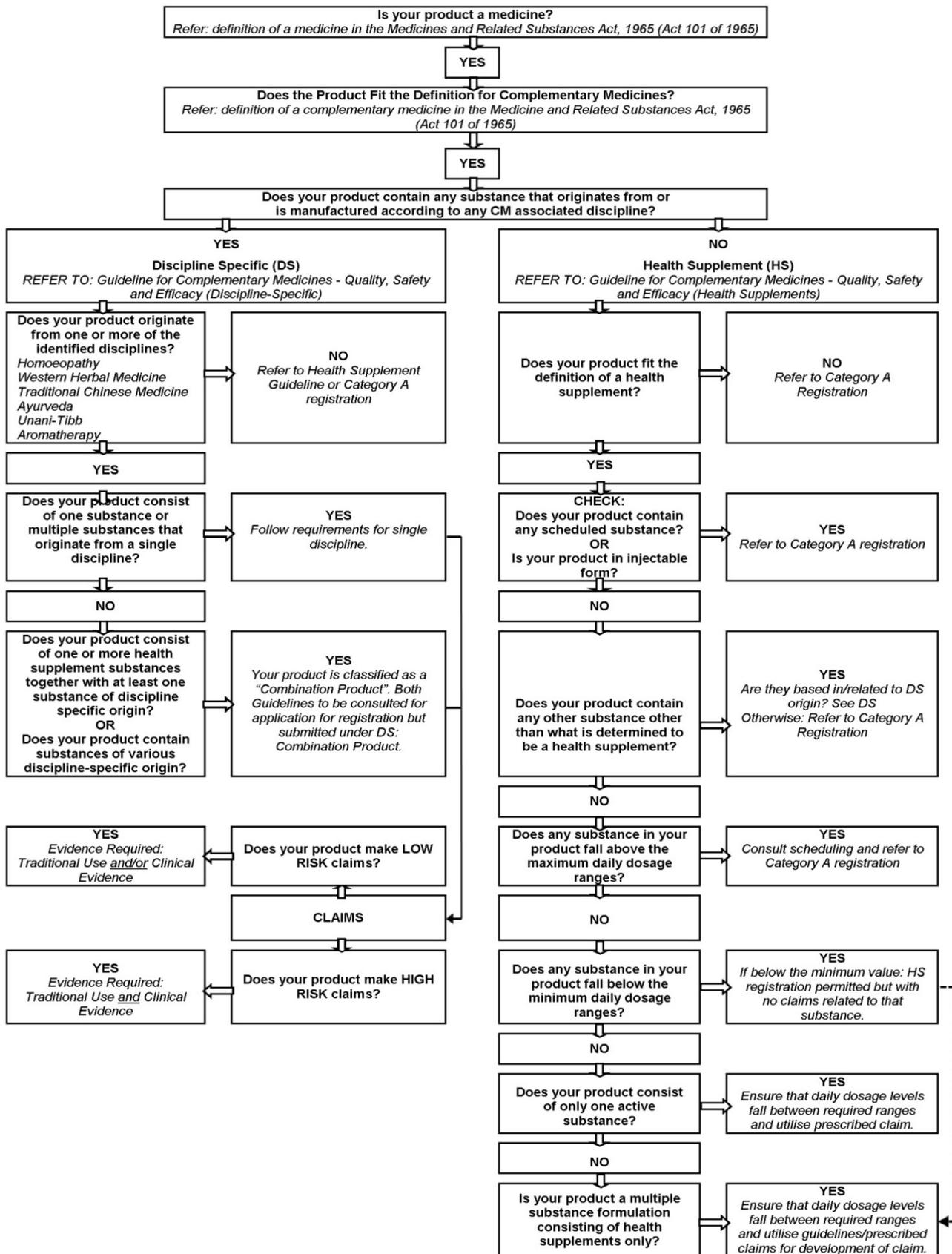
In the case of health supplements, means maintaining, complementing, or assisting the innate healing power or physical or mental state.

