Australian Government
Department of Health
Therapeutic Goods Administration

TGA approved terminology for therapeutic goods

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TGA Health Safety Regulation

Contents

1. What is approved terminology?

The Therapeutic Goods Administration (TGA) develops and maintains approved terminology to ensure the accuracy and consistency of information on the Australian Register of Therapeutic Goods (ARTG). This provides a consistent and standardised method for naming:

- ingredients
- components
- routes of administration
- dosage forms
- container types
- units of expression
- proportion.

Approved terminology provides a standardised format for identifying ingredients used in therapeutic goods as part of:

- Applications to register or list a medicine on the ARTG
- Labels and packaging for medicines
- Product Information documents provided with medicines
- Consumer Medicine Information documents provided with medicines
- Other promotional material where use of approved terminology is required.

2. The legal basis for using approved terminology

A number of legislative provisions underpin the use of approved terminology to ensure accuracy and consistency of information about goods on the Australian Register of Therapeutic Goods (ARTG).

Therapeutic Goods Act 1989:

- specifies the use of Australian Approved Names for ingredients:
    - Section 10 allows the Minister for Health to make an order (by legislative instrument) for matters to constitute a standard. Under this section, the Minister created a Therapeutic Goods Order outlining requirements for labels for medicines, which refers to the Australian Approved Names list.
    - Paragraph 23(2)(ba) requires applications for registration of restricted medicines (i.e. prescription medicines and some over-the-counter medicines) to be accompanied by a product information document which must use Australian approved names for all ingredients.

Therapeutic Goods Regulations 1990:

- Regulation 2 defines the Australian Approved Names list which refers to this document
- Schedules 12 and 13 require that the Consumer Medicines Information document be consistent with the Product Information (i.e. uses approved names).

The list of Australian Approved Names is published in the Code Tables and Ingredient Tables on the TGA Business Services website.

Reference to approved terminology is included in a number of Therapeutic Goods Orders, such as the medicine labelling Orders, which require Australian approved names to be used on medicine labels.

3. Approved names for ingredients

Approved names are used in the regulation of therapeutic goods to:

- ensure only one name is used to specify a substance (to avoid confusion)
- ensure that the name clearly and unambiguously identifies the substance for identification and testing purposes
- ensure consistency of names with international conventions, e.g. International Non-proprietary Names (INNs)

Names are included in the Ingredients Table to ensure the correct name is included in online medicine applications and any associated documentation.

Please note:

- The inclusion of a name in the Ingredients Table does not imply any recommendation or approval for the use of that substance in therapeutic goods.
- There are two stages to making an ingredient available for use in a product:
  - approval of the appropriate name

    and
  - evaluation of the ingredient/product for use.
- Some ingredients in the Ingredients Table may not currently be included in goods on the ARTG.

3.1 Ingredient and tissue name categories

There are various categories of ingredients, in accordance with their source. The approved ingredient and tissue name categories (and types of products they can be used in) are in Table 1 below.

Table 1: Ingredient categories

Name category	Substance type	Description
Australian Approved Name (AAN)	Chemical	Approved names for chemical substances. (includes antibiotics)
Approved Biological Name (ABN)	Biological	Approved names for biological substances derived from human, animal or microbiological sources for use in medicines. The ABN includes the name of the organism, and may include the part of the organism and the preparation. ABNs do not include plants, fungi, yeasts or antibiotics.

Name category	Substance type	Description
Approved Cell and Tissue Name (ACN)	Cell and tissue	For ingredients used in products that are regulated under the regulatory framework for biologicals, e.g. human and living animal cells and tissues. ACNs are not given to ingredients used in medicines.
Approved Herbal Name (AHN)	Herbal	The genus and species name (in the Latin binomial format) of a plant (including fungi, algae and yeasts). The genus, species, plant part and preparation (including solvents and extract ratio, if applicable) are included to name a herbal ingredient correctly.
Approved Herbal Substance Name (AHS)	Herbal	For herbal ingredients that are fully characterised in a monograph of an accepted pharmacopoeia (usually the British Pharmacopoeia, European Pharmacopoeia or United States Pharmacopeia) e.g. Orange Oil in the British Pharmacopoeia. The identity and quality of the substance **must comply** with the monograph that is the source of the substance name. This is an exception to the way that naming references usually apply (see section 3.3 Ingredient naming references).
Approved Ingredient Name (AIN)	Herbal	Used in association with complex herbal ingredients that: • have been assessed by TGA and • do not meet the *Therapeutic Goods Regulations 1990* definition of a herbal substance. Applicants cannot apply for an AIN. AINs are determined as part of the TGAs evaluation of the substance.
Herbal Component Name (HCN)	Herbal	These are used for a particular constituent or a class of constituents in herbal ingredients, and are most often needed where a class of constituents is restricted, e.g. hydroxyanthracene derivatives. An HCN is not a stand-alone name. It is used in conjunction with the name of the herbal ingredient of which it is a constituent (the 'parent' ingredient).

Name category	Substance type	Description
Approved Food Name (AFN)	Food grade	Allocated to food grade substances, e.g. orange. • In addition to the AFN, the name of the 'preparation' of the food ingredient (e.g. orange juice) is required to form the approved name for the substance. • AFNs are only for use as excipient ingredient names in therapeutic goods. • If the substance is to be included as an active ingredient in a product, the name of the substance is to be expressed in AHN format, e.g. *Citrus sinensis* fruit juice. The AFN category has been superseded and no new AFNs will be created. You should use the Approved Herbal Name (AHN) or the Approved Herbal Substance (AHS) name to identify botanical materials used as active ingredients in medicines.

3.1.1 Proprietary ingredients

Proprietary Ingredients (PIs) are fixed formulations comprising a mix of individual ingredients. Examples include flavours and fragrances. They are not given approved names and are not considered an ingredient category of their own. The ingredients within the proprietary formulation must be identified using Australian approved names.

These formulations are included in the Proprietary Ingredients Table, which is a separate list. PIs are given a unique number that can be used to identify the ingredient mix in online applications to the TGA.

For more information, see the Notification of a new proprietary ingredient page on the TGA website.

3.2 Requirements for approved names

3.2.1 Ingredients that require an approved name

An approved name is required for all ingredients in a therapeutic good. Ingredients can be single molecular entities or complex natural mixtures (e.g. herbal extracts).

3.2.2 Substances that do not require an approved name

Substances that are not required to be identified in the formulation of goods on the ARTG do not require an approved name. Examples include:

- chemical and biological starting materials
- some types of growth media
- manufacturing solvents that are removed in the manufacturing process.

Herbal components do not need approved herbal component names (HCNs) unless it is mandatory that they be declared in the ARTG entry. Sponsors may make claims about herbal components on their label without an approved HCN, as long as the claims are true and comply with regulatory requirements.

3.2.3 Trademarked ingredient names

If a substance has been registered under a trademark in Australia, the trademarked name cannot be used as an approved ingredient name.

If a trademarked name was adopted as an Australian approved name, other sponsors would be required to include that name on their labels. This could result in a breach of trademark legislation.

3.2.4 Punctuation and 'inversion' of names

Punctuation

Punctuation marks are not generally used in ingredient names as they reduce searchability within the Ingredients Table. Where appropriate, punctuation is used as descriptors and designators in the names of chemicals, e.g. 1,3-butylene glycol and cis-3-hexen-1-ol.

Inversion of names

Historically, some ingredient names were expressed in an inverted form to assist with indexing. For example, 'insulin - bovine' rather than 'bovine insulin'. In this example, the correct approved name that must be on a label is 'bovine insulin'.

3.2.5 Specific rules for spelling of chemical names

Alfa vs alpha

Use of 'alpha' or 'alfa' in an ingredient name depends on the context:

- 'alfa' is used for active ingredients in biological medicines, to differentiate between similar ingredients
- 'alpha' is used to name a structural isomer.

Sulfur & sulphur

Sulfur (rather than sulphur) is used in names containing this word or its derivatives, e.g. sulfate, sulfonate.

Alternative 's' or 'z' spellings

Ensure words that have alternative 's' or 'z' spellings, e.g. hydrolysed / hydrolyzed, are spelt with an 's', consistent with Australian spelling conventions.

International Non-proprietary Name (INN) spelling conventions

These conventions are applied to ingredient naming, where consistent with the international approach, and include:

- using 'i' instead of 'y' – e.g. sibutramine mesilate instead of sibutramine mesylate
- using 't' instead of 'th' – e.g. butizide instead of buthiazide

- using ‘e’ instead of ‘ae’ or ‘oe’ - e.g. estrogen instead of oestrogen
- using ‘f’ instead of ‘ph’ - e.g. sulphacetamide is now listed as sulfacetamide
- avoiding the use of ‘h’ and ‘k’ – e.g. colecalciferol instead of cholecalciferol.

Synonyms

Synonyms for ingredients are only included in the Ingredients Table for cross-referencing, to assist with identification and searchability.

Synonyms must **not** be used in place of the approved names:

- on labels of medicines or other therapeutic goods sold in Australia
- in applications for entry of goods on the ARTG
- anywhere else the approved name is required.

Medicines containing herbal ingredients

A synonym or common name can be included in addition to the approved botanical name on medicine labels, as long as the label complies with requirements in the medicine labelling Orders. See section 7.5 Additional information on medicine labels.

3.3 Ingredient naming references

Naming references are used to determine the most appropriate name for an ingredient. The naming reference is the publication that was the source of the proposed name, e.g. a monograph.

Naming references usually include the definition or description of the substance. These reference definitions provide a guide so the substance’s characteristics can be analysed to verify that it is correctly identified.

In most cases, the name stated in the title of the monograph (or other reference) will be adopted as the Australian approved name for the ingredient.

3.3.1 Naming reference versus quality standard

All therapeutic goods must comply with relevant standards. These can be ministerial standards (such as the Therapeutic Goods Orders) or default standards (for example, monographs in the British Pharmacopoeia or the United States Pharmacopeia-National Formulary).

Using a particular reference to define a name **does not** always mean that it is also the standard that defines the **quality** of the substance. For example, Merck is used as a naming reference but is not a standard under the Act.

In some instances, the naming reference is a standard, but it may not be the only relevant default standard. For example, the naming reference for ‘nicotinamide’ may be the British Pharmacopoeia, however a default standard that may be used to define the quality of the ingredient could be the monograph in the United States Pharmacopeia – National Formulary which refers to the same ingredient as ‘niacinamide.’ In these circumstances, the alternative ingredient name may be included as a synonym to assist with searchability in the Ingredients Table.

Please note

An exception to the way naming references usually apply is made for Australian Herbal Substance (AHS) names where the identity and quality of the substance **must comply** with the monograph that is the naming reference for the substance name.

3.3.2 Where there are different names for an ingredient

There may be situations where an ingredient appears under different names in several of our primary naming references. In this situation, the alternative names not accepted may be included in the Ingredients Table as a synonym of the approved name.

3.3.3 Modified reference codes in the Ingredients Table

The word 'modified' following a reference in the Ingredients Table indicates that the name has been adapted from the title or entry in the naming reference, rather than being identical. This is because the name in the reference is spelled slightly differently from the approved name, e.g. dimethylol dimethyl hydantoin as the AAN instead of DMDM hydantoin. To indicate the difference between the names, the reference is International Cosmetic Ingredient Dictionary (modified) and the suffix 'M' is included in the reference code as follows: ICIDM. The definition in the ICID still defines the ingredient.

Modified references are also used where a name with an INN and its salt are approved at the same time but an appropriate reference for the salt does not yet exist.

3.3.4 Default references for AANs and ABNs

International Non-proprietary name (INN) terminology, maintained by the World Health Organization (WHO), is the default naming reference for chemical ingredients (AANs) and biological ingredients derived from human or animal materials (most ABNs).

If you want to use a different name

If an ingredient has an INN and you want to use a different name:

- you will need to justify the use of a different name
- we will review the suitability of alternative names on a case-by-case basis.

Further guidance on INN naming

- WHO Guidance on INN

3.3.5 Additional references for AANs and ABNs

If no INN is available, we prefer the following alternative references:

- British Pharmacopoeia (BP)
- European Pharmacopoeia (EP)
- United States Pharmacopeia – National Formulary (USP)
- British Approved Names (BAN)
- United States Adopted Name (USAN)

- Other internationally recognised references include Martindale, Food Chemicals Codex, International Cosmetic Ingredient Dictionary, Chemical Abstracts Service and the Merck Index. The full list of references are available on ingredient proposal forms and the Code Tables.

