



Natural Health Products Standard Terminology Guide



Natural Health Products Online System Standard Terminology Guide

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About This Guide

The objective of this document is to provide guidance on the standards and terminologies to facilitate the exchange and practical use of natural health product information by the Natural Health Products (NHP) Online System.



Table of Contents

About this Guide

1. Introduction

1.1 Development and terminologies

1.2 Using the Terminologies

1.3 Adding, Deleting, Changing Terms in the Terminologies

2. Ingredients Naming Standard Terminology

2.1 Approved Names

2.2 Proper Names

2.3 Common Names

2.3.1 Organism substances

2.4 Taxonomical Synonyms

2.5 Authorized References

2.6 The Scope of the Terminology

2.7 Types of Ingredients/Organisms

2.8 Obtaining the Terminology

2.8.1 Guidelines for chemical substances information

2.8.2 Guidelines for herbal component information

2.9 Chemical Substances and Herbal Components

2.10 Protein Substances

2.10.1 Guidelines for herbal naming

2.10.1.1 Approved herbal name

2.10.1.2 Herbal substance names



2.10.1.3 Custom herbal substances

2.10.2 Biological substances

2.10.2.1 Approved biological name

2.10.2.2 Biological substances

2.10.2.3 Custom biological substances

2.10.3 Organism group

2.10.4 Traditional chinese medicines

2.11 Live Microorganisms

2.12 Homeopathic substances

2.12.1 Guidelines for homeopathic substance information

3. Organism Parts Standard Terminology

4. Organism Substance Preparation Terminology

4.1 Approved Organism Substance Preparation Name

4.2 Potency

4.3 Extraction Ratio

4.4 Solvents

5. Organism Types Standard Terminology

6. Ingredient Roles

6.1 Medicinal Ingredients

6.2 Non-medicinal Ingredients

6.3 Components

6.4 Non-Natural Health Products

6.5 Homeopathic

7. Ingredient Rules



7.1 Toxicity Restrictions

7.2 Non-medicinal Restrictions

7.3 Non-medicinal Purposes

7.4 Medicinal Restrictions

7.5 Non-NHP Restrictions

7.6 Sub-ingredients

7.7 Source ingredients and source materials

8. International Conference on Harmonization M5 Controlled Vocabularies

8.1 Dosage Form Standard Terminology

8.2 Routes of administration Standard Terminology

8.3 Units Standard Terminology

9. Non-medicinal Ingredient Purposes Standard Terminology

10. Test methods

11. Appendices

11.1 Organism substance preparation information required in electronic product licence application form

11.2 Some authoritative references

11.2.1 Organism scientific names

11.2.2 Organism substances

11.2.3 Chemicals

11.2.4 Proteins

11.2.5 Chemical constituents and herbal components

11.2.6 Non-medicinal ingredients

11.2.7 Additional references²

1. Introduction

The Natural Health Products Directorate (NHPD) and the natural health products industry engage in an intense information exchange during the Natural Health Product (NHP) licensing phase. One of the objectives of the NHP Online System is to capture and validate licence applications and to securely submit them electronically along with appropriate attachments. Applying standard terminology to NHP licence applications will provide the ability to exchange product information between the NHPD and industry in a structured and efficient way. Therefore, standard terminology is one of the essential elements in this information exchange.

Consistency in naming also assists in the retrieval of information from the NHP Online System and provides the ability of health professionals and the public to compare similar goods.

1.1. Development and Terminologies

Currently, no single internationally agreed upon list or primary reference comprehensively covers all substances or terms used, or likely to be used, with regards to natural health products in Canada. Consequently, the NHPD has been confronted with the challenge of adapting two major standards in order to meet the NHPD requirements for use by the NHP Online System:

- 1) Initially, naming conventions for ingredients were adapted from the Approved Terminology for Medicines, of the Australian Therapeutic Goods Administration (TGA). Further refinements and modifications to the terminology are described in this document.
- 2) Terminologies for dosage forms, routes of administration, and units and measurements have been adapted from the International Conference on Harmonization (ICH) controlled lists.

1.2. Obtaining and Using the Terminologies

Currently, tools such as the Natural Health Products Ingredients Database (NHPID) and the electronic product license application (e-PLA) have incorporated this standard terminology. Most of the terminology used by the NHP Online System can be accessed on the internet through the main page of the [NHP Ingredients Database Web Application](#).

The terminology described below is in the context of the presentation of information in the NHP Ingredients Database Web application. Information on how to search the

NHP Ingredients Database using the online Web application is available in the [Natural Health Products Ingredients Database Web Application Guide](#).

Wherever applicable, only approved terms should be used. NHPD encourages the use of the standard terminology in reports, emails, and other documents.

Ingredients can be entered into the electronic Product Licence Application Form either

- by choosing an ingredient name found in the NHP Ingredients Database, or
- by constructing a customized medicinal ingredient name by selecting an organism, an organism part, and a preparation type; for example: Echinacea angustifolia (organism), flower (organism part), extract dry (preparation type). The standard terminology for organism name, the organism part, and the preparation type is in the NHP Ingredients Database.

Thus, the names of substances derived from organisms can be defined organism substance names, which are in the NHP Ingredients Database, or custom organism substance names, which are constructed in the e-PLA form.

1.3. Adding, Deleting, Changing Terms in the Terminologies

For adding new terms, deleting existing terms, or changing any data associated with a term, the requestor should complete a [Natural Health Products Ingredients Database Issue Form](#) (Instructions for the form are in the [Natural Health Products Ingredients Database Issue Form Guide](#).) The change request process is summarized below.

- 1) The requestor collects necessary information about the issue and any appropriate references.
- 2) The requester prepares an NHP Ingredients Database Issue Form and then sends the completed form and reference documents to NHP Ingredients Database Support at ingredient_support@hc-sc.gc.ca by email, or by mail to:

**Online Solution Support
Bureau of Licensing Services and Systems
Qualicum Tower A
2936 Baseline Road
Ottawa, Ontario
K1A 0K9**



- 3) The change request is viewed by a Terminology Specialist at the NHPD.
- 4) The original requester is informed of the decision made at the NHPD or is asked for further clarification if required.

The time required for reviewing a request may vary depending on the quality and/or the complexity of the request.

2. Substance Names in Standard Terminology

Consistency in naming assists the retrieval of information from the NHP Ingredients Database and allows efficient handling of acceptable ingredient information including evidence to support safety and efficacy, and quality testing requirements.

NHPID names should be used when submitting applications for product licensing to the NHPD as well as in product information, consumer information and other promotional literature, wherever use of the terminology is applicable.

To understand conventions used in assigning approved names to the ingredients, and abbreviations presented in the NHP Ingredients Database, users are encouraged to review the [Therapeutic Goods Administration \(TGA\)- Approved Terminology for Medicines](#).

For names in the English language, both American and British spellings may be used.

In some cases, names in the NHP Ingredients Database appear in a word order that differs from that of normal language, such as “Angelica Root Dry”. On the product label, the words in the name can appear in the order appropriate for normal language. For example, on a product label either “Dry Angelica Root” or “Angelica Root Dry” would be acceptable. In addition, on the label, “dried” can be substituted for “dry”, and the plant part may be changed from singular to plural. For example “Dried Angelica Roots” could appear on the label.