## 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 section 2 "Quality Requirements" for inclusion in separate guideline Inclusion of new section 2 ZA-CTD format Amendments to 1 i), 1.1, 1.2, 3.1, 3.2, 3.2.1, 4, Annexure E	v2 June 2016

ANNEXURE A

Category D Decision Tree



**ANNEXURE B****Motivation for inclusion of Substance as Health Supplement**

If any substance is not listed in the annexures provided as a health supplement, applicants may submit an application to the MCC for consideration of the substance as a health supplement which outlines:

- The recognition of another international regulatory body with a similar regulatory mechanism/standard as a nutritional substance, dietary supplement, nutritional form or health supplement;
- The safety profile of the product including:
  - Therapeutic profile;
  - Minimum effective doses;
  - Maximum safe values;
  - Known side effects;
  - Contraindications, and
  - All known interactions (including interactions with medicines, other complementary medicines, health supplements, disease processes or diagnostics procedures), and
- Any other literature or motivation in substantiation of such substance as a health supplement and under specific circumstances.

The origin of any complementary medicine is defined to be from plants, fungi, algae, seaweeds, lichens, minerals, animals or other substance as determined by Council. 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 dietary supplementation or nutritional physiological 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, animals or minerals, 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.

<sup>1</sup>Minimum: Minimum Daily Levels Required for use of Health Supplement Claim

Probiotic	Health Supplement Claim	Minimum <sup>1</sup>
<p><i>Bifidobacterium adolescentis</i>  <i>Bifidobacterium animalis subsp. Animalis</i>  <i>Bifidobacterium animalis subsp. Lactis</i>  <i>Bifidobacterium bifidum</i>  <i>Bifidobacterium breve</i>  <i>Bifidobacterium lactis</i>  <i>Bifidobacterium longum subsp. Infantis</i>  <i>Bifidobacterium longum subsp. Longum</i>  <i>Lactobacillus acidophilus</i>  <i>Lactobacillus brevis</i>  <i>Lactobacillus caucasicus</i>  <i>Lactobacillus casei</i>  <i>Lactobacillus fermentum</i>  <i>Lactobacillus gasseri</i>  <i>Lactobacillus helveticus</i>  <i>Lactobacillus johnsonii</i>  <i>Lactobacillus lactis</i>  <i>Lactobacillus paracasei</i>  <i>Lactobacillus plantarum</i>  <i>Lactobacillus reuteri</i>  <i>Lactobacillus rhamnosus</i>  <i>Lactobacillus salivarius</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 10<sup>9</sup> CFU per dosage unit</p>

**ANNEXURE D**

**Allowable Levels and Claims: Prebiotics**

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

<sup>1</sup>**Minimum:** Minimum Daily Levels Required for use of Health Supplement Claim

<sup>2</sup>**Maximum:** Maximum Daily Levels Permitted as Health Supplement

<b>Prebiotic</b>	<b>Health Supplement Claim (Single Substance Formulations)</b>	<b>Health Supplement Claim (Multiple Substance Formulations)</b>	<b>Minimum<sup>1</sup></b>	<b>Maximum<sup>2</sup></b>
<b>Inulin</b>	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
<b>Fructooligosaccharides (FOS)</b>	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.			
<b>Galactooligosaccharides (GOS)</b>				
<b>Oligofructose</b>				
<b>Polydextrose</b>				
<b>Trans-galactooligosaccharide</b>				
<b>Xylooligosaccharides (fXOS)</b>				