If no monograph is available

If the ingredient does not have an entry in any of the references above, we will consider other references, preferably well-recognised, peer-reviewed journals.

Further information on preferred references is available on the proposal forms for ingredient names.

3.3.6 Herbal naming references for AHNs

Herbal ingredients are named using Latin binomial nomenclature, including genus and species. For example, the Latin binomial for sage is *Salvia officinalis*.

Subspecies are included where this better defines the ingredient and where the different species are therapeutically relevant such as *Brassica oleracea var. botrytis* for cauliflower or *Brassica oleracea var. italica* for broccoli.

We use a number of naming references to name herbal species for Approved Herbal Names (AHNs). The Kew Science Medicinal Plant Name Services is the preferred reference for Approved Herbal Names. This is because it is regularly updated and actively maintained. See preferred herbal naming references in Table 2.

Table 2: Preferred herbal naming references

Herbal Naming Reference	Acronym
Medicinal Plant Name Services	MPNS
The Plant List	TPL
Germplasm Resource	GRIN
Tropicos	TRP

Fungi, yeasts and algae are treated as plants in the International Code of Botanical Nomenclature. We include these in the Approved Herbal Name category but we use different references. See Table 3 for these preferred references.

Table 3: Other naming references (by kingdom)

Other Kingdom References	Naming Reference	Acronym
Algae	Algaebase	ALGA
Fungi	Index Fungorum	IF

3.3.7 TGA reference code

Some Australian approved names use the reference code 'TGA <year>'. This indicates that there no INN and/or a suitable entry in any of our accepted references.

To view the full list of reference codes, refer to the Code Tables homepage on the TGA Business Services website (TBS).

4. Approved names for chemical ingredients

This guidance provides information on approved names for chemical ingredients - Australian Approved Names (AANs).

4.1 Searching the list of AANs

The Ingredients Table on our TGA Business Services website contains all approved names for ingredients used in therapeutic goods.

For more information on how to search for ingredients, refer to Appendix 3.1.1.

Please note

The inclusion of an AAN in the Ingredients Table:

- indicates that the name is approved as the descriptor of the substance.
- **does not** imply that the substance has been approved for use in a therapeutic good.

4.2 If a chemical ingredient is not on the Approved List

If there is no AAN for a chemical ingredient in your therapeutic good's formulation:

- follow the process for a proposing a new ingredient name.
- use the form – Proposed Australian Approved Name (AAN).

4.3 Abbreviations for AANs

Chemical ingredients with long names may be abbreviated in the literature, for example:

- cyclohexanedimethanol is referred to as CHDM
- diethanolamine is referred to as DEA
- dimethyl sulfoxide is referred to as DMSO
- hydroxyethyl ethylenediamine triacetic acid is referred to as HEDTA

Please note

In your application for a therapeutic good or on medicine labels:

Û do not use these abbreviations in place of the Australian approved name

Ü use the full Australian approved name (AAN).

4.4 General guidelines for naming chemical ingredients

INN is the preferred reference for AANs (see section 3.3 Ingredient naming references). If there is no INN (or other preferred reference) available for your chemical substance you can propose a new name. Use the following rules when proposing a new name:

- use International Union of Pure and Applied Chemistry (IUPAC) naming conventions, e.g. 1-[3,3-dimethylcyclohexyl]-4-penten-1-one
- unless the name includes a salt, ester or glycol suffix, form names by joining elements of the name together to form a single word, e.g. ethylcellulose rather than ethyl cellulose
- capital letters are not generally used in chemical names except in the circumstances detailed below:
    - include the designator 'N-' in the name to indicate a constituent group attached to a nitrogen
    - where relevant, include stereochemical descriptors, such as 'R-' and 'S-'; 'd-', 'l-' and 'dl-'; and/or 'cis-' and 'trans-', in ingredient names, in accordance with IUPAC nomenclature. This increases the amount of information provided by the name and reduces ambiguity
- use the designators 2-, 3-, 4-, for chemicals that include aromatic rings rather than o-, m-, p-, or ortho-, meta-, para-
- use the designators n-, iso-, sec- and tert- to describe the branching of alkyl groups.
- use Table 4 to identify the acceptable approach for these chemical groups.

Table 4: Names for miscellaneous chemical groups

Acceptable name	Unacceptable name/spelling/format
allyl	propenyl, vinyl carbinyl
amyl	pentyl
anisate	methoxybenzoate
anthranilate	aminobenzoate
cetyl	hexadecyl
glycerol	glycerin
nonanoate	pelargonate
nonanoyl	pelargonyl
nonanoic	pelargonic
phenylpropionate	hydrocinnamate
phenylpropionic	hydrocinnamic
phenylpropionyl	hydrocinnamyl
xylene	xylol

4.5 Naming of specific types of chemical ingredients

4.5.1 Polymeric substances

Polymeric substances are frequently identified by a name part and a number that indicates the grade of polymer by:

- chain length or molecular weight
- viscosity.

Some common examples are in Table 5.

Table 5: Polymeric substances identified by a name part and a number

Type of polymer	Numbering system
Macrogols	Average molecular weight
Dimeticones	Kinematic viscosity
Carbomers, nylons, polyacrylates	Numbers indicate different chemical structures rather than different average polymer chain lengths; the numbering is not systematic, and the relevant references should be consulted to determine the structure

4.5.2 Macrogols (polyethylene glycols—PEGs)

The term macrogol is generally used by the pharmaceutical industry, whereas PEG is used in the chemical and cosmetics industries. 'Macrogol' will be used in AANs for polyethylene glycols (and their simple esters and ethers), rather than polyoxyl, polyoxyethylene, polyethylene glycol or PEG. This is consistent with INN terminology.

'Macrogol' is the INN for polymeric substances with the following general formula:

$HOCH_2(CH_2OCH_2)_mCH_2OH$

INNs have also been assigned to simple esters and some simple ethers of macrogols. Examples are macrogol stearate and lauromacrogol.

INN definitions

The INN definitions state that each name is followed by a number indicating the average molecular weight of the:

- macrogol
- macrogol portion of an ester or ether.

For example, macrogol 300 has an average molecular weight of about 300 (m = 5 or 6, giving a molecular weight of 282.3 or 326.4).

Average molecular weights

To prevent the creation of numerous macrogol names with only minor differences, such as macrogol 1500 and macrogol 1540, we will use average molecular weights in the ingredient name, rounded in the following manner:

> *Molecular weight for macrogols with shorter chain lengths is averaged to the nearest 50, up to a weight of 800. Following 800, the molecular weight is averaged to the nearest 100 up to 1500; then to the nearest 500 up to 8000 and so on.*

Size of the polymer molecule

In AANs, the size of the polymer molecule will be based on the average molecular weight of the polymer chain, not the chain length. (Chain length, based on the approximate number of oxyethylene units, is generally used for PEG-based nomenclature.)

Where names are converted to macrogol from PEG, the chain length designating number will also be appropriately amended, and the reference will be shown as 'modified' e.g. International Cosmetic Ingredient Dictionary (modified) (ICIDM). The name listed in the reference is included as a synonym.

For example, all pure macrogols (macrogol 2000, etc.) will have references as 'modified', because the reference does not usually list the number.

Complex polymers with polyethylene glycol components

Where there are no INNs for more complex polymers with polyethylene glycol components, these are named according to the best available reference.

For example, macrogol poly(vinylalcohol) grafted copolymer is named using the British Pharmacopoeia, whereas acrylates/PEG-10 maleate/styrene copolymer is named using the International Cosmetic Ingredient Dictionary.

4.5.3 Carbomers

When giving different names to carbomers, we follow the conventions of the USP. This approach relies on whether or not they are manufactured using benzene.

Ensure that you refer to the synonyms in the Ingredients Table, and/or the relevant USP references, to help determine the correct name for the substance.

4.5.4 Derivatives

Derivatives each have individual names to identify the salt or ester and distinguish the substances from the base.

For example, 'ibuprofen' and 'ibuprofen sodium' are two separate AANs.

If a derivative has an INN

This will be the approved name.

If there is no INN (or other common reference)

Ensure you name derivatives in accordance with the conventions described in the WHO document *International Non-proprietary Names Modified*, which you can find on the WHO INN Publications page.

4.5.5 Salts

There is no need to specify the molar ratio of the salt if:

- there is no INN or other common reference, and
- the salt can exist in only one form.

For example, if an ingredient can only exist as a monosodium salt, use 'sodium' in the name (e.g. sodium benzoate).

Monohydrochloride would be stated as hydrochloride, whereas dihydrochloride would be stated as is.

Please note

If there is no preferred reference, and there is more than one possible stoichiometry for the salt (and the stoichiometry is not specified), the ratio is assumed to be 1:1.

Common examples are sodium, potassium, magnesium, calcium, hydrochloride and hydrobromide.

4.5.6 Starches

Unmodified, naturally occurring starches are classified as herbal ingredients and have Approved Herbal Substance Names, e.g. maize starch*.

**Note: 'maize' is used to identify ingredients derived from corn.*

Some starches (such as soluble potato starch) have been chemically modified, and are therefore classified as AANs.

4.5.7 Alcohols, aldehydes, acids, esters and acyl groups

Alcohols, aldehydes, acids, esters and acyl groups should be named in accordance with references commonly used in the pharmaceutical industry, e.g. British Pharmacopoeia (BP), Merck Index.

If there is no suitable reference in the Reference Codes list on the Code Tables:

- use the currently accepted International Union of Pure and Applied Chemistry (IUPAC) nomenclature.

Where numbers are included in the name:

- place them in the middle of the name rather than at the start, e.g. butan-1-ol.

4.5.8 Ethanol

The Ingredients Table has two entries relating to ethanol, both of which use the British Pharmacopoeia as a naming reference. However, both have other default standards that sponsors can choose to comply with:

- 'ethanol absolute' (BPM) which is subject to either:
  - 'ethanol' (absolute alcohol) as described in the BP monograph of that title
  - 'dehydrated alcohol', as described in the USP monograph of that title
- 'ethanol' (BPM) which is subject to either:
  - 'ethanol (96 per cent)', as described in the BP monograph of that title
  - 'alcohol', as described in the USP monograph of that title.

4.5.9 Anions and cations

The quantities of individual ions (or ion equivalents) may need to be stated on a medicine label, in addition to the statement of strength for ingredients. The medicine labelling Orders include these requirements for:

- intravenous infusions (large-volume injections)
- concentrated haemodialysis solutions.

All approved anions and cations have AANs and are available in the Ingredients Table.

4.5.10 Amino acids, sugars and other chiral ingredients

Many chiral substances, such as amino acids, can exist as either:

- a single optical isomer (enantiomer) or
- a mixture of isomers.

The reference quoted for the name defines the isomer or mixture.

Some substances of biological origin exist in nature exclusively as a single enantiomer. These include amino acids, sugars and lactic acid. For these substances the:

- stereochemistry of the naturally occurring isomer isn't identified in the ingredient name, e.g. 'lysine' and 'glucose' are AANs, NOT 'l-lysine' or 'd-glucose'
- designators, 'dl-' and 'd-' should be included in the names of amino acids that occur naturally in these forms, to distinguish them from the 'l' form. This is consistent with INN naming conventions and reduces ambiguity
- designators 'R', 'RS' and 'S' are not used for chiral molecules, unless they are in the reference title or are required to distinguish between different approved names.

4.5.11 Metals

Use the common name for metals when naming metal salts or complexes. For example, use 'copper' and 'iron', rather than 'cuprous' or 'cupric', and 'ferrous' or 'ferric' as they are more readily understood by consumers.

- If a single oxidation state occurs, include it in the name, e.g. copper (I), copper (II), iron (II), iron (III))
- Where mixed oxidation states occur, use the names copper, iron, and so on; for example, iron phosphate.

4.5.12 Colour names

Do not include the Colour Index (CI) number for new ingredients that are colours.

Each colour and its lakes will have separate names.

For example, erythrosine and erythrosine aluminium lake are both approved names.

4.5.13 Radioactive pharmaceuticals

Use the INN format for radioactive ingredients, e.g. Iometin (131I); iometopane (123I)) noting that mass numbers in AANs are not in superscript format.

4.5.14 Stearates

The term 'stearate' in the name of a salt or ester refers to mixtures of fatty acids that have as their major component(s) either:

- stearic (octadecanoic) acid, or
- palmitic (hexadecanoic) and stearic acids in varying proportions.