2.1. NHPID Names

An NHPID name is a unique identifier of a substance. Each substance has only one NHPID name, which has been designated by NHPD as the name that should be used as the primary identifier of the substance, wherever it is applicable.

Selecting NHPID names is based on the following rules.

- It must be unique globally
- It must be the primary name used in the reference cited
- Avoid long names such as chemical International Union of Pure and Applied Chemistry (IUPAC) names
- Avoid uncommon synonyms
- Trade names, product IDs, registry numbers, and other terminology IDs (such as Flavour & Extract Manufacturers Association (FEMA)) cannot be used as approved names; and
- Although CAS Registry numbers appear in some entries in the NHP Ingredients Database, these numbers cannot be used as substance names.

For homeopathic ingredients, the NHPID name will consist of the pharmacopoeia name (abbreviated as EHP, HPUS etc.), an underscore, and a proper name of the ingredient in the NHPID. For example: HPUS_Tormentilla

A preparation that can reasonably be specified by listing its individual ingredients separately, usually will not be included in the standard terminology for ingredients, and therefore will not have an NHPID name.

2.2. Proper Names

The *Natural Health Products Regulations* sets out rules for ingredient proper names. The proper names are as follows.

- For vitamins, use Biotin, Folate, Niacin, Pantothenic acid, Vitamin A, Thiamine, Riboflavin, Vitamin B 6, Vitamin B 12, and Vitamins C, D and E.
- For chemical substances (except vitamins) and protein substances, use any unambiguous chemical name provided by an authoritative reference such as the Merck Index, the United States Pharmacopeia Dictionary, etc.
- For an organism, a plant material, or a non-human animal material, use the scientific Latin names of the organism, that is "its genus, and its specific epithet" (For example, for Black currant seed oil, the proper name is the scientific name of the plant species, *Ribes nigrum*.)
- For homeopathic ingredients, the proper names are as provided in the pharmacopoeia.

For some defined organism substances, the proper name is not the Latin binomial. When a substance comes from a group of organisms, then its proper name is usually the name of the substance. (For example, Shark cartilage is a proper name). When an organism substance is produced by an organism, but is normally outside the organism, as in the case of Honey, then the proper name can be the name of the substance. (Thus, Honey is a proper name).

2.3. Common Names

The [Product Licensing guidance document](#) states that the common name of an ingredient is "the name by which it is commonly known and is designated in a scientific or technical reference". However, in practice, especially for chemicals, determining an unambiguous common name is not always straightforward. According to the terminology presented here, ingredient common names are mapped based on the following rules:

- A common name must be supported by at least one authorized reference.
- For homeopathic ingredients, the common names are as provided in the pharmacopoeia.

2.3.1 Organism Substances

When a medicinal ingredient has a custom organism substance name that is constructed in the electronic Product Licence Application Form (by choosing an organism, organism part, and preparation method), the name that appears in the Common Name field is a common name of the organism. The organism part appears in the Source Material field for the ingredient. Using the common name of the organism, the organism part, and the preparation method, a common name for the organism substance can be assembled. (e.g. Carrot seed extract)

When a defined organism substance is chosen as a medicinal ingredient in the electronic Product Licence Application Form, the proper name is normally the scientific name of the organism, but the name in the Common Name field is a name of the defined organism substance, rather than a common name of the organism. For example, ingredient Saskatoon berry extract has "Saskatoon berry extract" in the Common Name field and "Amelanchier alnifolia" as its proper name.

2.4. Taxonomical Synonyms and Subordinate Taxa

Taxonomical synonyms are scientific names other than the NHPID names for organisms. For a particular scientific name, the subordinate taxa are scientific subdivisions. For example, for the species *Chamerion angustifolium*, a name of a subordinate taxon is *Epilobium angustifolium* subsp. *circumvagum*, which is a synonym of *Chamerion angustifolium* subsp. *circumvagum*. Each name must be supported by at least one authorized reference.

2.5. Authorized References

Generally, ingredients included in the terminology set must be supported by at least one authoritative reference. Addition of a new name to the NHP Ingredients Database may be proposed using the NHP Ingredients Database Issue Form, in which the authoritative reference for the name should be included.

It is important to note that the citation of an authority or reference for a name in the terminology does NOT imply that the standard specified by that authority is applicable to the substance used in a particular natural health product. For some substances, a particular standard is indicated in the NHP Ingredients Database. If no standard is specified for a substance, then the quality of the substance should comply with the requirements as defined in the [Evidence for Quality in Finished Natural Health Product](#) guide.

Conflicts may occur amongst certain authorized references with regards to the scientific names of organisms. The primary binomial name of a species may vary from one reference to another, or may even be put into different taxonomy nodes. In order to help the NHPD data managers capture taxonomy data and to help users search the NHP Ingredients Database, the NHPD gives precedence to some

references when adding organism names. For example, the scientific names of plants in the United States Department of Agriculture (USDA) Germplasm Resources Information Network (GRIN) Database are used, if the plant is included in that database.

2.6. The Scope of the Terminology

The ingredient naming standard terminology captures ingredient names and other NHPD-approved ingredient related information. The terminology captures the following data elements:

- NHPID name. The official name for a substance or organism. Usually, it should be used as the primary identifier for a substance or organism.
- Proper name. A proper name is an unambiguous name as defined in the *Natural Health Products Regulations*.
- Common name. A common name is a secondary identifier for a substance or organism.
- Taxon (taxonomical synonym, or other scientific name for an organism).
- CAS registry number. Chemical Abstracts Service registry number for a substance.
- Ingredient role. Medicinal, Non-medicinal role, Non-NHP, Homeopathic and Component.
- Schedule 1 classification. Medicinal ingredient classification defined by Schedule 1 of the *Natural Health Products Regulations*.
- Ingredient category. See Section 2.7 below.

2.7. Types of Substances and Organisms

Substances can be thought of as falling into three major groupings:

- Chemical, which includes Chemical Substances, Protein Substances, Herbal Components
- Herbal, which includes materials derived from plants, fungi, algae, and blue-green algae
- Biological (but not herbal), which covers substances of biological origin other than those derived from herbal sources

An ingredient has a name in one of following categories.

- Chemical (Category: Approved Chemical Name (ACN)). A chemical substance can be a substance that can be obtained from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material; or a substance that can be synthesized; or a substance that can be obtained from the non-organism part of the environment (for example by mining).

- Protein (Category: Approved Protein Name (APN)). A protein is a macromolecule composed of a chain of amino acids linked by peptide bonds. An enzyme is a protein that catalyzes a biochemical reaction.
- Herbal name (Category: Approved Herbal Name (AHN)). An organism that is considered an herbal organism (a plant, alga, fungus or blue-green alga).
- Defined Organism substance (Category: Approved Herbal Substance Name (AHS)). A substance from an herbal organism (which has an AHN).
- Defined Organism Substance (Category: Approved Food Name (AFN)). A food substance derived from an herbal organism (AHN).
- Defined Organism Substance (Category: Approved Biological Name (ABN)). An organism that is a non-human animal, bacterium (but not a blue-green alga) or a probiotic.
- Defined Organism Substance (Category: Approved Biological Substance Name (ABS)). A substance from a non-human animal or bacterium (but not from a blue-green alga).
- Homeopathic Substance (Category: Homeopathic Substance Name (HMN)). A substance as defined in a homeopathic pharmacopoeia.