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	
<b>Vitamin A</b> To be calculated as retinol or retinol activity equivalents (RAE)	Contributes to the maintenance of normal vision	Contributes to the maintenance of eyesight, skin, membranes and immune function	<b>10 months – 3 years</b> 30 µg	600 µg	65 µg	≤ 5 000 I.U. (1 500 µg)	
	i Vitamin A / All-trans retinol	Contributes to the development and maintenance of night vision	<b>4 - 8 years</b> 30 µg	900 µg			
	ii Vitamin A acetate/ All-trans retinyl acetate	Has a role in the process of cell differentiation	Contributes to the development and maintenance of bones and teeth	<b>9 - 13 years</b> 30 µg			≤1 500 µg
	iii Vitamin A palmitate / All-trans retinyl palmitate	Contributes to normal growth	A factor in the maintenance of good health	<b>14 - 18 years</b> 65 µg			≤1 500 µg
	iv Beta-carotene / All-trans beta-carotene*	Contributes to normal iron metabolism	Multi-vitamin supplement/ Multi-vitamin/mineral supplement				
	v Alpha-carotene / All-trans alpha-carotene*	Contributes to the maintenance of normal mucous membranes					
vi Beta-cryptoxanthin / All-trans beta-cryptoxanthin*	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> <i>Carotenes</i>  <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</i>  <i>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
<b>Vitamin B1 (Thiamine)</b> 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 carbohydrates, fats and proteins	<b>1- 13 years</b> 0,04	≤100 mg	0,07 mg	≤ 100 mg
	Helps to metabolise proteins	Contributes to normal growth	<b>14-18 years</b> 0,07 mg	≤ 100 mg		
	Helps to metabolise fats	A factor in the maintenance of good health				
	Contributes to normal energy-yielding metabolism	Multi-vitamin supplement/ Multi-vitamin/mineral supplement				
	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						
<b>Vitamin B2 (riboflavin)</b> To be calculated as riboflavin i riboflavin 5'-phosphate, sodium	Helps to metabolise carbohydrates	Helps to metabolise carbohydrates, fats and proteins	<b>1- 13 years</b> 0,04 mg	≤100 mg	0,08 mg	≤ 100 mg
	Helps to metabolise fats and proteins	Contributes to tissue formation	<b>14-18 years</b> 0,08 mg	≤1 00 mg		
	Contributes to normal energy-yielding metabolism	A factor in the maintenance of good health				
	Contributes to the normal functioning of the nervous system	Multi-vitamin supplement/ Multi-vitamin/mineral supplement				

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Vitamin B2 (riboflavin) cont.</b>	Contributes to the maintenance of normal mucous membranes					
	Contributes to the maintenance of normal skin					
	Contributes to the maintenance of normal vision					
	Contributes to the normal metabolism of iron					
	Contributes to the protection of cells from oxidative stress					
	Contributes to the reduction of tiredness and fatigue					
	Contributes to tissue formation					
	A factor in the maintenance of good health					
<b>Vitamin B3, Nicotinic Acid, Niacin and derivatives)</b> To be calculated as niacin* i nicotinic acid	Helps to metabolise carbohydrates, fats and proteins	Helps to metabolise carbohydrates, fats and proteins	<b>1 - 3 years</b> 0,6 mg	10 mg	1 mg	≤ 35 mg
	Contributes to the maintenance of normal mucous membranes	Contributes to normal growth and development	<b>4 - 8 years</b> 0,6 mg	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 iv inositol hexanicotinate (inositol hexaniacinate)	Contributes to the maintenance of normal skin	A factor in the maintenance of good health	<b>9 - 13 years</b> 0,6 mg	20 mg		
	Contributes to normal psychological function	Multi-vitamin supplement/ Multi-vitamin/mineral supplement	<b>14 - 18 years</b> 1 mg	30 mg		
	Contributes to the reduction of tiredness and fatigue					
	Contributes to normal growth and development					
	A factor in the maintenance of good health					
<i>*1 mg niacin equivalents (NE) = 1 mg niacin = 60 mg tryptophan</i>						
<b>Vitamin B3 - Nicotinamide (niacinamide)</b>	Helps to metabolise carbohydrates, fats and proteins	Helps to metabolise carbohydrates, fats and proteins	<b>1 - 3 years</b> 0,6 mg	10 mg	2,4 mg	≤ 500 mg
	Contributes to normal growth and development	Contributes to normal growth and development	<b>4 - 8 years</b> 0,6 mg	15 mg		
	A factor in the maintenance of good health	A factor in the maintenance of good health	<b>9 - 13 years</b> 0,6 mg	20 mg		
		Multi- Vitamin supplement/ Multi-vitamin/mineral supplement	<b>14 - 18 years</b> 1 mg	30 mg		