The term 'palmitostearate' is sometimes used where the mixture of fatty acids contains approximately equal quantities of palmitic and stearic acids.

4.5.15 Vitamin E substances

There are no INNs for vitamin E substances—that is, alpha-tocopherol and its derivatives. The USP and BP systems for naming vitamin E substances are different.

The AANs are essentially the same as the names specified in the USP monograph 'Vitamin E', with an additional hyphen, as demonstrated in Table 6.

Table 6: AANs and BP names for vitamin E substances

AAN	BP name
d-alpha-tocopherol	*RRR*-alpha-tocopherol
d-alpha-tocopheryl acetate	*RRR*-alpha-tocopherol acetate
d-alpha-tocopheryl acid succinate	*RRR*-alpha tocopheryl hydrogen succinate
dl-alpha-tocopherol	all-*rac*-alpha-tocopherol
dl-alpha-tocopheryl acetate	all-*rac*-alpha-tocopheryl acetate
dl-alpha-tocopheryl acid succinate	alpha tocopheryl hydrogen succinate

4.5.16 Waters of hydration

Use the following approach for identifying waters of hydration, e.g. the waters of crystallisation of a substance:

- if a hydration state is not included in the name, the ingredient is anhydrous. This policy is used even if the 'normal' state of the ingredient is hydrated.

  Note: In a small number of cases, the term 'anhydrous' is retained in the ingredient name to avoid confusion, e.g. 'colloidal anhydrous silica' and 'hydrophobic colloidal anhydrous silica'.

- there are separate names for each hydration state in which the substance occurs.
- substances that occur with a mixed hydration state are called '*substance* hydrate'.

This approach to ingredient naming is consistent with INN naming conventions. The objective is to provide an unambiguous name, without users needing to refer to other documents to determine which state of hydration is defined.

Exceptions to this approach

If the water is not part of the crystal structure then some substances may include the word 'dried' as part of their name, e.g. 'dried magnesium sulfate'.

Use on labels

Waters of hydration may be expressed differently on labels.

For information on how an ingredient is expressed on a medicine label, see the medicine labelling Orders and related guidance.

5. Approved names for biological ingredients (not cells and tissues)

This guidance provides information on approved names for biological ingredients in therapeutic goods.

5.1 Approved Biological Names (ABNs)

ABNs are used to identify ingredients of biological origin (other than antibiotics) derived from human, animal or microbiological sources.

Under TGA terminology, ABNs **do not** include:

- ingredients derived from plants, e.g. organisms treated as plants in the International Code of Botanical Nomenclature, including fungi, algae and yeast. Plant names are described in section 7. Approved names for herbal ingredients.
- antibiotics, which are given Australian Approved Names (chemical) (AANs) – see section 4. Approved names for chemical ingredients.
- ingredients used in products regulated under the regulatory framework for biologicals (such as cell- and tissue- based products). These are given Approved Cell and Tissue Names (ACNs).

5.2 Searching the list of ABNs

The Ingredients Table on our TGA Business Services website contains all approved names for ingredients used in therapeutic goods.

For more information on how to search for ingredients, refer to Appendix 3.1.1.

Please note

The inclusion of an ABN in the Ingredients Table:

- indicates that the name is approved as the descriptor of the substance
- **does not** imply that the substance has been approved for use in a therapeutic good.

5.3 If the biological ingredient is not on the Approved List

If there is no ABN for a biological ingredient for your medicine:

- follow the process for proposing a new ingredient name.
- use the form –Proposed Approved Biological Name (ABN).

5.4 Naming references for biological ingredients

Reference codes are included against each entry in the Ingredients Table to indicate the reference or authority that defines the biological substance name.

Please note

INN terminology is preferred and is to be used wherever possible.

Where there is no INN or pharmacopoeial monograph to reference, you may need to provide further information about the ingredient with the application for an ABN.

For further details on references, see section 3.3 Ingredient naming references.

5.5 General guidelines for naming biological ingredients

A wide range of substances have been identified as ABNs in the Ingredients Table.

In some instances, common names have been chosen as these are more readily understood, e.g. 'honey bee venom'. The Latin binomial species name is then included as a synonym, e.g. '*Apis mellifera* venom'.

All microorganisms must be named using the Latin binomial species name, e.g. *Streptococcus salivarius*.

In the past, ABNs have been used to identify some products. For example, 'pertussis vaccine' (a product) was historically an ABN. This approach is no longer in place. In this example, the approved name for the ingredient is the ABN *Bordetella pertussis*.

5.5.1 Referring to animal species

ABNs for animal-based ingredients should use the scientific name, not the common animal name.

For example:

- bovine (cow)
- ovine (sheep)
- canine (dog)
- feline (cat)
- porcine (pig)
- equine (horse)

The common name (cow, etc.) can be included as a synonym to improve searchability of the Ingredients Table.

5.6 Naming specific types of biological ingredients

5.6.1 Naming microorganisms

Microorganisms are generally identified to species level. Subspecies and biovar names are only included where proven to be therapeutically relevant.

To avoid proliferation of multiple strain names, the strain reference can only be used in the ingredient name if identification of an individual strain:

- is therapeutically relevant
- if therapeutic activity is exclusive to the particular strain
- can be otherwise justified.

Information about strains may be included as additional information in an entry in the Ingredients Table. Medicine labels can include strain information, as long as this information is presented in accordance with the relevant labelling order.

5.6.2 Naming animal parts and preparations

To provide an accurate description of animal derived substances, the approved name for biological ingredients will incorporate

- part,
- preparation,
- source details

rather than as adjunct names (as is done for herbal ingredients).

Bovine cartilage powder and snake venom powder are examples of ABN ingredients of animal origin.

5.6.3 Transmissible Spongiform Encephalopathies (TSEs)

The animal source and part is information that we use to evaluate the safety of the substance with respect to transmissible spongiform encephalopathies (TSEs). The animal source and part will not be used separately as names in their own right.

Further information on our TSE policy (and which ingredients are eligible for self-assessment) can be found in Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising the risk of exposure.

5.6.4 Ingredients of animal origin to be used in listed medicines

For TSE safety, new ingredients of animal origin that are used in listed medicines must be pre-cleared before they can be added to the Ingredients Table.

For further information, refer to the Australian Regulatory Guidelines for Complementary Medicines.

5.6.5 Naming biological ingredients of human origin

If a biological substance is of human origin, the origin of the substance is not specified in the name.

For example, the ABN ‘calcitonin’ refers to the human protein, whereas ‘porcine calcitonin’ and ‘salmon calcitonin’ are obtained from pigs and salmon respectively.

6. Approved names for biological cell and tissue substances

This guidance provides information on approved names for biological cell and tissue substances in biological therapies.

6.1 Approved Cell and Tissue Names (ACNs)

ACNs identify ingredients of biological origin, blood, blood components, tissue and cellular products, and tissue- and cell- based derivatives.

Under TGA terminology, ACNs **do not** include:

- ingredients derived from plants, e.g. organisms treated as plants in the International Code of Botanical Nomenclature, including fungi, algae and yeast. Plant names are described in section 7. Approved names for herbal ingredients
- antibiotics, which are given Australian Approved Names (chemical) (AANs) (see section 4. Approved names for chemical ingredients)
- biological ingredients that are not regulated under the regulatory framework for biologicals such as vaccines, peptides and monoclonal antibodies.

6.2 Searching the list of ACNs

The Ingredients Table on our TGA Business Services website contains all approved names for ingredients used in biological therapies.

For more information on how to search for ingredients, refer to Appendix 3.1.1.

Please note

The inclusion of an ACN in the Ingredients Table:

- indicates that the name is approved as the descriptor of the substance
- **does not** indicate that the substance has been approved for use in a biological therapy.

6.3 If the biological cell and tissue ingredient is not on the Approved List

If there is no ACN for a biological cell and tissue ingredient for your biological:

- follow the process for proposing a new ingredient name
- use the form –Proposed Australian Approved Cell and Tissue Name (ACN).

6.4 Naming references for biological cell and tissue substances

Reference codes are included against each entry in the Ingredients Table to indicate the reference or authority that defines the biological cell and tissue substance name.

Please note

INN, USAN and ISBT 128 terminology are preferred and should be used wherever possible.

Where there is no INN or other pharmacopoeial monograph to reference, you may need to provide further information about the ingredient with an application for an ACN.

For further details, see section 3.3 Ingredient naming references.

6.5 General guidelines for naming biological cell and tissue ingredients

General guidance on naming biological ingredients is currently under development and will be published soon. For enquiries please contact the Biological Sciences Section by email: bloodandtissues@tga.gov.au.

7. Approved names for herbal ingredients

This guidance provides information on approved names for herbal ingredients in therapeutic goods.

Most medicines that contain herbal ingredients are regulated as complementary medicines. Further information is available in the Australian Regulatory Guidelines for Complementary Medicines (ARGCM).

7.1 Herbal ingredient name categories

There are different categories of approved names for herbal ingredients:

- **Approved Herbal Name (AHN)** refers to a species name expressed as its Latin binomial, for example, '*Hypericum perforatum*' and includes fungi, algae and yeasts. AHNs are used in conjunction with information on the plant part and preparation to make a complete name such as '*Vaccinium macrocarpon* fruit powder'. This approach is used for both active ingredients and excipients.
- **Approved Herbal Substance name (AHS)** refers to a single herbal substance that is defined by a pharmacopoeial monograph, for example, 'St John's Wort herb dry'.
- **Approved Ingredient Name (AIN)** refers to an ingredient derived from a plant that is highly refined but is not a pure chemical. AINs will be described by a default standard (an individual or specific monograph in the BP, EP or USP) or by a TGA compositional guideline. Requests cannot be made for an AIN, they are determined by the TGA.
- **Approved Food Name (AFN)** refers to a food name, for example, 'blueberry'. These can only be used to identify excipients.

All herbal ingredient names must be 'complete'. See section 8 for more information on how to make complete names.

7.2 Searching the list of approved herbal names

The Ingredients Table on the TGA Business Services website contains all approved names for ingredients used in therapeutic goods.

For more information on how to search for ingredients, refer to Appendix 3.1.1.

Please note

The inclusion of a herbal ingredient name in the Ingredients Table:

- indicates that the name is approved as the descriptor of the substance
- **does not** imply that the substance has been approved for use in therapeutic goods.

7.2.1 If a herbal name is not on the Approved List

If there is no approved herbal name to describe a new ingredient:

- follow the process for proposing a new ingredient name
- review section 9.2: Proposing a new herbal ingredient name
- use the form –Proposed Approved Herbal Name.

7.3 Using common names for herbal species

Common names do not unambiguously identify herbal species. Generally, the scientific species name must be used as the approved name.

In some cases, it might be appropriate to also include the common name for a plant in other documentation, including the medicine label. This might be appropriate where there are closely related species, subspecies, varieties and cultivars.

For example, *Brassica oleracea*, has several subspecies including cabbage, broccoli, Brussel sprouts, kale and cauliflower. For this ingredient, common names have been included in the list of synonyms in the Ingredients Table for clarity.

7.4 Herbal component names (HCNs)

Herbal Component Names (HCNs) are used to identify a component or group of components within parent herbal ingredients. These names are also in the Ingredients Table.

Please note

A HCN is not an ingredient in its own right. It can only be used in conjunction with an AHN or AHS.

7.4.1 How HCNs are used

Some HCNs must be declared in listed medicine applications due to specifications for the parent ingredient in the Therapeutic Goods (Permissible Ingredients) Determination or requirements in the Standard for Uniform Scheduling of Medicines and Poisons (SUSMP). These 'mandatory' components must be declared in the medicine application, but may not be required to be declared on the medicine label.

In the past, TGA approved new HCNs for non-mandatory components, however this process has been discontinued and you cannot apply for a new HCN.

New HCNs are only created when a legislative requirement comes into force. In this situation, the TGA will consider whether an existing approved name should be linked as an equivalent to the parent AHN or if a new HCN is needed.

Claims for listed medicines

Listed medicines may make claims on their labels about herbal components without pre-market evaluation of HCNs as long as they are true and the labels comply with regulatory requirements. Sponsors are required to hold evidence to support any claims that they make about herbal components. This evidence can be reviewed as part of a post-market compliance review.