Some defined organism substances are organisms and other defined organism substances are derived from organisms. In the NHP Ingredients Database, organisms can be identified by family, genus, species, subspecies, varieties, strains, and forms. In addition, some groups of organisms are included in the database, for example sharks.

- The terminology also captures Herbal Components. Herbal Components are chemical compounds that can be found in an herbal organism or herbal substance as an active/marker constituent. Although Chemical Substances isolated from plant materials may be used as ingredients, Herbal Components cannot have medicinal or non-medicinal ingredient roles. Herbal Component (Category: Herbal Component Name (HCN)). Chemical compounds found in an herb (which has an AHN) or an herbal substance (which has an AHS) as an active or marker constituent.

Aggregated categories are also used for convenience, such as with the ingredient search tools. The categories above are further aggregated as chemical (ACN), protein (APN), organism (AHN and ABN), and organism substance (AHS and AFN, and ABS).

2.8. Chemical Substances and Herbal Components

A chemical substance in some cases is a purified constituent of a defined molecular structure, which may be isolated from a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material; may be chemically synthesized; and may have a medicinal, non-medicinal, or non-NHP role. Inherently, herbal components are chemicals as well. However, since herbal

components are not isolated for medicinal or non-medicinal use, they have been assigned an individual category.

The data for chemical substances is organized and displayed by category, synonyms, CAS registry numbers, reference (for NHPID name), etc. The NHPID name together with the reference will define the molecular species in the case of a single substance; the composition of the substance in the case of a mixture; or the characteristics of a variable material. However, when specifications for a substance are provided in the reference for the NHPID name (such as the United States Pharmacopeia), these are not usually the specifications required for the substance when used as an ingredient. Chemical structures are only available for selected chemical substances in the NHPID.

2.8.1 Guidelines for Chemical Substances Information

Table 1 provides an explanation of how chemical substance information is organized and displayed in the [NHP Ingredients Database](#)

Table 1 - The required data members for chemical substances

Chemical Substance Information	Description
NHPID Name	The NHPID (Natural Health Products Ingredients Database) name is a well-characterized chemical substance name.
Category	The category that the ingredient name belongs to -- in this case, Approved Chemical Name
Structure	Chemical structure of substance
Schedule 1	Category of substances according to the <i>Natural Health Products Regulations'</i> Schedule 1 (for example, plants, non-human animals, vitamins, probiotics, etc). Provided only for medicinal ingredients.
Proper Names	Unambiguous name(s) as per the <i>Natural Health Products Regulations</i> .
Common Names	Common name(s) are other valid names. Selecting their hyperlink will display the reference for the name (e.g. Joint FAO/WHO Expert Committee on Food Additives (JECFA), Merck Index (MI), United States Pharmacopoeia (USP), British Pharmacopoeia (BP), European

Chemical Substance Information	Description
	Pharmacopoeia (EP)).
Chemical Abstracts Services (CAS) Registry Number	The CAS Registry Number is assigned by the Chemical Abstracts Service to identify a specific chemical substance. Selecting the CAS number will display its reference.
Other Registry Numbers	A chemical name may have more than one registry number. For these other registry numbers, selecting their hyperlink will display the reference for that number.
Reference	A name reference code is included for each chemical substance to indicate the reference for the NHPID name. Selecting the reference code hyperlink will display the reference information. The citation of a reference for a name in the terminology does NOT imply that the standard specified by that reference is applicable to the substance used in a particular natural health product.

2.8.2 Guidelines for Herbal Component Information

Herbal components (HCN) are chemical compounds or groups of chemical compounds that are components of plant and plant materials. Herbal components themselves cannot be medicinal or non-medicinal ingredients and their role can only be defined as a Component (see Section 6.0 - Ingredients Roles). An herbal component may be used as a marker or/and active constituent of a standardized herbal ingredient or in claims which concern the strength or concentration of the component in an herbal ingredient.

Since all herbal components are chemicals in nature, naming herbal components follows the convention of naming general chemicals. Furthermore, herbal components belong to one of the five following chemical classes: carbohydrates and lipids, nitrogen-containing compounds, alkaloids, phenolics, and terpenoids. Each class is further divided into several subclasses.

An herbal component can be contained in various herbal substances and the relative quantities may vary. In order to supply information on the herbal components, the NHP Ingredients Database sometimes provides the lower and/or



upper amounts of the components in the parts of the source organisms (see Section 7.6 - Sub-ingredients).

Table 2 provides an explanation of how herbal component information is organized and displayed in the NHP Ingredients Database.

Table 2 - Required data members for herbal components

Herbal Component Information	Description
NHPID Name	The NHPID (Natural Health Products Ingredients Database) name is a well-characterized name for a component of an herbal ingredient.
Category	The category that the ingredient name belongs to - in this case Herbal Component Name.
Proper Names	Unambiguous name(s) as per the <i>Natural Health Products Regulations</i> .
Common Names	Common names are other valid names. Selecting the hyperlink will display the reference for the name.
Single or Group	Belonging to a <i>single</i> chemical or a <i>group</i> of chemicals.
Chemical Class	One of five chemical classes: carbohydrates and lipids, nitrogen-containing compounds, alkaloids, phenolics, and terpenoids.
Chemical Subclass	One of the subordinate chemical groups of chemical classes.
Chemical Abstracts Service (CAS) Registry Number	The CAS Registry Number is assigned by the Chemical Abstracts Service to identify a specific chemical substance. Selecting the CAS number will display its reference.
Other Registry Numbers	A chemical name may have more than one registry number. For these other registry numbers, selecting the hyperlink will display the reference for that number.
Reference	A name reference code is included to indicate the reference for the NHPID name. Selecting the reference code hyperlink will display the reference information. The citation of a reference for a name in the terminology does NOT imply that the standard specified by that reference is applicable to the substance used in a particular natural health

Herbal Component Information	Description
	product.

2.9 Protein Substances

Proteins consist of amino acids which are a class of organic molecules that contain amino and carboxyl groups. Proteins can be found in parts of plants, algae, fungi, bacterium or non-human animal material. Enzymes primarily act as a catalyst increasing the rate at which a specific biochemical reaction occurs. Enzymes are considered to be protein molecules and are mainly of three types: metabolic enzymes, digestive enzymes and food enzymes. An approved protein name (APN) is an NHPD-approved name for the protein, and the name is supported by an authoritative reference.

2.9.1 Guidelines for Protein Substances Information

Table 3 provides an explanation of how protein information is organized and displayed in the NHP Ingredients Database.