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Vitamin B5 (Pantothenic Acid)</b> 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	Helps to metabolise carbohydrates, fats and proteins	<b>1 – 13 years</b> 0,2 mg	≤ 200 mg	0,4 mg	≤ 200 mg
	Contributes to normal energy-yielding metabolism	Contributes to tissue formation				
	Contributes to normal synthesis and metabolism of steroid hormones, vitamin D and some neurotransmitters	A factor in the maintenance of good health				
	Contributes to the reduction of tiredness and fatigue	Multi-vitamin supplement/ Multi-vitamin/mineral supplement	<b>14 – 18 years</b> 0,4 mg	≤ 200 mg		
	Contributes to normal mental performance					
	Contributes to tissue formation					
	A factor in the maintenance of good health					
	1 mg d-pantothenic acid = 1,07 mg d-panthenol 1 mg d-pantothenic acid = 0,92 mg calcium-d-pantothenate 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-pantothenate					

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Vitamin B6 (pyridoxine)</b> 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	Helps to metabolise carbohydrates, fats and proteins	<b>1 - 3 years</b> 0,05 mg	30 mg	0,1 mg	≤ 100 mg
	Contributes to normal cysteine synthesis	Contributes to tissue formation	<b>4 - 8 years</b> 0,05 mg	40 mg		
	Contributes to normal energy-yielding metabolism	A factor in the maintenance of good health	<b>9 - 13 years</b> 0,05 mg	60 mg		
	Contributes to normal functioning of the nervous system	Multi-vitamin supplement/ Multi-vitamin/mineral supplement	<b>14 - 18 years</b> 0,1 mg	80 mg		
	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						

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

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Vitamin C (Ascorbic Acid)</b> To be calculated as vitamin C 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	<b>1 - 3 years</b> 2,2 mg	400 mg	6 mg	≤ 1 000 mg
	Helps to metabolise fats and proteins	Helps in the development and maintenance of bones, cartilage, teeth and gums	<b>4 - 8 years</b> 2,2 mg	650 mg		
	Contributes to cell protection from free radical damage	Helps in connective tissue formation	<b>9 - 13 years</b> 2,2 mg	≤ 1 000 mg		
	Contributes to maintain the normal function of the immune system during and after intense physical stress <b>(the claim may be used for a daily intake of 200 mg in addition to recommended daily intake)</b>	Helps in wound healing	<b>14 - 18 years</b> 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				
	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
<b>Vitamin C (Ascorbic Acid) cont.</b>	Contributes to normal collagen formation for the normal function of skin					
	Contributes to normal collagen formation for the normal function of teeth					
	Contributes to normal energy-yielding metabolism					
	Contributes to normal functioning of the nervous system					
	Contributes to normal psychological function					
	Contributes to the normal function of the immune system					
	Contributes to the protection of cells from oxidative stress					
	Contributes to the reduction of tiredness and fatigue					
	Contributes to the regeneration of the reduced form of Vitamin E					
	Helps in connective tissue formation					
	Contributes to wound healing					

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

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Vitamin D cont.</b>	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					
<b>Vitamin E</b> To be calculated as d-alpha-tocopherol i D-alpha-tocopherol <sup>(1)</sup> ii DL-alpha-tocopherol iii D-alpha-tocopheryl acetate iv DL-alpha-tocopheryl acetate v D-alpha-tocopheryl acid succinate vi mixed tocopherols <sup>(2)</sup> vii tocotrienol tocopherol <sup>(3)</sup>	Contributes to the protection of cells from oxidative stress	An antioxidant for the maintenance of good health	<b>1- 3 years</b> 0,6 mg	100 mg	1 mg	≤ 400 I.U. (273,3 mg)
		A factor in the maintenance of good health	<b>4 - 8 years</b> 0,6 mg	150 mg		
			<b>9 - 13 years</b> 0,6 mg	≤ 273,3 mg		
		A factor in the maintenance of good health	Multi-vitamin supplement/ Multi-vitamin/mineral supplement	<b>14 - 18 years</b> 1 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: <math>mg = TE \ 1 \ mg \ (d \ alpha \ tocopherol) = 1,49 \ I.U. \ (international \ units) \ of \ vitamin \ E</math></p> <p>(2) alpha-tocopherol &lt; 20 %, beta-tocopherol &lt; 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"> <li>• 115 mg/g alpha-tocopherol (101 mg/g minimum),</li> <li>• 5 mg/g beta-tocopherol (&lt; 1 mg/g minimum),</li> <li>• 45 mg/g gamma-tocopherol (25 mg/g minimum),</li> <li>• 12 mg/g delta-tocopherol (3 mg/g minimum),</li> <li>• 67 mg/g alpha-tocotrienol (30 mg/g minimum),</li> <li>• &lt; 1 mg/g beta-tocotrienol (&lt; 1 mg/g minimum),</li> <li>• 82 mg/g gamma-tocotrienol (45 mg/g minimum),</li> <li>• 5 mg/g delta-tocotrienol (&lt; 1 mg/g minimum)</li> </ul> <p><b>OR</b></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>						
<b>Vitamin K</b> 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	<b>1 - 3 years</b> 3 ug	30 ug	6 ug	≤ 120 ug
	A factor in the maintenance of good health	A factor in the maintenance of good health	<b>4 - 8 years</b> 3 ug	55 ug		
			<b>9 - 13 years</b> 3 ug	60 ug		
			<b>14 - 18 years</b> 6 ug	60 ug		