Standardised herbal ingredients

When submitting a listing application, extracts can only be identified as being standardised if the standardised component has an AAN or HCN. If there isn't an approved name for the component, a non-standardised plant preparation type should be used to describe the extract. For example, use 'ext. dry conc.' instead of 'ext. dry conc. stand'.

Sponsors may make claims on their labels about herbal components without declaring this information on the medicine application. Any such statement must be true and comply with regulatory requirements.

7.4.2 Principles for herbal component naming

The following principles apply to the naming of new mandatory HCNs by the TGA.

HCNs for simple, well-characterised components

For a simple and well-characterised component, e.g. 'menthol', the HCN only includes the name of the chemical entity (i.e. not the name of the parent AHN), for example:

- ‘arbutin’, rather than ‘arbutin (of *Achillea millefolium*)’

The HCN is linked in TGA’s Business Systems as a mandatory equivalent component to the parent AHN (e.g. arbutin will be linked to the parent *Achillea millefolium*).

HCNs for complex components

The naming of complex components is assessed on a case-by-case basis. In some instances, it may be appropriate to include the parent plant species in the HCN. For example, ‘purine alkaloids calculated as caffeine (of *Paullinia cupana*)’.

Examples include chemical groups that are unique to the plant species or may not be easy to characterise.

- ‘fucoidan (of *Fucus vesiculosus*)’ and ‘fucoidan (of *Undaria pinnatifida*)’.

  Note: *In this instance, the component fucoidan represents a mixture of polymeric constituents, the composition of which varies between fucoidan-containing species. Therefore, each of these HCNs includes the parent AHN.*

7.5 Additional information on medicine labels

Extra information about herbal ingredients, such as common names, can be included on medicine labels if:

- complete approved name is present
- all other information required under the legislation is present
- the additional information is both correct and unlikely to mislead consumers.

Common names must reflect common usage and understanding in Australia, e.g. black cohosh is the common name for *Actaea racemosa*.

8. Methods to complete an approved herbal name

Herbal ingredient names used in an application or on medicine labels must be the full or 'complete' name. The category of your ingredient will determine what you need to do to construct the complete name. Hyperlinks in Table 7 take you to the relevant section.

Table 7: Complete names for herbal ingredient categories

Ingredient category	Method used to complete name
AHN	AHN + the plant part + the plant preparation
AHS	*These are considered complete names*
AFN	AFN + the food preparation

For more information on plant parts and preparations used in conjunction with AHNs, see Appendix 1 and Appendix 2.

8.1 Method 1: AHN + plant part + plant preparation

This method is generally used for extracted herbal preparations, such as:

- '*Thymus serpyllum'* + 'herb' + 'dry'
- '*Frangula purshiana'* + 'stem bark' + 'tincture 1:5 in 35% E:W'
- '*Pulsatilla vulgaris'* + 'whole plant' + '6X'.

8.1.1 Approved Herbal Names (AHNs)

In the botanical name:

- the first word is the genus name
- the second word is the species name (specific epithet)
- both words together are needed to name the plant species
- the botanical name is written in italics, with the first letter of the genus name capitalised.

For example: *Hypericum perforatum*.

8.1.2 Plant part

The Plant Part section on the Code Tables contains all TGA approved plant part names.

For more information on searching the Code Tables, refer to Appendix 3.2.1.

Ensuring you use the most correct plant part name

- Confirm the name of the plant part with the raw material supplier.
- Check the Herbal ingredients plant parts index (Appendix 1) for your plant part. If:
    - there is only one **bolded** approved plant part name, and no other instructions, use that term.
    - there are two (or more) approved plant part names or instructions, select the term that most accurately describes the part(s) used.
    - there are no approved names listed for your plant part, follow the instructions under the 'Refer and compare' subheading to help determine the most correct plant part name.
    - the supplier's name for the part is not listed at all, contact TGA names by email: tganames@tga.gov.au to find out if this is a new plant part.

Using the plant part in applications and medicine labels

Plant parts in medicine applications

Use the approved name for your plant part.

Plant parts on medicine labels

Use the approved name, or an acceptable alternative if one is listed for that plant part in the plant parts index.

Please note

AHNs on medicine labels can differ from the approved name used in the ARTG in the following ways:

- special names may be used. For example, instead of 'fruit', other words such as 'berry', 'hip', 'capsule', 'legume', 'follicle' or 'pod' may be used
- the plural can be used, e.g. 'leaves'
- the word order can be changed and words can be written in full to achieve plain English, e.g. 'flowering herb top'
- simplifications may be used, e.g. 'flowering tops'.

Further information can be found in section 7.5 Additional information on medicine labels.

Using combinations of plant parts

You can use more than one plant part if there is an approved plant part name available for that combination in the Code Tables, for example, 'root & rhizome', 'whole plant' and 'herb fruiting'.

If a combination of plant part names is not available e.g. 'leaf & root', name the two substances separately. For example:

- ingredient 1—dandelion root: '*Taraxacum officinale* root powder'
- ingredient 2—dandelion leaf: '*Taraxacum officinale* leaf powder'.

8.1.3 Plant preparation

The Plant Preparations section on the Code Tables contains all TGA approved preparation names.

For more information on searching the Code Tables, refer to Appendix 3.2.1.

Ensuring you use the most correct plant preparation name

- Confirm the plant preparation details with the raw material supplier.
- Check the Herbal ingredient plant preparations index (see Appendix 2) to find your preparation type e.g. 'tincture' or 'oil fixed'. If:
    - an approved name is listed here (**in bold**), ensure this is used in applications and on product labels.
    - there is limited space on your label, you may be able to select an optional name or abbreviation (if one or more is listed).
- You may need to include information on final extraction ratio and solvents, equivalent dry/fresh weight or component names.
- Some information on the plant preparation must be included in applications but does not need to be included on a medicine label.

If a new plant preparation is required

Contact TGA names by email for advice: tganames@tga.gov.au.

Using plant preparations in medicine applications

Plant preparations can be a single term, such as 'fresh', 'dry', 'powder' and 'oil essential'. More complex preparations need additional information to fully describe the ingredient.

If the ingredient is not an extract

If the ingredient is not an extract, e.g. an essential oil or a powder, you don't need a dry or fresh weight equivalence statement.

If the ingredient is an extract

The complete plant preparation name for non-oil extracts has two parts in addition to the type of plant preparation (e.g. ext. dry conc.):

1. The extraction ratio and solvent details. For example, '(3:1 in 55% E:W [ethanol in water])'.
2. The type of raw material used. For example, 'dry' or 'fresh' (preceded by 'EQUIV.', the AHN and the plant part); 'EQUIV.' means 'equivalent to'. A medicine application containing this type of raw material may need to include additional statements of fresh or dry weight equivalence.

See below for more information about plant preparations.

Extraction ratio and solvent details

The concentration of preparations (e.g. tinctures, extracts, spagyrics, infusions and decoctions) should be given as the ratio of the weight of the herbal material used as a starting material to the quantity of the final preparation that is the ingredient. Units for quantities of the raw herbal material and the final preparation in the extraction ratio are in Table 8.

Table 8: Units used to derive extraction ratio

Herbal raw material unit	Final preparation (i.e. extracted ingredient) unit
kg	kg or L
g	g or mL
mg	mg or microlitres

For preparations that are 'concentrates', the final extraction ratio is expressed in the form 'x:1' and a dilute preparation as '1:x', as described in Table 9 and Table 10.

Table 9: Examples of extraction ratios for dry herbal material

Extraction ratio	Meaning	Examples
1:10	One (1) part of dry herb is used to make ten (10) parts of preparation.	1 g of dry herb is used to make 10 mL of tincture.
1:1	One (1) part of dry herb is used to make one (1) part of preparation.	1 g of dry herb is used to make 1 g of dry extract. 1 g of dry herb is used to make 1 mL of liquid extract.
3:1	Three (3) parts of dry herb is used to make one (1) part of a concentrated preparation.	3 g of dry herb is used to make 1 g of dry extract. 3 g of dry herb is used to make 1 mL of liquid extract.

Table 10: Examples of extraction ratios for fresh herbal material

Extraction ratio	Meaning
fresh 1:5	1 part of fresh herb is used to make 5 parts of preparation
fresh 4:1	4 parts of fresh herb is made into 1 part of a concentrated preparation

Solvents

Where the herbal substance is an **active ingredient** (and is an extract, spagyric, or tincture), the name and concentration of the solvents used to extract the herbal substance are usually required. This will be indicated in Appendix 2: Herbal Ingredients Plant Preparations Index.

For preparations that are **infusions or decoctions**, the solvent is always water and this does not need to be stated.

For preparations that are **tinctures**, alcohol with or without water is used. For example, 40% ethanol in water would be expressed as 'in 40% E:W'.

Solvent names

Use the AAN for the solvent name. Alternatively, solvent name abbreviations can be used in some applications (e.g. 'E' for ethanol). Abbreviations can only be used in conjunction with extraction ratios. State the relative solvent concentrations as percentages, as outlined in Table 11.

Table 11: Examples of expression of relative solvent concentrations

Number of solvents	Examples	Comments
1	'in 100% W'	
2	'in 45% E:W'	The percentage figure refers to the proportion of the first-named solvent.
3	'in glyc:E:W 15:20:QS'	The % sign is not necessary. The last of the solvents used to make up the total volume is indicated as 'QS' (from the Latin, *quantum sufficit*).

Examples for expression of extraction ratios and solvents are in Table 12.

Table 12: Examples for expression of extraction ratios and solvents

Name	Meaning	Comments
(1:4 in 15% E:W)	A 1:4 aqueous–alcohol tincture made using 15% ethanol in water.	Any preservative, such as additional ethanol, should not be named or quantified here.
(fresh 1:1 in 27% pr-gl:ether)	A 1:1 fresh plant extract made using 27% propylene glycol in ether.	Any diluent, such as lactose or ethanol and water, should not be named here.
(6:1 in glyc:E:W 10:25:QS)	A 6:1 concentrated extract made using 10% glycerol and 25% ethanol in water.	
(4:1 in 35% E:W; in 40% p-gl:E)	A 4:1 concentrated extract made in two stages: initially using 35% ethanol in water and then using 40% propylene glycol in ethanol.	Where a series of extractions occurs, each solvent mix is detailed in turn.

The type and quantity of raw material

The type of raw material used is part of the plant preparation and the quantity used is a measure of the strength of the ingredient. This information is provided as a separate statement, which incorporates the AHN and plant part for the material.

If the ingredient is a liquid extract, decoction, infusion or juice concentrate:

- the type of raw material used to make the ingredient is to be named as indicated in Appendix 2: Herbal ingredient plant preparations index
- choose the appropriate term from 'dry', 'fresh', 'juice dry' or 'juice fresh'.

If the ingredient is a dry herbal material, equivalent fresh weight claims can also be made.

Further information on listed medicine applications

For further information, refer to the Listed medicines application and submission user guide.

Using plant preparations on medicine labels

For information on the inclusion of plant preparations on labels of finished goods, refer to the labelling orders and associated guidance.

Details of the solvents used in the extraction of herbal materials are not required on medicine labels. This does not remove the need to declare the presence of any alcohol in the medicine. Disclosure of product alcohol content on labels must be in accordance with the labelling orders.

The type and quantity of raw material

Use metric units as stated in the labelling Orders, noting that

- where there is only one ingredient in the product, use '1 g/g' or '1 mL/mL'.

The equivalent dry/fresh weight is calculated as follows:

extraction ratio (as fraction) × quantity of ext./tinct. = equivalent dry/fresh weight

Use comparable units. For example:

- quantity of tincture in microlitres gives dry/fresh weight in ml
- quantity of dry extract in mg gives dry/fresh weight in mg.

Examples are in Table 13.

Table 13: Examples of calculation of equivalent dry/fresh weight from extraction ratio

Name	Equivalent dry or fresh extract	Extraction ratio	Quantity of extract/tincture	Equivalent dry/fresh weight
Gentiana lutea root tinct. (1:5 in 40% E:W)	EQUIV. *Gentiana lutea* root dry	1:5	200 microlitre/mL	1/5 × 200 microlitre/mL = 40 mg/mL
Chamaemelum nobile flower ext. dry (fresh 1:1 in 35% E:W)	EQUIV. *Chamaemelum nobile* flower fresh	1:1	500 mg/g	1/1 × 500 mg/g = 500 mg/g
Frangula purshiana bark ext. dry conc. (3:1 in 30% E:W)	EQUIV. *Frangula purshiana* bark dry	3:1	70 mg/g	3/1 × 70 mg/g = 210 mg/g

8.2 Method 2: AHS

The Approved Herbal Substance (AHS) is the only complete approved name for a herbal ingredient. For example:

- 'Orange Oil', as specified in the BP.