Table 3 - The required data members for protein substances

Protein Substance Information	Description
NHPID Name	The NHPID (Natural Health Products Ingredients Database) name is a well-characterized name for protein substances.
Category	The category that the ingredient name belongs to - - in this case Approved Protein Name.
Proper names	Unambiguous name(s) as per the <i>Natural Health Products Regulations</i> .
Common names	Common names are other valid names. Selecting their hyperlink will display the reference for the name (e.g. Merck Index (MI), United States Pharmacopoeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (EP), Food Chemicals Codex (FCC).
Chemical Abstracts Registry (CAS) Number	The CAS Registry Number is assigned by the Chemical Abstracts Service to identify a specific chemical substance. Selecting the CAS number will

Protein Substance Information	Description
	display its reference.
Other Registry Numbers	A protein name may have more than one registry number. For these other registry numbers, selecting the hyperlink will display the reference for that number.
Reference	A name reference code is included for each protein to indicate the reference for the NHPID name. Selecting the reference code hyperlink will display the reference information. The citation of a reference for a name in the terminology does NOT imply that the standard specified by that reference is applicable to the substance used in a particular natural health product.

2.10 Organisms and Defined Organism Substances

The naming standard for ingredients from organisms (i.e. a plant or a plant material, an alga, a bacterium, a fungus or a non-human animal material, an extract of the preceding or a probiotic) defines three types of names for organism substances: approved scientific names for an organism (i.e. Latin binomials), approved names found in authoritative references, and approved names assembled from organism names, organism part names, and preparation methods found in an authoritative reference.

Organism substances can belong to either herbal substances (Approved Herbal Name, Approved Herbal Substance, Approved Food Name) or biological substances (Approved Biological Name, Approved Biological Substance). Herbal substances are preparations of plants, and other organisms that are treated as plants in the International Code of Botanical Nomenclature, such as fungi and blue-green algae. Biological substances are substances of biological origin that are not antibiotics; biological substances are derived from non-human animals and bacteria (other than blue-green algae).

In the NHP Ingredients Database, an organism that has been included in the database has a page with the main heading "Organism" that includes information on the organism's family and usually information on taxonomical synonyms and subordinate taxa. Those organisms which have medicinal roles have a second web page which also has "Organism" as the main heading; this page indicates that the organism has a medicinal role. An organism with a medicinal role can be chosen as a medicinal ingredient in the electronic Product Licence Application Form. Although the Organism –medicinal role page lists the parts as either Whole or Whole plant, and the preparation as Dry or Fresh, in the electronic Product Licence Application

Form a wide range of parts and preparations can be selected to create a custom medicinal ingredient name.

2.10.1 Guidelines for Herbal Naming

2.10.1.1 Approved Herbal Name

An Approved Herbal Name (AHN) is an NHPD-approved name for a plant or fungus or blue-green alga. It must be a scientific name (usually a binomial Latin name) supported by an authoritative reference. (For some authoritative references, see the Appendix, section 11.2).

An AHN consists of a genus name, species descriptor, and any subordinate taxonomical names such as subspecies, variety, and form when applicable. Please note that there may be more than one binomial name (synonyms, spelling variants) for one species. Only those with authoritative references are included in the NHP Ingredients Database (approved herbal name and taxonomical synonyms). Some example AHNs are as follows:

- *Coffea arabica*
- *Triticum aestivum* subsp. *spelta*
- *Coix lacryma-jobi* var. *ma-yuen*
- *Cucumis melo* subsp. *melo* var. *cantalupensis*

2.10.1.2 Herbal Substance Names

There are two categories of names for substances derived from organisms with an AHN: Approved Herbal Substances Names (AHS) and Approved Food Names (AFN). AHS and AFN are NHPD-approved ingredient names.

Usually, an AHS or AFN must be in English, French, or Latin. If an AHS or AFN originates from another language, it is usually translated to English or French, either by meaning or pronunciation. An AHS or AFN must be supported by at least one authoritative reference and there must be at least one source organism name (AHN) or organism group name. Information for organism parts and preparation methods for AHS and AFN is also included. An organism part is represented by an approved organism part name (see Section 3.0 - Organism Parts Standard Terminology) and a preparation is represented by an approved organism preparation name (see Section 4.0 - Organism Substance Preparation Terminology).

For some AFN, the preparation method is indicated in the name; examples are apple cider vinegar and *Pyrus Communis* (Pear) Fruit Juice. Typical preparations for AFN are: dry, fresh, powder, juice dry, juice fresh, and juice concentrate.

AFNs refer only to edible substances fit for human consumption as foods. Even though an inedible substance otherwise complies with the description of a food

substance in the category AHS, that inedible substance may not be named as an AFN.

Some examples of AHS and AFN are shown in Table 4.

Table 4 - AHS and AFN examples

Name	AHS/AFN	Parent AHN	Organism Parts	Organism Preparations
Ambrette Essential Oil	AHS	<i>Abelmoschus moschatus</i>	Seed	Oil Essential
Amaranth Sprout Powder	AHS	<i>Amaranthus cruentus</i>	Sprout	Powdered
Radix Isatidis	AHS	<i>Isatis tinctoria</i>	Root	Dry
Rice	AFN	<i>Oryza sativa</i>	Seed	Dry, Fresh, Powdered

2.10.1.3 Custom Herbal Substances

Custom Herbal Substances are herbal medicinal which are not part of the NHP Ingredients Database, but can be identified in the electronic Product Licence Application. Naming a Custom Herbal Substance must follow the rules outlined below.

An herbal substance consists of three parts: AHN, the organism part name, and the organism preparation method, where organism part name is an NHPD- approved organism part name (see Section 3.0 - Organism Parts Standard Terminology) and organism preparation method is an NHPD-approved organism part preparation name (see Section 4.0 - Organism Substance Preparation Terminology). The following illustrates the composition of a custom herbal substance:

"Thymus serpyllum" + "herb" + "dry" = "Thymus serpyllum herb dry"

2.10.2 Biological Substances

2.10.2.1 Approved Biological Name

Approved Biological Names (ABN) are the scientific names (usually binomial Latin names) of organisms other than herbal organisms (non-human animals and bacteria that are not blue-green algae). Like an AHN, an ABN can consist of three parts: genus name, species epithet, and any subordinate taxonomical names. Trinomial Latin names are also acceptable. An NHPD-approved biological name

must be supported by at least one authoritative reference (see the Appendix). Some examples are:

- Bos Taurus
- Gekko gekko
- Bufo bufo
- Clupea harengus subsp. harengus

2.10.2.2 Biological Substances

Biological Substances have Approved Biological Substances (ABS) names and are derived from organisms with Approved Biological Names (ABN). Like an AHS, an ABS is a substance name usually in English, French, or Latin that is supported by at least one authoritative reference (see Appendix). An ABS can be used as an NHPD-approved ingredient name. Some ABS examples are as follows:

- Royal jelly
- Batryticatus Bombyx
- Cornu Cervi Pantotrichum
- Fish oil

2.10.2.3 Custom Biological Substances

Like Custom Herbal Substances, Custom Biological Substances are biological substances that are not part of the NHP Ingredients Database. In the electronic Product Licence Application Form, naming a Custom Biological Substance is similar to naming a Custom Herbal Substance, i.e. approved organism name + organism part name + organism preparation name.