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

Vitamin	Health Supplement Claim (Single Substance Products)	Health Supplement Claim (Multiple Substance Products)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Folic Acid</b> To be calculated as folic acid* i pteroylmonoglutamic acid ii calcium-L-methylfolate	Contributes to maternal tissue growth during pregnancy	Helps to reduce the risk of neural tube defects when taken daily prior to becoming pregnant and during early pregnancy	<b>1 - 13 years</b> 15 µg	199 µg	30 ug	≤ 500 ug
	Helps the body to metabolise proteins	Helps the body to metabolise proteins				
	Helps to form red blood cells	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	<b>14 - 18 years</b> 30 µg	≤ 500 µg		
	A factor in the maintenance of good health	Multi-vitamin supplement/ Multi-vitamin/mineral supplement				
*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

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Boron</b> <i>Boracic acid/Orthoboric acid</i> <i>Borax/Disodium tetraborate / Sodium biborate / 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	A factor in the maintenance of good health			225 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
<b>Calcium</b> <i>Including the following sources:</i> Bone meal* Calcium acetate Calcium ascorbate Calcium bisglycinate Calcium carbonate Calcium chloride Calcium chloride, hexahydrate Calcium chloride dehydrate Calcium citrate Calcium citrate malate Calcium citrate tetrahydrate Calcium fumarate Calcium glubionate anhydrous Calcium glubionate monohydrate Calcium gluceptate Calcium gluconate Calcium gluconate monohydrate Calcium glutarate Calcium glycerophosphate Calcium hydrolyzed animal protein (HAP) chelate Calcium hydrolyzed vegetable protein (HVP) chelate Calcium hydroxide Calcium lactate	Contributes to the development and maintenance of bones and teeth;	Contributes to the development and maintenance of bones and teeth	<b>1 - 18 years</b> 65 mg	≤ 1 300 mg	65 mg	≤ 1 300 mg
	Contributes to normal muscle function	A factor in the maintenance of good health				
	Contributes to normal blood clotting	Mineral supplement/ Vitamin/Mineral supplement/ Multi-mineral supplement				
	Contributes to normal energy-yielding metabolism	Calcium intake, when combined with sufficient vitamin D, a healthy diet, and regular exercise, may reduce the risk of developing osteoporosis				
	Contributes to normal neurotransmission					
	Contributes to normal function of digestive enzymes					
	Has a role in the process of cell division and specialisation					
	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					

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<i>Calcium lactate gluconate</i> <i>Calcium lactate pentahydrate</i> <i>Calcium lactate trihydrate</i> <i>Calcium lactobionate dihydrate</i> <i>Calcium levulinate</i> <i>Calcium lactate pentahydrate</i> <i>Calcium lactate trihydrate</i> <i>Calcium lactobionate dihydrate</i> <i>Calcium levulinate</i> <i>Calcium levulinate dihydrate</i> <i>Calcium malate</i> <i>Calcium oxide</i> <i>Calcium phosphate, dibasic</i> <i>Calcium phosphate, monobasic</i> <i>Calcium pidolate</i> <i>Calcium pyrophosphate</i> <i>Calcium silicate</i> <i>Calcium sodium lactate</i> <i>Calcium succinate</i> <i>Calcium sulfate</i> <i>Calcium sulphate dihydrate</i> <i>Coral (Whole)</i> <i>Dolomite</i> <i>Oyster (Shell)</i>						
<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>						
<b>Chromium</b> <i>Chromium (III) bisglycinate/Chromic bisglycinate</i> <i>Chromium (III) chloride/Chromic chloride</i> <i>Chromium (III) chloride hexahydrate/Chromic chloride hexahydrate</i>	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			2,2 µg	≤ 50 µg