8.2.1 Approved Herbal Substance Names (AHSs)

Relevant monograph for AHS ingredients

AHS names are linked to a specific or individual monograph in a pharmacopoeia e.g. BP 2014.

Please note

The monograph reference is **not** part of the AHS name.

Capitalising each word in an AHS

The first letter of each word in an AHS is capitalised as it is the title of the monograph that describes and defines the ingredient.

For example:

- 'Cedar Leaf Oil', 'Benzoin Sumatra' and 'Garlic Bulb Powder'.

Database of AHS ingredients

To search the full list of AHS ingredients, go to the ingredients list on the TGA Business Services website.

8.2.2 Selecting the AHS

You can only use an AHS to name the herbal ingredient where the:

- Herbal substance is derived from herbal raw material that has an AHN.
- Herbal ingredient is made from the herbal raw material identified in the specified monograph.

  Most monographs name a single herb species and plant part from which the substance is to be prepared. In some cases, two or more herb species and/or two or more plant parts are named as suitable raw material to make the same herbal substance.
- Ingredient can be positively identified from the characteristics given in the monograph.

  The monograph description of dry or powdered herbs usually includes the macroscopic and microscopic appearance of the herbal material and the expected results of physical and chemical identification tests. Oils are usually identified by physical characteristics such as optical rotation and specific density, chromatographic pattern and chemical identification tests.

AHS monographs

Where there is an appropriate monograph in the current edition of a pharmacopoeia (pursuant to the definition of a standard in the Act), the herbal substance must comply with the description and requirements specified in the monograph. The AHS name is used in this instance.

8.2.3 Using the AHS

If you use the AHS in your medicine, there is no need to add further details about the plant part and plant preparation in the application or on the medicine label. Ensure the AHS is stated on a label exactly as it appears in the Ingredients Table.

8.3 Method 3: AFN + food preparation

8.3.1 Approved Food Names (AFNs)

AFNs use common names to refer to edible substances fit for human consumption. In some instances, these names include a plant part or preparation.

The AFN format has been superseded and no new AFNs will be created.

You should use a plant's Latin binomial name (the AHN) in place of an AFN where possible.

Please note

AFNs can only be used to name excipient ingredients, not active ingredients.

8.3.2 Using AFNs

When using AFNs

- If the food preparation name is included in the AFN do not repeat the preparation name; for example, 'walnut oil' and 'apple cider vinegar'.
- Where the preparation is not specified in the AFN, add a food preparation to complete the name; for example, apple (AFN) + fresh (food preparation) = apple fresh.
- Do not capitalise. This helps to distinguish them from AHSs.

8.3.3 Food preparation

Only fresh, dry and powdered plant material and fresh, dry and concentrated juices are named with AFNs.

For example, the AFN 'apple', is the edible fruit of any of the varieties of *Malus × domestica*, can be used to name the following food excipients;

- apple fresh
- apple dry
- apple powder
- apple juice fresh
- apple juice dry (including powder, flour, meal)
- apple juice concentrate (partially but not completely dried).

Approved food preparation names

Only the following food preparation names are approved:

- dry
- fresh
- juice dry
- juice fresh

- juice concentrate
- oil
- powder.

You can only name juice preparations where the fresh plant part has a high water content.

Please note

AFNs are not generally adopted for extracted preparations other than oils.

9. Proposing a new ingredient name

If an ingredient name is not on the Approved Names List, you can submit a proposal for it to be included.

You can do this:

- as a 'stand-alone' proposal for a new approved ingredient name, or
- by including your proposal with the related application.

9.1 Preparing your proposal

There are four steps in the approval process for a new name.

Step 1 – Select the appropriate form

Choose the most appropriate form for your substance from the list in Table 14. If you are unable to determine the correct form, please contact TGA names by email: tganames@tga.gov.au.

Table 14: Ingredient name proposal categories

Ingredient type	Form link
Chemical ingredients	Proposed Australian Approved Name (AAN)
Biological ingredients	Proposed Approved Biological Name (ABN)
Herb (plant)	Proposed Approved Herbal Name (AHN)
Herbal substance	Proposed Approved Herbal Substance Name (AHS)
Cell and Tissue ingredients	Proposed Approved Cell and Tissue Name (ACN)

Step 2 – Prepare and submit your proposal form and supporting information

You will need to:

- Provide **a monograph or other reference** that contains enough information to allow the name to be defined with certainty. This includes any details about salts and other derivatives.
- Provide a justification if you are proposing a name that differs to an existing INN for that substance.
- Check the relevant application form for any additional requirements for supporting information.

Step 3 – Consideration of the proposed name

- We will check the form for completeness, including attached references.
- We will not process incomplete forms until you provide the required information.

If insufficient information is provided

- There may be delays in processing your proposal.
- We may decide to reject the proposal.

Reviewing your proposed name

Relevant technical experts at the TGA will consider the proposed name for approval.

We have three internal committees to review proposed names:

- Australian Approved Names Committee (AANC) - considers naming of AANs and terminology, as well as AANs for chemical substances derived from plants.
- Approved Biological Names Committee (ABNC) - considers naming of ABNs and ACNs, as well as new terms for animal: parts, origins and preparations.
- Herbal Ingredient Names Committee (HINC) - considers naming of AHNs, AHSs, AINs and HCNs, as well as new terms for plant parts and plant preparations.

Please note

The naming committees do not consider names for finished goods, e.g. trade names for medicines.

Step 4 – Approval

We will advise you of the outcome of our considerations in writing.

If the proposed name is accepted

We will update the Ingredients Table on the TGA Business Services website with enough information to identify the ingredient.

You can then use the approved ingredient name in other applications. For more information on searching for ingredient names in the Ingredients Table, refer to Appendix 3.1.1.

If your proposed name is not accepted

We will notify you and outline the reasons why the proposed name is unacceptable. Alternatively, we may propose an alternative name.

Please note

- TGA approval of a name does not mean that the ingredient has been approved (or recommended) for use in therapeutic goods.

9.2 Proposing a new herbal ingredient name

When proposing a new herbal ingredient name, follow the process in section 9.1. You will also need to refer to the following:

- Methods to complete an approved herbal name
- Proposing a new plant part or preparation

9.3 Proposing a new plant part or preparation

There is no form for proposing a new plant part or plant preparation.

To do this, please contact TGA names by email: tganames@tga.gov.au.

10. Other terminology

In addition to ingredient names, Australian approved terms have been created to describe the way therapeutic goods are presented.

These terms include:

- container types
- dosage forms
- routes of administration
- units of measurement.

The availability of these terms will depend on whether the goods are registered medicines, listed medicines, biologicals or devices.

To view the full list of approved terms, refer to the Code Tables on the TGA Business Services website. For more information on how to search the Code Tables, refer to Appendix 3.2.1.

If the term you want to use does not appear in the Code Tables, please contact TGA names by email: tganames@tga.gov.au.

Definitions of container types in the Code Tables

Container type definitions in the code tables are for guidance only. Although the examples may refer to specific materials, the names can be used for containers:

- made from other materials
- that are of varying sizes.

Formal definitions are not provided for container types which have a well-understood meaning.

To view the full list of approved terms to describe container types, with definitions, go to the TGA Business Services website.

Appendix 1 Herbal ingredients plant parts index

This page will help you where plant part terms are required in product applications and on medicine labels. The guidance will ensure that you're using the most correct plant part name from the approved names in the TBS Plant Part Code Table.

A1.1 Information in the plant parts index

Plant part term (column 1)

- Appearing in alphabetical order, these are either commonly used names or technical terms for plant parts.
- Some of these terms are not TGA approved names, or are broad descriptions of the plant part (e.g. bark). Refer to the description to confirm if it has (or is) an approved name.

Approved name differentiation (column 2)

- If an approved name is listed here (in **bold**), ensure this is used in applications and on product labels. You can search the TBS Plant Part Code Table for the **bolded** plant parts.
- If more than one approved name is suggested, select the most correct term for the plant part used to make the ingredient.
- If there is no approved name listed, follow the instructions under the '**Refer and compare'** section.
- **Refer and compare:** Where the approved name is not obvious (e.g. broad terms such as bark, and fruit), this section will refer you to one or more alternate names/terms to help you find the most correct approved name.

NOTE

These are suggestions only, and usually (but not always) include the correct plant part.

Each suggested alternate term is also hyperlinked for easier web navigation.

- **Alternative term for label**: Label AANs are optional if you need a different term for your label (if one or more is listed).

  The label name will not always be listed under the approved name. When label names are not listed under the AAN, you will be referred back to the relevant plant part in column 1 for the label name.

Table A1: Herbal ingredients plant parts index

Plant part	Approved name differentiation (approved names from Code Tables in bold)
achene	**seed**
aerial parts	refer herb top or, if applicable, herb (contrast with whole plant)
aerial root	**root aerial** (label AAN: aerial root, root, root aer.)
albedo (*Citrus* fruit)	white layer of fruit peel (mesocarp): **fruit peel inner** (label AAN: fruit peel in.)
androecium	**stamen** (label AAN: flower stamen)
anther	**anther** (label AAN: flower anther)
antheridium	**fruiting body**
archegonium	**fruiting body**
aril	**seed aril** (label AAN: aril)
arillus	**seed aril**
ascocarp	refer fruiting body
balsam	• where applicable, refer to oil, oleoresin, resin, gum, gum oleoresin • where not as above: add plant part from which balsam was derived e.g. **gum balsam**, **sap balsam** or **stem balsam**, as applicable, and refer to Plant Preparations code table for the preparation: e.g. fresh, extract, etc. • where none of the above apply, **balsam**
balsamum	refer balsam
bark	as appropriate: • **rhizome bark, rhizome bark inner, rhizome bark outer** • **root bark, root bark inner, root bark outer** • **stem bark, stem bark inner, stem bark outer** • **twig bark, twig bark inner, twig bark outer**
bark inner	state part, e.g. refer rhizome bark inner, root bark inner, stem bark inner, twig bark inner

Plant part	Approved name differentiation (approved names from Code Tables in bold)
bark outer	state part, e.g. refer rhizome bark outer, root bark outer, stem bark outer, twig bark outer
basidiocarp	**mushroom**
bean	**seed** or refer bean pod, if applicable
bean pod	• with bean seeds: **fruit** (label AAN: pod, bean pod, fruit/legume pod) • without bean seeds: **fruit pericarp** (label AAN: fruit peri., pod, bean pod, fruit/legume pod)
berry	This term is broader than the strict botanical meaning: • where soft fruit of flowering plants: **fruit** (label AAN: berry) Do not use the label AAN 'berry' if there is any hard tissue in the fruit, e.g. not for *Crataegus* (hawthorn) fruits • where soft fruit of conifers, e.g. *Juniperus*: **fruit** (label AAN: berry) • where seed has a fleshy layer around the embryo, e.g. *Zanthoxylum*: **seed**
blade	• where leaf-like blade of seaweeds: **blade** (label AAN: refer frond, if applicable) • where broad portion of leaf (lamina) without leaf stalk (petiole): **leaf blade** • where broad portion of leaf (lamina) with leaf stalk (petiole), i.e. whole leaf: **leaf** • where blade and stem: **blade and stem**
blade and stem	**blade and stem**
blossom	**flower**
bough	refer branch
bracket fungus	**fruiting body** (label AAN: bracket fungus)
bract	**bract** or where applicable, **seed husk** (label AAN: flower bract)
bran	**seed bran** (label AAN: bran)
branch	**branch**, or where applicable, **stem** or **stem wood**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
branch terminal	**branch terminal** (label AAN: branch, terminal branch) refer: • twig, twig dormant • twig flower budding, twig flowering, twig flowering and fruiting, twig fruiting • twig leafy, twig leafy young • twig leafy flowering, twig leafy flowering and fruiting, twig leafy fruiting
branch terminal leafy	**branch terminal leafy** (label AAN: leafy branch, leafy terminal branch) refer: • twig, twig dormant • twig flower budding, twig flowering, twig flowering and fruiting, twig fruiting • twig leafy, twig leafy young • twig leafy flowering, twig leafy flowering and fruiting, twig leafy fruiting
bryophyte	refer moss, liverwort, hornwort
bud	either **leaf bud** or **flower bud**, as applicable (label AAN: flower bud, if applicable)
bulb	**bulb**
bulbus	**bulb**
calyx	**sepal** (label AAN: flower sepal) - this term is broader than the strict botanical meaning.
capsule	• where a moss capsule (sporangium): **fruiting body** (label AAN: capsule [of moss], fruit. body) • where any type of dry hollow fruit: **fruit** • where a simple dry fruit formed from several united ovary carpels, opening with pores or splits, e.g. lilies and poppies: **fruit** (label AAN: capsule) - this term is broader than the strict botanical meaning. Do not use the label AAN 'capsule' for legume pods, follicle pods, siliqua and silicule.
carcerulus	**seed**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
caryopsis	refer fruit/seed
catkin	**flower** (label AAN: catkin)
caulis	**stem**
cell	• cells of single celled, colonial and filamentous algae and fungi including yeasts (e.g. *Saccharomyces*), blue–green algae (e.g. *Spirulina* and *Arthrospira*) and unicellular green algae (e.g. *Chlorella*): **cell** (label AAN: may be left blank) • **cell wall**, where applicable
cell wall	**cell wall**
cellulose	refer fibre (dietary fibre)
cereal grain	refer fruit/seed
clove	**clove**
cone	• **fruit** (label AAN: cone, berry, if applicable, refer strobile) • the seed-bearing body of conifers is termed a cone. Where the cone scales are fleshy and join around the seeds, as in the case of *Juniperus*, use **fruit** (label AAN: berry)
corm	**corm**
corolla	**flower petal** (label AAN: petal)
cortex	• where peelings refer to peel, fruit peel, skin, bark, bark outer, where applicable • where parenchyma, refer root pith or stem pith, as applicable
cotyledon	**leaf cotyledon** (label AAN: cotyledon)
cremocarp	refer fruit/seed
cypsela	**fruit**
drupe	**fruit**
embryo	**seed germ**
embryon	refer shoot