2.10.3 Organism Group

The source materials of some ingredients, especially organism substances, are groups of organisms. An approved group name should be created to deal with such situations. An organism group consists of an approved organism group name, and usually an included member list, and a possible excluded member list. If there is not a member list for the group, then the membership of the group must be clear, either from the group name or because there is a definition of the group in the NHP Ingredients Database. The members can be a family name, genus name, species, or any subordinate taxonomical names. The name of each member must be supported by an authoritative reference. The following table (Table 5 - Organism group examples) provides an example of an organism group for cottonseed oil.

Table 5 - Organism group examples

Group Name	Included List	Excluded List
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Cotton group*	Gossypium [genus]	
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* The group can be the source of several related substances including cotton.

2.10.4 Traditional Chinese Medicines

In the NHP Ingredients Database, most medicinal ingredients used in traditional Chinese medicine have the names that appear in the Chinese pharmacopoeia and *Materia Medica*. When determining names, precedence is given to the Pharmacopoeia of the People’s Republic of China, followed by the Chinese Herbal Medicine, *Materia Medica* (Bensky et al. 2004).

2.11 Live Microorganisms

The medicinal ingredient in a natural health product can be a probiotic (Schedule 1 to the *Natural Health Product Regulations*). NHPD has adopted the internationally accepted Food and Agriculture Organization (FAO)/World Health Organization (WHO) (2006) definition of a probiotic: “live microorganisms which when administered in adequate amounts confer a health benefit to the host.” This includes probiotics that might confer a health benefit in humans by benefiting the microbiota indigenous to humans as in the *Natural Health Products Regulations*.

Many health effects of live microorganisms depend on the specific strain, and strain is important for surveillance and epidemiology studies (Probiotics in Food, FAO Food and Nutrition Paper 85). The rules for naming Organisms in section 2.10, above, apply to live microorganisms. In addition, the strain must be specified, which is in accordance with proposed nomenclature for bacteria used as active ingredients in ICH M5 (Data Elements and Standards for Drug Dictionaries). For some live microorganisms, the NHP Ingredients Database contains a specified strain, for example *Lactobacillus plantarum* DSM 9843. For other microorganisms, the species name is included in the NHP Ingredients Database, and the applicant indicates the strain in the electronic Product Licence Application Form.

2.12 Homeopathic Substances

Homeopathic substances are substances as defined in one of the five pharmacopoeias acceptable to NHPD: the Homeopathic Pharmacopoeia of the United States (HPUS), the Encyclopedia of Homeopathic Pharmacopoeia (EHP), the German Homeopathic Pharmacopoeia (HAB), the French Pharmacopoeia (Pharmacopée française or PhF), and the European Pharmacopoeia (PhEur).

2.12.1 Guidelines for Homeopathic Substance Information

Table 6 provides an explanation of how homeopathic substance information is organized in the NHP Ingredients Database.

Table 6 – The required data members for homeopathic substances

Homeopathic Substance Information	Description
NHPID Name	NHPID names consist of the pharmacopoeia, an underscore, and a proper name of the ingredient
Category	The category that the ingredient name belongs to – in this case Homeopathic Name.
Proper name	As provided in the pharmacopoeia
Common name	As provided in the pharmacopoeia
Reference	Pharmacopoeia applicable to the ingredient.

3. Organism Parts Standard Terminology

Organism parts are used for three purposes:

1. as a part of the ingredient name,
2. to identify the raw materials (source materials) of a Custom Defined Organism Substance, and
3. to identify the source of a substance, such as an isolate, when the source material is a part of an organism.

The organism part standard terminology is developed at the NHPD based on the Australian TGA Terminology for Naming Medicines. The full list of organism parts is searchable through the NHP Ingredients Database using the Controlled Vocabulary Search. Only the approved names of the list are acceptable wherever the terminology is applicable. If additions of new parts or changes to existing part names are required, a request for change should be sent to the NHPD via the NHP Ingredients Database Issue Form (see section 1.3 above).

Please note that an Approved Organism Part Name may mean either a single organism part (such as a leaf or seed) or a combination of organism parts when they are difficult or impossible to separate, or they can provide the same medicinal activity profiles (such as “root and root nodule” and “whole plant”). Unapproved combination organism part names are not acceptable.

4. Organism Substance Preparation Terminology

The organism substance preparations standard terminology captures preparation names and other related data on preparing or processing Defined Organism Substances and Custom Organism Substances from raw materials. In all, the following data may be captured:

- Approved organism substance preparation name (method of preparation)
- Potency
- Extraction ratio
- Quantity Crude Equivalent (QCE)
- Whether the source material for an extract is dry or fresh
- Solvents

4.1. Approved Organism Substance Preparation Name

For each organism substance, a method of preparation must be chosen from the approved organism substance preparation names. Examples of approved preparation names are: Decoction, Decoction concentrate, Decoction standardized, and Decoction concentrate standardized. A full list of the acceptable methods of preparation along with their definitions can be found using the Controlled Vocabulary Search of the NHP Ingredients Database with the category set to Organism Part Preparation Types.

In the electronic Product Licence Application form, the requirements for other data depend on the preparation names. For example, only standardised preparations require potency. Please refer to Appendix (section 11.1) for the information requirements associated with each organism substance preparation.

4.2. Potency

A potency is required only for standardised preparations. It captures the concentration of an active or marker constituent of an ingredient. In the electronic Product Licence Application, potency consists of the name of the active or marker constituent and the amount of the constituent in the ingredient. In the NHPID, the active marker constituent is indicated as a sub-ingredient of the ingredient.

4.3. Extraction Ratio

Extraction ratios usually do not appear in the NHPID. However, in the Product Licence Application Form, extraction ratios are required for medicinal ingredients that are extracts, tinctures, or similar preparations.

The extract ratio captures how the preparation is concentrated or diluted in comparison with the raw (crude) material used. It is always expressed as 1:X, X:1, or 1:1. The first quantity is the amount of raw materials (in weight) and the second the amount of final preparation (in weight or volume). No units are required. It always means Kg:Kg, or Kg:L, or g:g ,or g:ml, or mg:mg, or mg:microliter.

1:X is used for diluted preparations, and X:1 for concentrated ones. The extract ratio 1:1 is for liquid extraction preparations only.

4.4. Solvents

This refers to solvents remaining in final preparations. It is required only when the final preparation contains solvents. The solvent term captures a solvent name and its strength (percentage). Only approved solvent names are allowed and these can be found using the NHP Ingredients Database.

5. Organism Types Standard Terminology

Organism types are NHPD-authorized terms for organism group types, such as “Plant”, “Fungi”, “Algae”, and different animal types. Please refer to the Controlled Vocabulary Search of the [NHP Ingredients Database](#) for all NHPD-authorized organism types.

6. Ingredient Roles

Ingredients approved and named in the terminology by the NHPD under the *Natural Health Products Regulations* are subsequently assigned a role(s) and any applicable restrictions. Presently, ingredients can be assigned one or more of the following roles: medicinal, non-medicinal, non-NHP, component or homeopathic role.