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

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>	Contributes to normal functioning of the nervous system	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				
	Contributes to normal hair pigmentation					
	Contributes to normal skin pigmentation					
	Contributes to maintenance of normal connective tissues					
	Contributes to the normal function of the immune system					
	Helps to produce and repair connective tissue					
	Helps to form red blood cells					
	A factor in the maintenance of good health					
<p><b>Iodine</b></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>	Contributes to the normal production of the thyroid hormones and normal thyroid function	Contributes to the normal production of the thyroid hormones and normal thyroid function	<p><b>1 - 3 years</b></p> <p>6 µg</p>	133 µg	14 µg	≤ 150 µg
	Contributes to normal cognitive function					

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
	Contributes to normal energy-yielding metabolism Contributes to normal functioning of the nervous system Contributes to the maintenance of normal skin A factor in the maintenance of good health	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement	> 14 years 14 µg	≤ 150 µg		
<b>Iron</b> <i>Ferritin</i> <i>Ferrocyclinate</i> <i>Iron, carbonyl (not pentacarbonyl)</i> <i>Iron, electrolytic</i> <i>Iron HAP chelate</i> <i>Iron HVP chelate</i> <i>Iron, reduced</i> <i>Iron (II) ascorbate/Ferrous ascorbate</i> <i>Iron (II) aspartate/Ferrous aspartate / Ferrous chloride</i> <i>Iron (II) aspartate tetrahydrate/ Ferrous aspartate tetrahydrate</i> <i>Iron (II) bisglycinate / Ferrous bisglycinate</i> <i>Iron (II) carbonate / Ferrous carbonate</i> <i>Iron (II) chloride</i> <i>Iron (II) chloride tetrahydrate/Ferrous chloride tetrahydrate</i>	Contributes to normal energy - yielding metabolism Contributes to normal oxygen transport in the body Contributes to normal formation of red blood cells and haemoglobin and proper function Contributes to normal cognitive function Contributes to the reduction of tiredness and fatigue Contributes to the normal functioning of the immune system A factor in the maintenance of good health	Helps to form red blood cells and helps in their proper function A factor in the maintenance of good health Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement	0 - 18 years 0,6 mg	≤ 24 mg	1,4 mg	≤ 24 mg

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

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<i>Iron (III) citrate/Ferric citrate</i> <i>Iron (III) glycerophosphate / Ferric glycerophosphate</i> <i>Iron (III) phosphate / Ferric phosphate</i> <i>Iron (III) pyrophosphate / Ferric pyrophosphate</i>						
<b>Magnesium</b> <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>	Contributes to normal energy - yielding metabolism	Helps to metabolise carbohydrates, fats and proteins	<b>1 - 3 years</b> 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	<b>4 - 8 years</b> 12 mg	≤ 100 mg		
	Contributes to normal electrolyte balance	Contributes to tissue formation	<b>9 - 13 years</b> 12 mg	≤ 250 mg		
	Contributes to a reduction of tiredness and fatigue	Contributes to the maintenance of normal muscle function	<b>14 - 18 years</b> 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					

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<p><i>Magnesium phosphate dibasic trihydrate / Magnesium hydrogen phosphate trihydrate / 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>	Contributes to the maintenance of normal teeth.					
	Helps to metabolise carbohydrates, fats and proteins					
	Contributes to tissue formation					
	A factor in the maintenance of good health					
<p><b>Manganese</b></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>	Helps the body to metabolise carbohydrates, fats and protein	Helps the body to metabolise carbohydrates, fats and protein			0,13 mg	4 mg
	Contributes to the development and maintenance of normal bones	Contributes to the development and maintenance of normal bones				
	Contributes to the protection of cells from oxidative stress	A factor in the maintenance of good health				
	Contributes to normal energy-yielding metabolism	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				
	Contributes to the normal formation of connective tissue					
	A factor in the maintenance of good health					