Plant part	Approved name differentiation (approved names from Code Tables in bold)
embryonic shoot	refer shoot
endocarp	refer fruit endocarp
endosperm	**seed endosperm** (label AAN: seed starch, where applicable)
endosperm liquid	**endosperm liquid**
endospermum	**seed endosperm**
epidermis	refer skin, or where relevant, fruit skin
exocarp	refer fruit exocarp
exocarpus	refer fruit exocarp
fasciculus	refer vascular tissue
fat	state part, e.g. **seed**, **fruit flesh** and refer Herbal Ingredients Plant Preparations index (Appendix 2) for preparation: i.e. fat
fern	refer whole plant, herb, leaf, leaf fertile, rhizome, root, fruiting body (sporangium), spore, etc.
fertile leaf	where reproductive structures are born on the leaf, e.g. sporangia on fern leaves: **leaf fertile** (label AAN: leaf)
fibre	• where 'dietary' fibre or fibre cells, refer to fruit fibre, stem fibre, root fibre, seed fibre, seed bran, as applicable • where fibre cells refer fruit skin fibre, root pith fibre, stem bark fibre, etc. as appropriate • where vascular tissue, refer vascular tissue
fibrous root	with or without root hairs: **root** (label AAN: fibrous root)
filament	refer stamen filament; or cell, leaf (needle), hyphae (of fungi), spine, thorn, as appropriate
flavedo (*Citrus* fruit)	coloured layer of fruit peel (mesocarp): **fruit peel outer**
flesh	refer: fruit flesh, root pith, stem pith, seed endosperm, as appropriate

Plant part	Approved name differentiation (approved names from Code Tables in bold)
flos	refer flower
flower	**Flower** refers both to flowers alone and to whole inflorescences, including branching flower stalks. Where present, leafy bracts may be included. • where whole flowers: **flower** (label AAN: refer flowering head) • where a cluster of flowers (infloresence) with included flower stalks (pedicels and peduncles) and any leafy bracts: **flower** • where leaves and stems are also included: **herb flowering** or **herb top flowering** • where flower and leaf: **flower and leaf** COMPARE WITH 'HERB FLOWERING' AND 'HERB TOP FLOWERING' where only a part of the flower, refer to: • bract, flower receptacle, flower stalk (pedicel, peduncle, rachis, rachilla) • sepal, petal, tepal • stamen, stamen filament • anther, pollen, ovary, style, stigma
flower and leaf	**flower and leaf**
flower bud	**flower bud** (label AAN: fl. bud)
flower bud resin	**flower bud resin** (label AAN: fl. bud resin)
flower petal	• **flower petal** (including tepal appearing as a petal) OR **petal** (both are correct) • (label AAN: fl. petal)
flower rachilla	**flower stalk,** compare and refer flower
flower rachis	**flower stalk,** compare and refer flower
flower receptacle	**flower receptacle** (label AAN: fl. rec.)
flower sepal	**flower sepal** (including tepal appearing as a sepal) (label AAN: fl. sepal)
flower stalk	**flower stalk** (label AAN: fl. stalk)
flowering head	**flower** (label AAN: flowering head)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
flowering herb	**herb flowering**, compare and refer herb
flowering herb top	**herb top flowering**, compare and refer herb top
flowering top	**herb top flowering,** compare and refer herb top
flowering twig	**twig flowering**, compare and refer herb top
folium	refer leaf
follicle	**fruit** (label AAN: fruit pod, pod)
folliculus	**fruit**
frond	• where leaf of ferns: **leaf** (label AAN: frond) • where leaf-like part of seaweeds: **blade** (label AAN: frond, where applicable) • where seaweed blade and stem (stipe): **herb** • where seaweed blade, stem (stipe) and holdfast: **whole plant** (label AAN: whole seaweed)
frucificatio	refer fruiting body
fructus	refer fruit

Plant part	Approved name differentiation (approved names from Code Tables in bold)
fruit	**Fruit** refers to the seed-bearing structure of flowering plants, including all types of simple, aggregate and multiple (compound) fruits. Fruit includes the seeds, all the surrounding tissue layers, any persistent bracts and the individual fruit stalk, and may include any branching fruit stalks. • where the whole fruit including the seeds, the surrounding soft/leathery/hard fruit tissue and any individual fruit stalks: **fruit** (label AAN: refer hip, cone) • where any type of dry hollow fruit: **fruit** (label AAN: refer capsule) • where a simple dry fruit formed from several united ovary carpels, opening with pores or splits, e.g. lilies and poppies: **fruit** (label AAN: refer capsule) • bean/legume pod with bean seeds: **fruit** (label AAN: refer pod) • where soft fruit of flowering plants: **fruit** (label AAN: refer berry) • where soft fruit of conifers, e.g. *Juniperus*: **fruit** (label AAN: refer berry) • where the whole fruit including shell and seed (dry, hard, single-seeded fruit that does not split open regularly), e.g. acorn, hazel nut: **fruit** (label ANN: refer nut) • where fruit is a legume (pea or bean pod), follicle, siliqua or silicula AND includes seeds: **fruit** (label AAN: refer pod) • pod with fruit and seeds: **fruit** (label AAN: refer pod) • where a strobile of a flowering plant: **fruit** (label AAN: refer strobile) • where leaves and stems are also included: **herb fruiting** or **herb top fruiting** • gourd: **fruit** (label AAN: refer gourd) Refer also: • where a fruiting (reproductive) body of an algae, seaweed, fungus, lichen, liverwort, moss, hornwort, fern, refer fruiting body • where the whole fruit looks like a seed, e.g. wheat, borage parsley, aniseed, fennel, refer fruit/seed • where only a single part of the fruit, refer fruit stalk, fruit pericarp, fruit epidermis, fruit exocarp, fruit skin, fruit mesocarp, fruit peel, fruit peel outer, fruit peel inner, fruit hull, fruit shell, fruit flesh, fruit pith, fruit endocarp, fruit without juice, fruit vascular tissue, seed
fruit endocarp	**fruit endocarp** (label AAN: fruit endo.) refer fruit shell, if applicable
fruit epidermis	**fruit skin**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
fruit exocarp	outer layer of fruit (exocarp): **fruit exocarp** (label AAN: fruit exo.) also refer to fruit skin, fruit peel, fruit rind or fruit hull, where applicable.
fruit fibre	**fruit fibre**
fruit flesh	• exocarp and mesocarp, e.g. pitted cherry: **fruit flesh** • mesocarp, e.g. peeled and stoned peach: **fruit flesh** • endocarp, e.g. juice cells of orange: **fruit flesh** • various tissues, e.g. peeled pineapple, peeled apple: **fruit flesh**
fruit hull	outer tough/leathery layer of fruit (exocarp), e.g. leathery walnut hull outside walnut shell: **fruit hull** (label AAN: walnut hull, if applicable) where hard/stony layer of fruit, refer fruit shell
fruit husk	• where sepals (often papery/leafy) remaining around fruit: **sepal** • where bracts (often papery) from around seed: **seed husk**
fruit juice	if juice of fruit: **fruit juice** refer juice
fruit mesocarp	**fruit mesocarp** (label AAN: fruit meso.) refer fruit flesh, fruit peel inner, fruit pith, as appropriate
fruit oleoresin	**fruit oleoresin**
fruit pedicel	**fruit stalk**
fruit peduncle	**fruit stalk**
fruit peel	• exocarp + mesocarp, e.g. orange peel: **fruit peel** • other tissue, e.g. apple peel: **fruit peel** • exocarp only: refer fruit skin
fruit peel inner	mesocarp, e.g. white layer (albedo) of *Citrus* (oranges, lemons, etc.): **fruit peel inner**
fruit peel outer	endocarp, e.g. coloured layer (flavedo) of *Citrus* (oranges, lemons, etc.): **fruit peel outer**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
fruit pericarp	all fruit tissue except seeds, e.g. legume pods without the seeds (pericarp = exocarp + mesocarp + endocarp): **fruit pericarp** (label AAN: fruit peri., refer bean pod)
fruit pith	• central pithy tissue that seeds attach around (placenta): **fruit pith** • mesocarp, e.g. granadilla flesh: **fruit pith** • refer fruit flesh or fruit peel inner, if applicable
fruit pitted	refer fruit flesh
fruit pulp	**fruit without juice**, if applicable refer fruit flesh or fruit
fruit rachilla	**fruit stalk**
fruit rachis	**fruit stalk**
fruit resin	**fruit resin**
fruit rind	refer fruit peel
fruit rind inner	**fruit peel inner**
fruit rind outer	**fruit peel outer**
fruit seed	refer seed and fruit/seed
fruit seedless	refer fruit pericarp
fruit shell	• outer hard layer of fruit (i.e. pericarp is hard/stony, not tough/leathery), e.g. hazelnut shell: **fruit shell** (label AAN: shell) • inner hard/stony layer around seed (e.g. endocarp in a drupe), e.g. walnut and almond shells: **fruit shell** • where inner hard/stony shell (as above) with enclosed seed: **seed & fruit shell** refer fruit
fruit skeleton	**fruit vascular tissue**
fruit skin	exocarp/epidermis, e.g. peach skin, tomato skin: **fruit skin**
fruit skin fibre	**fruit skin fibre**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
fruit stalk	fruit pedicel, peduncle, rachis, rachillas: **fruit stalk**
fruit stone	• where stone only, refer fruit shell • where stone and seed, refer nut
fruit vascular bundles	**fruit vascular tissue**
fruit vascular tissue	nutrient conducting tissue (xylem and phloem), sometimes stringy, e.g .bean pod strings: **fruit vascular tissue** (label AAN: fruit vasc.)
fruit wax	**fruit wax**
fruit without juice	**fruit without juice,** refer also fruit pulp