6.1. Medicinal Ingredients

A medicinal ingredient (MI) is any substance that contributes to the pharmacological activity of the product. These substances include plants, plant materials, algae, bacteria, fungi, non-human animal materials, extracts, isolates, vitamins, amino acids, essential fatty acids, synthetic duplicates, minerals and probiotics, as described in Schedule 1 of the [Natural Health Product Regulations](#). In addition, based on the definition of “natural health product” in the Natural Health Product Regulations (Section 1(1)), some ingredients used in traditional medicines that are not included in Schedule 1 can have a medicinal role in natural health products, for example Crinis Carbonisatis (charred human hair). A natural health product ingredient must not require a prescription under the Food and Drug Regulations, when it is sold other than in accordance with section C.01.043 of those Regulations (i.e. no substances on [The Prescription Drug List](#) unless it is in homeopathic medicine), as per Section 2(2) of the *Natural Health Product Regulations*.

Homeopathic substances are never given a medicinal role. They are assigned a homeopathic role, meaning they are considered medicinal in homeopathic applications only.

6.2. Non-medicinal Ingredients

A non-medicinal ingredient (NMI) is any substance such as a binder, colouring agent or flavour added to an NHP that is necessary for the formulation of dosage forms. Non-medicinal ingredients should not exhibit any pharmacological effects of

their own, and, where applicable, should not exceed the maximum concentration allowed.

As per section 5 of the *Natural Health Product Regulations*, the proper name and common name of all medicinal ingredients as well as the common name and purpose of all non-medicinal ingredients must be provided on the Product Licence Application form. The NHP Ingredients Database includes many substances with non-medicinal ingredient roles. Where appropriate, certain limitations regarding quantity, dosage form, and route of administration are listed. For a non-medicinal ingredient listed in a Product Licence Application Form, if the quantity of this ingredient is not included in the form, then the amount used in the product must not exceed any limits in the NHP Ingredients Database. Whether or not there are limits indicated in the NHP Ingredients Database, the amount of a non-medicinal ingredient used in a product must not exceed levels appropriate for good manufacturing practice (GMP).

A full list of substances with non-medicinal purposes can be found using the NHP Ingredients Database. Substances with a non-medicinal ingredient role in the NHP Ingredients Database have been evaluated for the validity of the substance names and for evidence supporting their non-medicinal ingredient purposes. However, inclusion of a non-medicinal ingredient role and purpose for a substance in the database does not imply that the substance has actually been used as a non-medicinal ingredient. Also, a non-medicinal ingredient role for a substance in the database does not indicate that the safety of this non-medicinal use has been evaluated and approved by Health Canada. For any non-medicinal ingredient, the NHPD may require a safety assessment as per Section 7d of the *Natural Health Product Regulations*. If there is a particular safety concern with a non-medicinal ingredient, the NHPD may request additional information. If there is a particular safety concern with a non-medicinal ingredient, the NHPD may request additional information. For a generic (non-proprietary) non-medicinal ingredient not contained in the NHP Ingredients Database or used outside of the stated limitations, the applicant can request an addition to the database by submitting an NHP Ingredients Database Issue Form to Online Solutions Support, as described in section 1.3 above. The applicant should provide evidence supporting the non-medicinal use of the ingredient..

6.3. Components

An ingredient which is assigned a component role is a substance which can be present naturally in plant material and which has neither a medicinal nor a non-medicinal role. Components can be listed on the Product Licence Application form as marker or active constituents in the potency section for standardized extracts.

6.4. Non-Natural Health Product

A non-NHP (non-natural health product) is any substance which cannot be considered to be a medicinal ingredient in an NHP under some condition of use. It

may not belong to one of the items in Schedule 1 of the *Natural Health Product Regulations* (for example, a synthetic drug is not included in Schedule 1) or it may be listed in Schedule 2 of the *Natural Health Product Regulations*. (For example, marijuana, being a restricted substance, is not allowed as a natural health product.)

Some ingredients have either a medicinal role or a non-NHP role depending on the condition of use. For example, Vitamin A below 10 000 IU/day is considered medicinal, but above this threshold is treated as a prescription drug, which makes it a non-NHP.

6.5 Homeopathic

An ingredient which is assigned a homeopathic role is a substance defined in a homeopathic pharmacopoeia and which has a medicinal role in homeopathic applications. Only homeopathic substances can have a homeopathic role, and they cannot have any other role.



7. Ingredient Rules

One of the objectives of the NHP Ingredients Database is to interface with other parts of the NHP Online System in order to be able to automatically and completely validate natural health product licence applications by providing a repository of acceptable medicinal and non-medicinal ingredients and associated validation rules. Applications are validated against a set of rules which derive from legislation, regulations, monographs and other sources, such as approved controlled vocabulary lists. Applications will be matched against rules to determine which rules apply and then be accepted or rejected according to these rules.

There are a number of different rule types necessary for application entry and validation. Some of them are required solely for validation, while others are needed simply to assist the various users or determine screen flow.

The rules described in this section are toxicity restrictions, medicinal rules, non-medicinal rules, non-NHP rules and sub-ingredient rules.

7.1. Toxicity Restrictions

Toxicity restrictions are restrictions which are inherent as part of an ingredient (i.e. safety limits). One of the restrictions for ingredients in oral products is given in terms of the acceptable daily intake (ADI). ADI is an estimate of the amount of a substance, expressed on a body-weight basis that can be ingested daily without appreciable risk. The safety limit or ADI is listed in units of mg per kg of body weight per day.

7.2. Non-medicinal Restrictions

Some natural health product ingredients have non-medicinal limitations which are listed based on the quantity, route of administration and dosage form. However, an additional factor to take into consideration for non-medicinal restrictions is the fact that, in natural health product licence applications, some ingredients can be both medicinal and non-medicinal. For such ingredients that appear in monographs, it is important to capture both the medicinal and non-medicinal levels for various product types (such as antacids, sunburn protectants, etc). In NHPD and Therapeutic Products Directorate (TPD) Category IV (CAT IV) monographs for various product types, the medicinal ingredients are given an allowable range. For those ingredients that are both medicinal and non-medicinal, the medicinal lower limit translates into an upper non-medicinal restriction. For example, the NHPD Diaper Rash monograph has a medicinal dose range of 10 to 98% for Corn starch (NHPID name of Starch – Maize), but Corn starch can be a non-medicinal ingredient with many purposes. Any product attesting to the Diaper Rash monograph and containing Corn starch must list Corn starch as a medicinal ingredient if the dose is



10% or greater even though the presence of Corn starch is really for non-medicinal purposes. The non-medicinal restriction description can be provided in terms of daily acceptable intake, single dose, percentage of preparation, etc.

7.3. Non-medicinal Purposes

Acceptable non-medicinal ingredient (NMI) purposes and their descriptions can be found using the Controlled Vocabulary Search of the [NHP Ingredients Database](#).

7.4. Medicinal Restrictions

Based on the definition provided in Section 6.1 for medicinal ingredients, some product ingredients could be classified as prescription drugs under [The Prescription Drug List](#), at some quantity levels or for some routes of administration. These Prescription Drug List restrictions, along with some NHPD and TPD monograph limits as well as other types of medicinal limits, are captured for selected medicinal ingredients.