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<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><i>Manganese (IV) dioxide</i></p>						
<p><b>Molybdenum</b></p> <p><i>Ammonium molybdate (VI)</i></p> <p><i>Ammonium molybdate (VI) tetrahydrate</i></p> <p><i>Molybdenum bisglycinate</i></p> <p><i>Molybdenum citrate</i></p> <p><i>Molybdenum fumarate</i></p> <p><i>Molybdenum glutarate</i></p> <p><i>Molybdenum HAP chelate</i></p> <p><i>Molybdenum HVP chelate</i></p> <p><i>Molybdenum malate</i></p> <p><i>Molybdenum succinate</i></p> <p><i>Sodium molybdate (VI)</i></p> <p><i>Sodium molybdate (VI) dihydrate</i></p>	<p>Contributes to normal sulphur amino acid metabolism</p> <p>Helps the body to metabolise proteins</p> <p>A factor in the maintenance of good health</p>	<p>Helps the body to metabolise proteins</p> <p>A factor in the maintenance of good health</p> <p>Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement</p>			2,5 µg	≤ 230 µg
<p><b>Phosphorus</b></p> <p><i>Bone meal*</i></p> <p><i>Calcium glycerophosphate</i></p> <p><i>Calcium phosphate dibasic</i></p> <p><i>Calcium phosphate monobasic</i></p> <p><i>Calcium phosphate tribasic</i></p>	<p>Helps to metabolise carbohydrates, fats and proteins</p> <p>Contributes to the development and maintenance of normal bones</p>	<p>Helps to metabolise carbohydrates, fats and proteins</p> <p>Contributes to the development and maintenance of normal bones and teeth</p>	<p><b>1 years - 18 years</b></p> <p>62 mg</p>	≤ 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 dibasic</i> <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 normal function of the cell membranes 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	A factor in the maintenance of good health Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				
<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>						
<b>Potassium</b> <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 sulfate</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			75 mg	≤1 500 mg

Minerals	Health Supplement Claim (Single Substance Formulations)	Health Supplement Claim (Multiple Substance Formulations)	Children		Adults	
			Minimum	Maximum	Minimum	Maximum
<b>Selenium</b> <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	An antioxidant for the maintenance of good health			3,5 µg	≤ 60 µg
	Contributes to normal spermatogenesis	A factor in the maintenance of good health				
	Contributes to the maintenance of normal hair	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				
	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					
<b>Vanadium</b> <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	A factor in the maintenance of good health			9,1 µg	≤ 182 µg
	Mineral supplement	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
<b>Zinc (and derivatives)</b> 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 sulfate</i> <i>Zinc sulfate heptahydrate</i>	Contributes to the maintenance of immune function	Helps in connective tissue formation	<b>0 - 12 months</b> 0,2 mg	2 mg	0,7 mg	≤ 25 mg
	Contributes to the maintenance of normal skin	Helps to maintain healthy skin	<b>1 - 3 years</b> 0,4 mg	7 mg		
	Contributes to normal acid-base metabolism	Helps the body to metabolise carbohydrates, fats and proteins	<b>4 - 8 years</b> 0,4 mg	12 mg		
	Contributes to normal cognitive function	Helps to maintain immune function	<b>9 - 13 years</b> 0,4 mg	23 mg		
	Contributes to normal DNA synthesis	A factor in the maintenance of good health	<b>14 - 18 years</b> 0,7 mg	≤ 25 mg		
	Contributes to normal fertility and reproduction	Mineral supplement/ Vitamin/ Mineral supplement/ Multi-mineral supplement				
	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
<b>Zinc (and derivatives) cont.</b>	Contributes to the protection of cells from oxidative stress					
	Has a role in the process of cell division					
	Contributes to connective tissue formation					
	Helps the body to metabolise carbohydrates, fats and proteins					
	A factor in the maintenance of good health					