Plant part	Approved name differentiation (approved names from Code Tables in bold)
fruit/seed	Fruits that contain very little tissue other than the seeds are described in some pharmacopoeias as a fruit and in others as seeds. Where: • two-seeded schizocarp of the Umbelliferae/Apiaceae family (which includes celery, parsley, carrot, coriander, cumin, anise and fennel), the schizocarp should be named in product applications as **fruit/seed** (label AAN: either fruit or seed) • referring to fruits that are composed almost entirely of seed tissue, **seed** is usually the correct term, but in some cases **fruit** is also correct • dry splitting two-seeded cremocarp schizocarps of Umbellifera/Apiaceae family including species of *Aegopodium* (goatweed), *Ammi* (bisnaga), *Anethum* (dill), *Angelica, Anthriscus* (chervil), *Apium* (celery), *Bupleurum, Carum* (caraway), *Cicuta* (cowbane), *Conium* (hemlock), *Coriandrum* (coriander), *Crithmum* (samphire), *Cuminum* (cumin), *Daucus* (carrot), *Eryngium* (eryngo), *Ferula* (galbanum), *Foeniculum* (fennel), *Heracleum* (cow parsnip), *Hydrocotyle, Levisticum* (lovage), *Ligusticum* (lovage), *Myrrhis* (sweet chervil), *Oenanthe* (dropwort), *Petroselinum* (parsley), *Pimpinella* (anise, burnet saxifrage), *Sanicula* (sanicle) and *Zizia* (golden Alexanders): either **seed** or **fruit** may be used, both are correct • dry single-seeded caryopsis of the Graminae/Poaceae grass family, including *Avena* (oats), *Oryza* (rice), *Secale* (rye), *Triticum* (wheat), *Zea* (corn, maize): **seed** • four-seeded carcerulus schizocarps, e.g. Labiatae/Lamiaceae family (*Mentha* (mints), *Ocimum* (basil), etc.) and Boraginaceae family (*Borago* (borage), etc.): **seed** • single-seeded achenes, e.g. *Ranunculus* (buttercup): **seed** • cypselas with no pappus, e.g. some Compositae/Asteracea: **seed** • many-seeded lomentum schizocarps, e.g. pea pods that fragment: **seed**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
fruiting body	• where a strobile of a horsetail, e.g. *Equisetum*: **fruiting body** (label AAN: fruit. body refer strobile, refer cone) • where a fern spore cluster (sporangium): **fruiting body** (label AAN: fruit. body, refer sporangium) • where a fruiting body of a moss, liverwort or hornwort (sporangium, archegonium or antheridium): **fruiting body** (label AAN: fruit. body, refer sclerotium, capsule (of moss), toadstool, as applicable) • where a fruiting body of a fungus, not with a mushroom shape (e.g. acsocarp): **fruiting body** (label AAN: fruit. body, refer puff ball, bracket fungus, as applicable) • where a fruiting body of a lichen: **fruiting body** (label AAN: fruit. body) • where an algae/seaweed fruiting body (sporangium or gametangium): **fruiting body** (label AAN: fruit. body, spore body, as applicable) • where a moss capsule (sporangium): **fruiting body** (label AAN: fruit. body, refer capsule) COMPARE WITH 'FRUIT' • Refer mushroom, mushroom cap, mushroom stem
fruiting herb	**herb fruiting,** refer herb
fruiting herb top	**herb top fruiting,** refer herb
fruiting top	**herb top fruiting,** refer herb top
fruiting twig	**twig fruiting**, refer herb top
fungus	• mushroom-shaped spore-bearing bodies of basidiomycetes: **mushroom** (label AAN: whole fungus) • all other types of spore-bearing bodies of fungi: refer fruiting body • for basidiocarp or ascocarp, etc.—e.g. mushroom, puff ball, bracket fungus: refer fruiting body • refer whole plant, cell, hyphae, spore
gall	**gall**
galla	**gall**
gallnut	**gall**
gemma	refer bud

Plant part	Approved name differentiation (approved names from Code Tables in bold)
germ	**seed germ**
glume	**bract** or, if applicable, **seed husk**
gourd	**fruit** (label AAN: gourd)
grain (of cereal)	refer 'fruit/seed'
grain bract	**seed husk**
grain glume	**seed husk**
grain husk	**seed husk**
gram	where seeds of legume plants, e.g. beans: **seed**
gum	**gum** and refer and refer to Plant Preparation code table for preparation: e.g. fresh, extract, etc.
gum balsam	**gum balsam** and refer and refer to Plant Preparation code table for preparation: e.g. fresh, extract, etc. refer oil, oleoresin, resin, gum, gum oleoresin, as applicable
gum oleoresin	**gum oleoresin** and refer to and refer Plant Preparation code table for preparation: e.g. fresh, extract, etc.
gummi	refer gum
gynoecium	**ovary** (label AAN: flower ovary)
heartwood	refer root heartwood or stem heartwood, as applicable
herb	• all the aerial parts present at harvesting when only vegetative parts are present—that is, the reproductive structures of flowers and fruits are not present: **herb** • stems with attached leaves where there is little flower or fruit material in the harvest (not with root or rhizome): **herb** • where seaweed thallus without holdfast: **herb** • where seaweed blade and stem (stipe): **herb** COMPARE WITH 'HERB TOP' AND 'WHOLE PLANT' Refer also to herb young, herb flowering, herb fruiting, herb flowering and fruiting, sprout, shoot, leaf, leaf fertile, fungus or cell, if applicable

Plant part	Approved name differentiation (approved names from Code Tables in bold)
herb flowering	stems with attached leaves where flowers always present and little fruit material in the harvest (not with root or rhizome): **herb flowering** (label AAN: herb fl.)
herb flowering and fruiting	stems with attached leaves where flowers and fruit material are always present in the harvest (not with root or rhizome): **herb flowering and fruiting** (label AAN: herb fl.fr.)
herb fruiting	stems with attached leaves where fruit always present and little flower material in the harvest (not with root or rhizome): **herb fruiting** (label AAN: herb top fr.)
herb top	terminal ends of stems/branches with attached leaves where there is little flower or fruit material in the harvest (not with root or rhizome): **herb top** COMPARE WITH 'HERB' AND 'WHOLE PLANT' Refer and compare with: • branch terminal, branch terminal leafy • herb top flowering, herb top flowering and fruiting, herb top fruiting, herb top young, shoot top • twig, twig dormant, twig flowering, twig flower budding, twig fruiting, twig flowering and fruiting • twig leafy, twig leafy flowering, twig leafy flowering and fruiting, twig leafy fruiting, twig leafy young
herb top flowering	terminal ends of stems/branches with attached leaves where flowers always present and little fruit material in the harvest (not with root or rhizome): **herb top flowering** (label AAN: herb top fl., flowering herb top)
herb top flowering and fruiting	terminal ends of stems/branches with attached leaves with flowers and fruit material always present in the harvest (not with root or rhizome): **herb top flowering and fruiting** (label AAN: herb top fl. fr., flowering & fruiting herb top)
herb top fruiting	terminal ends of stems/branches with attached leaves with fruit always present and little flower material in the harvest (not with root or rhizome): **herb top fruiting** (label AAN: herb top fr, fruiting herb top.)
herb top young	terminal ends of stems/branches of immature plant with attached leaves (not with root or rhizome) before flowers or other reproductive structures form and before stems become woody: **herb top young** (label AAN: herb top)
herb young	immature stems with attached leaves where there is little flower or fruit material in the harvest (not with root or rhizome) before flowers or other reproductive structures form: **herb young**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
herba	refer herb and herb top
hesperidium (*Citrus*)	**fruit**
hip (of *Rosa*)	• where whole fruit including seeds: **fruit** (label AAN: rose hip) • where fruit without seeds: **fruit pericarp** (label AAN: fruit peri., rose hip)
holdfast (seaweed)	**holdfast**
hornwort	refer whole plant, herb, leaf, rhizoid, spore, fruiting body (archegonium, anteridium, sporangium), etc.
horsetail (e.g. Equisetum)	refer whole plant, herb, stem, sterile stem, ('stem' includes any whorls of minute leaves), leaf, rhizome, fruiting body (strobile), spore, etc.
hull	refer fruit hull
husk	**seed husk**, if applicable refer fruit peel, if applicable
hyphae (of fungi)	**hyphae**
hypocotyl	**hypocotyl**
inflorescence	refer flower
inflorescentia	refer flower
juice	refer fruit juice state part, e.g. **leaf**, **stem** and refer Plant Preparation code table for preparation, e.g. juice fresh, juice dry, juice concentrated
juice cells (of *Citrus*)	• fruit flesh • or **fruit juice** (see Herbal Ingredients Plant Preparations index [Appendix 2] for 'juice') • where fruit pulp without juice: **fruit without juice**
kernel	**seed** (label AAN: kernel)
kernel shell	refer fruit shell