7.5. Non-Natural Health Product Restrictions

Normally, ingredients with a non-NHP role can never be medicinal. However, there are some ingredients that are non-NHPs that can also have a medicinal role below a well-defined threshold. For those ingredients, a non-NHP restriction is provided indicating at which level they become non-NHPs. Below the well-defined threshold, the ingredient is medicinal while above the threshold it is a non-NHP.

7.6. Sub-Ingredients

Sub-ingredient rules are an important part of the NHP Ingredients Database. An ingredient is sometimes equivalent to certain amounts of ingredients or made up of certain components which are known as sub-ingredients in the NHP Ingredients Database. Sub-ingredients are associated with the source, which can be a chemical substance, a protein substance or an organism part. The quantity of the sub-ingredient in the source chemical substance is given in percentage (%). The quantity of sub-ingredient in a specific part of an organism often is given in microgram/g.

In the NHP Online System, if a chemical substance has an indicated sub-ingredient, then that chemical substance is considered to be an acceptable source of the indicated sub-ingredient. For example, Thiamine hydrochloride has Thiamine indicated as a sub-ingredient, which implies that Thiamine hydrochloride is an acceptable source of Thiamine. Similarly, Calcium carbonate has Calcium as an indicated sub-ingredient, which implies that Calcium carbonate is an acceptable source of Calcium. However, for medicinal ingredients, such as vitamins and minerals, that are sub-ingredients of chemical substances in the NHP Ingredients Database, bioavailability may not have been shown. In NHPD monographs,

bioavailability of the medicinal ingredient from the source ingredients listed in the monograph has been supported by evidence.

For sub-ingredients of organism parts, the database contains the organism name, part name, and the reference where the information was found. Two of the references used for the dataset are [Dr. Duke's Phytochemical and Ethnobotanical Databases](#) and "*Phytochemical Dictionary: A Handbook of Bioactive Compounds from Plants*." The latter is also used to assign HCN chemical classes and subclasses. (see Appendix, section 11.2 for additional authoritative references.)

7.7 Source Ingredients and Source Materials

The origin of the ingredients can be source ingredients or source materials. Source ingredients are other ingredients, often chemical substances that are sources of the ingredient, while Source materials are parts of organisms containing the ingredient. For example, Limestone is a source ingredient of Calcium, and the leaf of the organism *Urtica dioica* is a source material for Calcium.

8. International Conference on Harmonization M5 Controlled Vocabularies

Controlled vocabularies in the context of health products are being developed by the International Conference on Harmonization (ICH) to facilitate the exchange and practical use of medicinal product data by regulators and the pharmaceutical industry (see "[ICH; Draft Guideline M5 Data Elements and Standards for Drug Dictionaries](#)"). The ICH M5 defines controlled vocabulary as a standards related to the following terminologies:

- 1) Active ingredients
- 2) Pharmaceutical dosage forms
- 3) Routes of administration
- 4) Units and measurements.

The NHP Online System project has adapted the TGA Terminology for naming medicines (see Section 2) since this terminology suits the NHPD requirements for naming substances included in natural health products for sale in Canada. NHP Online has recognized the remaining terminologies, namely dosage forms, routes of administration, and units and measurements from ICH M5 and has integrated these controlled vocabularies as part of the overall standard.

8.1. Dosage Form Standard Terminology

Dosage form standard terminology captures all of the dosage forms approved by NHPD. The dosage form controlled vocabulary includes pharmaceutical dosage form terms of standard terminologies in use by the regulators in the ICH regions and observer countries. A dosage form as defined by ICH is a physical manifestation ["entity"] that contains the medicinal and/or non-medicinal ingredients that deliver the dose of the medicinal product. The key defining characteristics of the dosage form can be the state of matter, delivery method, release characteristics, and the administration site or route for which the product is formulated. All dosage forms for natural health products are among those approved by Canada Vigilance for adverse reaction reporting. NHPD has also recognized approved synonyms for dosage forms. All of the approved dosage forms, their synonyms, and definitions can be found with a Controlled Vocabulary Search of the NHP Ingredients Database.

8.2. Routes of administration Standard Terminology

Routes of administration standard terminology captures all routes of administration approved by NHPD. The routes of administration controlled vocabulary uses terms from standard terminologies in use by regulators in the ICH regions and observer countries and defined in the ICH M5 guideline "[Data Elements And Standards For](#)

[Drug Dictionaries](#)". The route of administration indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. The approved routes of administration can be found with a Controlled Vocabulary Search of the NHP Ingredients Database.

8.3. Units Standard Terminology

Units standard terminology captures all of the units approved by NHPD. The units and measurements controlled vocabulary includes units and measurements in use by the regulators in the ICH regions and observer countries and defined in the ICH M5 guideline "[Data Elements And Standards For Drug Dictionaries](#)." All of the approved units can be found by using the NHP Ingredients Database.

9. Non-medicinal Ingredient Purposes Standard Terminology

Non-medicinal ingredient purposes standard terminology captures all of the approved non-medicinal ingredient purposes approved by NHPD. A list of these purposes can be found with a Controlled Vocabulary Search of the NHP Ingredients Database.

10. Test Methods

As part of the quality requirements to obtain a license to sell a natural health product, applicants must provide information on the test methods used for identity, microbial testing, chemical contaminant testing, and so on. The Controlled Vocabulary Search section of the NHP Ingredients Database allows for a search on pre-cleared test method names and types. To request addition of missing test methods to the database, the NHP Ingredients Database Issue Form should be filled and submitted as described in section 1.3 above.

11 Appendices

11.1 Organism Substance Preparation Information Required in Electronic Product Licence Application Form

Please note that new methods of preparation are constantly being added and that the information below was correct as of October 2013.

Table 7: Organism Substance Preparation Information

Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Absolute	-	Required	X:1	Required	Required	Required	all
Attenuated	-	-		-	-	-	
Cold infusion	-	Required	X:1	Required	Required	Required	all
Concentrated juice	-	Required	X:1	Required	Required	Required	all
Decoction	-	Required	1:X	Required	Required	Required	all
Decoction concentrate	-	Required	X:1	Required	Required	Required	all
Decoction concentrate standardised	Required	Required	X:1	Required	Required	Required	all
Decoction standardised	Required	Required	1:X	Required	Required	Required	all
Defatted, ground	-	-		-	-	-	



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Distillation	-	Required	1:X	Required	Required	Required	Water – potable; Water - purified
Distillate concentrate	-	Required	X:1	Required	Required	Required	Water – potable; Water - purified
Distillate concentrate standardised	Required	Required	X:1	Required	Required	Required	Water – potable; Water - purified
Distillate standardised	Required	Required	1:X	Required	Required	Required	Water – potable; Water - purified
Dry	-	-		-	-	-	
Dry damaged	-	-		-	-	-	
Dry standardised	Required	-		-	-	-	
Extract dry	-	Required	X:1	Required	Required	Required	all
Extract dry standardised	Required	Required	X:1	Required	Required	Required	all
Extract liquid	-	Required	1:X	Required	Required	Required	all



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Extract liquid standardised	Required	Required	1:X	Required	Required	Required	all
Fermentation	-	-		-	-	-	
Fluid extract	-	Required	1:1	Required	Required	Required	all
Fluid extract standardised	Required	Required	1:1	Required	Required	Required	all
Freeze-dried	-	-		-	-	-	
Fresh	-	-		-	-	-	
Gelatinized	-	-		-	-	-	
Inactivated	-	-		-	-	-	
Infusion	-	Required	1:X	Required	Required	Required	all
Infusion concentrate	-	Required	X:1	Required	Required	Required	all
Infusion concentrate standardised	Required	Required	X:1	Required	Required	Required	all
Infusion standardised	Required	Required	1:X	Required	Required	Required	all
Juice	-	-		-	-	-	
Juice powdered	-	-		-	-	-	



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Juice powdered standardised	Required	-		Required	Required	-	
Juice standardised	Required	-		Required	Required	-	
Killed	-	-		-	-	-	
Live	-	-		-	-	-	
Oil, Animal fixed (render)	-	-		-	-	-	
Oil, Animal fixed (render) Standardised	Required			-	-	-	
Oil, Essential (Distillation from absolute)	-	-	-	-	-	-	
Oil, Essential (enfleurage)	-	-		-	-	-	
Oil, Essential (enfleurage) Standardised	Required	-		-	-	-	
Oil, Essential (expression)	-	-		-	-	-	
Oil, Essential (expression) Standardised	Required	-		-	-	-	



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Oil, Essential (other methods of preparation)	-	-		-	-	-	
Oil, Essential (other methods of preparation) Standardised	Required	-		-	-	-	
Oil, Essential (water steam distillation)	-	-		-	-	-	
Oil, Essential (water steam distillation) Standardised	Required	-		-	-	-	
Oil fixed	-	-		-	-	-	
Oil fixed standardised	Required	-		-	-	-	
Oil infused	-	-		-	-	-	
Oil infused standardised	Required	-		-	-	-	
Oil, Medicated from dried plant	-	-	-	-	-	-	
Oil, Medicated from fresh plant	-	-	-	-	-	-	



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Oil, Plant fixed (expression)	-	-		-	-	-	
Oil, Plant fixed (expression) Standardised	Required	-		-	-	-	
Oil, Plant fixed (solvent)	-	-		-	-	-	
Oil, Plant fixed (solvent) Standardised	Required	-		-	-	-	
Ointments and salves	-	-		-	-	-	
Powdered	-	-		-	-	-	
Powdered standardised	Required	-		-	-	-	
Preservation	-	-		-	-	-	
Pressed (mechanical) extraction	-	Required	X:1	Required	Required	Required	all
Pressed (mechanical) extraction standardised	Required	Required	X:1	Required	Required	Required	all
Roasted ground	-	-		-	-	-	
Tincture	-	Required	1:X	Required	Required	Required	all
Tincture standardised	Required	Required	1:X	Required	Required	Required	all



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
Traditional	-	-		-	-	-	
Traditional Chinese Medicine	-	-		-	-	-	
Traditional Chinese Medicine extract 1:X	-	Required	1:X	Required	Required	Required	all
Traditional Chinese Medicine standardised	Required	-		-	-	-	
Traditional Chinese Medicine standardised extract 1:X	Required	Required	1:X	Required	Required	Required	all
Traditional Chinese Medicine standardised extract X:1	Required	Required	X:1	Required	Required	Required	all
Traditional Chinese Medicine	-	Required	X:1	Required	Required	Required	all



Approved Name	Potency	Ratio		Quantity Crude Equivalent	Original Material Used	Solvents	
extract X:1							
Traditional extract 1:X	-	Required	1:X	Required	Required	Required	all
Traditional extract X:1	-	Required	X:1	Required	Required	Required	all
Traditional standardised	Required	-		-	-	-	
Traditional standardised extract 1:X	Required	Required	1:X	Required	Required	Required	all
Traditional standardised extract X:1	Required	Required	X:1	Required	Required	Required	all



11.2 Some Authoritative References

11.2.1 Organism Scientific Names

Plants

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- Integrated Taxonomic Information System (ITIS) [Online Database]. <http://www.itis.gov/>
- Catalogue of Life [Online Database]. <http://www.catalogueoflife.org/annual-checklist/2010/search/all>
- Global Biodiversity Information Facility (GBIF) [Online Database]. <http://data.gbif.org/welcome.htm>
- International Organization for Plant Information (IOPI) [Online Database]. <http://bgbm3.bgbm.fu-berlin.de/iopi/gpc/default.asp>
- International Plant Names Index (IPNI) [Online Database]. <http://www.ipni.org/>
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Various Organisms

- Integrated Taxonomic Information System (ITIS) [Online Database]. <http://www.itis.gov/>
- Catalogue of Life [Online Database]. <http://www.catalogueoflife.org/annual-checklist/2010/search/all>
- Global Biodiversity Information Facility (GBIF) [Online Database]. <http://data.gbif.org/welcome.htm>
- National Center for Biotechnology Information (NCBI) Taxonomy [Online Database]. <http://www.ncbi.nlm.nih.gov/guide/taxonomy/>
- World Register of Marine Species (WoRMS) [Online Database]. <http://www.marinespecies.org/>
- Index to Organism Names (ION) [Online Database]. <http://www.organismnames.com/query.htm?searchType=tree&q=Organisms>

Non-human animals

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- Fishbase [Online Database]. <http://www.fishbase.org/search.php>

Algae

- Algaebase [Online Database]. <http://www.algaebase.org/search/species/>

Fungi



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11.2.2 Organism Substances

- Approved Terminology for Medicines (Australian TGA) [Online].
<http://www.tga.gov.au/industry/medicines-approved-terminology.htm>
- Pharmacopoeia of the People's Republic of China [Book]
- Chinese Herbal Medicine, Materia Medica (Bensky et al. 2004) [Book]
- Chinese Medical Herbology and Pharmacology (Chen and Chen 2004) [Book]
- A Comprehensive Textbook of Chinese Herbology (Lu 1999) [Book]
- British Herbal Pharmacopoeia [Book]
- British Pharmacopoeia [Online/Book]
- Food Chemicals Codex [Online/Book]
- Ayurvedic Pharmacopoeia of India [Online/Book].
<http://www.ayurveda.hu/api/API-Vol-1.pdf>
<http://www.ayurveda.hu/api/API-Vol-2.pdf>
<http://www.ayurveda.hu/api/API-Vol-3.pdf>
<http://www.ayurveda.hu/api/API-Vol-4.pdf>
<http://www.ayurveda.hu/api/API-Vol-5.pdf>

11.2.3 Chemicals

- Merck Index [Online/Book]
- Dictionary of Natural Products [Online Database]
- Martindale: The Complete Drug Reference [Online/Book]
- British Pharmacopoeia [Online/Book]
- United States Pharmacopeia [Online/Book]
- European Pharmacopoeia [Online/Book]
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