Plant part	Approved name differentiation (approved names from Code Tables in bold)
kino	state part, e.g. **root wood kino**
lamina	**leaf blade**
lateral root	**root lateral** (label AAN: lateral root, root lat., root)
latex	**latex**
leaf	• where true leaf, including leaf blade and stalk of simple leaf, or leaflets and stalks in compound leaf, with any stipules and axillary buds: **leaf** (label AAN: refer needle, if applicable) • leaf like structures of simple plants such as mosses: **leaf** • where leaf of fern or fern frond without spores: **leaf** (label AAN: refer frond, where applicable) • where broad portion of leaf (lamina) with leaf stalk (petiole), i.e. whole leaf: **leaf** • where the leaf has a specialised form, more accurate terms should be used—for example **clove** and **bulb** • where leaf-like blade/frond of seaweed: **blade** (label AAN: refer frond) • where leaf-like stems with tiny or absent leaves, e.g. *Equisetum* (horsetail): **stem**
leaf and stem	refer herb and herb top
leaf and twig	refer herb top
leaf blade	• where broad portion of leaf (lamina) without leaf stalk (petiole): **leaf blade** (label AAN: frond) • where leaf-like blade of seaweeds: **blade** (label AAN: frond)
leaf bud	**leaf bud**
leaf bud resin	**leaf bud resin**
leaf cotyledon	**leaf cotyledon** (label AAN: cotyledon, leaf cot.)
leaf fertile	• where reproductive structures are born on the leaf, e.g. sporangia on fern leaves: **leaf fertile** • where fern frond with spores: **leaf fertile**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
leaf inner	**leaf inner** (e.g. of *Aloe*: leaf in. juice fresh/extract, etc.) (label AAN: inner leaf, leaf in., leaf)
leaf inner juice	**leaf inner juice** (e.g. of *Aloe*: leaf in. juice extract, etc.) (label AAN: leaf in. juice)
leaf outer	**leaf outer**
leaf rachilla	**leaf rachilla**
leaf rachis	**leaf rachis**
leaf radicle	**leaf radicle** (label AAN: leaf)
leaf resin	**leaf resin**
leaf skeleton	**leaf vascular tissue** (label AAN: leaf skeleton, leaf vasc.)
leaf stalk	**leaf stalk**
leaf vascular bundles	**leaf vascular tissue** (label AAN: leaf vasc.)
leaf vascular tissue	**leaf vascular tissue** (label AAN: leaf vasc.)
leaf wax	**leaf wax,** refer wax
leaf young	**leaf young** (label AAN: leaf)
leaflet	**leaf** (label AAN: leaflet)
legume pod	• with pea/bean seeds: **fruit** (label AAN: pod, pea pod, bean pod, fruit pod, legume pod) • without pea/bean seeds: **fruit pericarp** (label AAN: fruit peri. pod, pea pod, bean pod, fruit pod, legume pod)
legume seed	**seed** (label AAN: pea seed, bean seed)
legumen	refer legume pod
lichen	refer whole plant, fruiting body, spore, etc.
lignin	refer fibre (dietary)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
lignum	refer wood
liverwort	refer whole plant, herb, leaf (where leaf-like), rhizoid, spore, fruiting body (sporangium, archegonium or antheridium), etc.
lycopod (e.g. Lycopodium)	refer whole plant, herb, stem, leaf, root, strobile, spore, etc.
medulla	refer pith
mesocarp	refer fruit mesocarp
mesocarpium	refer fruit mesocarp
moss	refer whole plant, herb, stem, leaf, rhizoid, spore, fruiting body (sporangium capsule, archegonium or antheridium)
mushroom	• where fruiting body of fungus, with a mushroom (or toadstool) shape (basidiocarp): **mushroom** (label AAN: toadstool, if applicable) • where fruiting body of fungus, not with a mushroom shape (e.g. ascocarp): **fruiting body** (label AAN: fruit. body, refer puff ball, bracket fungus, if applicable) • for specific parts of the mushroom, refer also mushroom cap, mushroom stem etc.
mushroom cap	where the cap of a mushroom: **mushroom cap** (label AAN: toadstool cap, if applicable)
mushroom stem	**mushroom stem** (label AAN: toadstool stem, if applicable)
mycelium (of fungi)	**hyphae** or refer cell
needle (of conifer)	**leaf** (label AAN: needle)
node	**node**
nodule	**root nodule**
nodule and root	**root and root nodule**
nodus	**node**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
nut	• where seeds/kernels only: **seed** (label AAN: kernel, if applicable) • where the whole fruit including shell and seed (dry, hard, single-seeded fruit that does not split open regularly), e.g. acorn, hazel nut: **fruit** (label AAN: nut) • where seed and inner shell from a fruit (drupe) with the outer soft or leathery layer removed, e.g. walnuts, almonds: **seed and fruit shell** (label AAN: seed & shell)
nut shell	refer fruit shell
nux	refer nut
oil	state part, e.g. **seed**, **herb** or **flower**, as applicable, and refer to the Plant Preparation code tables for preparation, e.g. oil fixed, oil essential, oil infused
oleoresin	state part, e.g. **gum oleoresin**, **fruit oleoresin**, **stem bark oleoresin** and refer to the Plant Preparation code tables for preparation, e.g. fresh or extract
ovary	**ovary** (label AAN: flower ovary)
ovary stigma	**stigma** (label AAN: flower stigma)
ovary style	**style** (label AAN: flower style)
parenchyma	refer pith
pea	**seed** (label AAN: pea)
pea pod	• with pea seeds: **fruit** (label AAN: pod, pea pod, fruit pod, legume pod) • without pea seeds: **fruit pericarp** (label AAN: fruit peri. pod, pea pod, fruit pod, legume pod)
pedicel	either **flower stalk** or **fruit stalk**, as applicable
pedicellus	refer pedicel
peduncle	either **flower stalk** or **fruit stalk**, as applicable
peel	state part, e.g. fruit peel, root peel, rhizome peel, stem peel, twig peel, etc. as applicable refer also skin, fruit peel, bark, bark outer
pepo	**fruit**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
pericarp	refer fruit pericarp
pericarpium	refer fruit pericarp
petal	• **petal** (label AAN: flower petal) OR • **flower petal** (both are correct) • where tepal appearing as a petal: **petal**
petiole	**leaf stalk**
phloem	refer bark and vascular tissue
pinna	**leaf**
pinnule	**leaf**
pith	• state part, e.g. **stem pith** or **root pith**, as applicable • refer fruit pith
placenta	refer fruit flesh and fruit pith
plant	refer herb, herb top and whole plant
plant immatura	refer herb young
plantula	**sprout**
plumula	**plumule**
plumule	**plumule**
pod	• where fruit is a legume (pea or bean pod), follicle, siliqua or silicula AND includes seeds: **fruit** (label AAN: fruit pod, pod, pea pod, bean pod, legume pod, follicle pod, all as applicable) • where fruit is as above, without seeds: **fruit pericarp** (label AAN: fruit peri. fruit pod, pod, pea pod, bean pod, legume pod, follicle pod) • where fruit is not as above, with seeds: **fruit** (label AAN: fruit pod, pod) • where fruit is not as above, without seeds: **fruit pericarp** (label AAN: fruit peri.)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
pollen	• where collected by mechanical means: **pollen** • where collected by bees, use the Australian approved biological substance name 'Pollen' to name the substance
pomace (of apples)	refer fruit pulp
pome	**fruit**
pressed seed cake	**pressed seed cake**
pteridophyte	refer fern, horsetail (e.g. *Equisetum*), lycopod (e.g. *Lycopodium*)
puff ball	**fruiting body** (label AAN: fruit. body, puff ball)
pulp	refer fruit pulp or stem pith, as applicable
pulse	where seeds of legume plants, e.g. beans: **seed** (label AAN: bean seed)
rachilla	**leaf stalk**, **fruit stalk** or **flower stalk**, as applicable
rachis	**leaf stalk**, **fruit stalk** or **flower stalk**, as applicable
radix	**root**
ramu	refer twig entries under herb top and refer stem
ramulus	refer twig entries under herb top and refer stem
receptacle	**flower receptacle** (label AAN: fl. rec.)
recetaculum	**flower receptacle**
resin	state part, e.g. **flower bud resin**, **stem resin**, or **stem bark resin**, as applicable
resina	refer resin
rhizoid	**root**
rhizoma	**rhizome**
rhizome	**rhizome**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
rhizome and root	**root and rhizome** (label AAN: root & rhiz.)
rhizome and root and stolon	**root and rhizome and stolon** (label AAN: root, rhizome and stolon, root, rhiz & stolon)
rhizome and stolon	**rhizome and stolon** (label AAN: rhiz and stolon, rhiz & stolon)
rhizome bark	**rhizome bark** (label AAN: rhiz. bark)
rhizome bark inner	**rhizome bark inner** (label AAN: rhizome bark, rhiz. bark, rhiz. bark in.)
rhizome bark outer	**rhizome bark outer** (label AAN: rhizome bark, rhiz bark, rhiz. bark outer)
rhizome heartwood	**rhizome heartwood** (label AAN: rhizome wood, rhiz. heartwood, rhiz. wood)
rhizome oleoresin	**rhizome oleoresin**
rhizome peel	**rhizome peel** or **rhizome skin**, if applicable
rhizome sapwood	**rhizome sapwood** (label AAN: rhizome wood, rhiz. wood)
rhizome skin	**rhizome skin** or **rhizome peel**, if applicable
rhizome wood	**rhizome wood** (label AAN: rhiz. wood)
rind	refer peel, fruit peel, skin, bark, bark outer
root	• all or most of the rooting system, such as fibrous roots and tap roots with any lateral roots and nodules: **root** (label AAN: refer taproot, fibrous root if applicable) • true roots with or without root hairs and root-like rhizoids: **root** (label AAN: rhizoid) • where only some of the rooting system is used, refer root lateral, root aerial or root nodule • where an underground stem is also used, name each part (e.g. **root & rhizome**).

Plant part	Approved name differentiation (approved names from Code Tables in bold)
root aerial	**root aerial** (label AAN: aerial root, root aer.)
root and rhizome	**root and rhizome** (label AAN: root & rhiz.)
root and rhizome and stolon	**root and rhizome and stolon** (label AAN: root, rhiz. & stolon)
root and root nodule	**root and root nodule** (label AAN: root & root nodule)
root and stolon	**root and stolon** (label AAN: root & stolon)
root bark	**root bark**
root bark inner	**root bark inner** (label AAN: root bark)
root bark outer	**root bark outer** (label AAN: root bark)
root epidermis	**root skin**
root fibre	**root fibre**
root heartwood	**root heartwood** (label AAN: root wood)
root lateral	**root lateral** (label AAN: lateral root, root lat.)
root nodule	**root nodule**
root peel	**root peel** or **root skin**, if applicable
root pith	**root pith** or **root pith fibre**, if applicable
root pith fibre	**root pith fibre**
root sapwood	**root sapwood** (label AAN: root wood)
root skin	**root skin** or **root peel**, if applicable
root tap	**root tap**
root vascular bundles	**root vascular tissue** (label AAN: root vasc.)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
root vascular tissue	**root vascular tissue** (label AAN: root vasc.)
root wood	**root wood**
root wood inner	**root heartwood** (label AAN: root wood)
root wood kino	**root wood kino**
root wood outer	**root sapwood** (label AAN: root wood)
samara	**fruit**
sap	**sap** and refer to Plant Preparations code table for the preparation: e.g. fresh, powder, extract, etc.
sap balsam	refer oil, oleoresin, resin, gum, gum oleoresin, or sap resin, as appropriate where not as above: **sap balsam** and refer to Plant Preparations code table for the preparation: e.g. fresh, extract, etc.
sap resin	**sap resin**
sapwood	refer root sapwood, stem sapwood, twig sapwood, rhizome sapwood, as applicable
sawdust	refer wood
scape	**scape**
scapus	**scape**
schizocarp	refer fruit/seed
schlerenchyma	refer fibre
sclerotium	**fruiting body** (label AAN: fruit. body, spore body)
scobis	refer wood
seaweed	refer whole plant, holdfast, stem (stipe), blade (or if applicable, frond), fruiting body (gametangium, sporangium)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
seed	• **seed** • where seed has a fleshy layer around the embryo, e.g. *Zanthoxylum*: **seed** • where seeds/kernels only: **seed** refer also fruit/seed
seed and fruit shell	where seed and inner shell from a fruit (drupe) with the outer soft or leathery layer removed, e.g. walnuts, almonds: **seed and fruit shell** (label AAN: seed & shell)
seed aril	**seed aril** (label AAN: aril)
seed bran	**seed bran** (label AAN: bran)
seed coat	**seed coat**
seed coat aril	**seed aril** (label AAN: aril)
seed embryo	**seed germ**
seed endosperm	**seed endosperm** (label AAN: seed endo., seed starch, if applicable), refer endosperm liquid, if applicable
seed epidermis	**seed skin** or **seed bran**, if applicable
seed fibre	**seed fibre**
seed germ	**seed germ**
seed germinating	refer sprout
seed husk	**seed husk**, including where bracts (often papery) from around seed
seed mucilage	**seed mucilage**
seed shell	refer fruit shell
seed skin	**seed skin**, or where applicable, **seed bran**
seed sprout	refer sprout
seed/fruit	refer fruit/seed

Plant part	Approved name differentiation (approved names from Code Tables in bold)
semen	**seed**
sepal	• **sepal** (label AAN: flower sepal) • where sepals (often papery/leafy) remaining around fruit: **sepal** • where tepal appearing as a sepal: **sepal**
shell	refer fruit shell
shoot	• immature stem offshoots of mature plant: **shoot** • where only the stem: **stem** also refer shoot top and compare herb and herb top
shoot top	terminal ends of immature stems with leaves, emerging as offshoots of a mature plant: **shoot top**
silicula	**fruit** (label AAN: fruit pod, pod)
siliqua	**fruit** (label AAN: fruit pod, pod)
silk (of corn, Zea)	**style** or **stigma** (both are correct) (label AAN: flower style, flower stigma)
skin	state applicable part, e.g. **fruit skin**, **root skin**, **rhizome skin**, **stem skin**, **twig skin** refer also peel, fruit peel, bark, or bark outer, where relevant
sorosis	**fruit**
spina	refer to spine or thorn, as applicable
spine	**spine**
spora	**spore**
sporangium	• where an algae/seaweed fruiting body (sporangium or gametangium): **fruiting body** (label AAN: fruit. body, spore body, refer capsule or mushroom, if applicable) • where a fern spore cluster (sporangium): **fruiting body** (label AAN: spore body) • where a fruiting body of a moss, liverwort or hornwort (sporangium, archegonium or antheridium): **fruiting body**

Plant part	Approved name differentiation (approved names from Code Tables in bold)
spore	**spore**
sprout	germinating seed with first leaves: **sprout** refer also herb and herb top for comparison
stalk	refer stem, stolon, twig, leaf stalk (petiole), flower stalk or fruit stalk (pedicel, peduncle), leaf rachis and rachilla, flower rachis and rachilla or fruit rachis and rachilla
stamen	**stamen** (label AAN: flower stamen)
stamen anther	**anther** (label AAN: flower anther)
stamen filament	**stamen filament** (label AAN: flower filament, stamen fil.)
staminis	**stamen**
stem	• central stem(s) and the branches: **stem** (label AAN: vine stem, where applicable) • where stem growth form not specialised: **stem** • where leaf-like stems with tiny or absent leaves, e.g. *Equisetum* (horsetail): **stem** • where stipe of seaweed or flowering plant: **stem** (refer also flower stalk, or fruit stalk, as applicable) • where stem growth form specialised, refer rhizome, stolon, corm, tuber, bulb (includes leaves), etc. • where other plant parts are included, refer herb, herb top, whole plant and related terms.
stem and leaf	refer herb and herb top where leaf-like stems with tiny or absent leaves, e.g. *Equisetum* (horsetail): **stem**
stem balsam	refer oil, oleoresin, resin, gum, gum oleoresin, as applicable where not as above: **stem balsam** and refer Plant Preparation code table for preparation: e.g. fresh, extract, etc.
stem bark	stem includes branches and twigs: **stem bark** (label AAN: bark)
stem bark fibre	**stem bark fibre** (label AAN: bark fibre)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
stem bark inner	**stem bark inner** (label AAN: inner bark, stem bark in., bark)
stem bark oleoresin	**stem bark oleoresin** (label AAN: bark oleoresin)
stem bark outer	**stem bark outer** (label AAN: outer bark, bark)
stem bark resin	**stem bark resin** (label AAN: bark resin)
stem epidermis	**stem skin**
stem fibre	**stem fibre**
stem gum	refer gum
stem heartwood	**stem heartwood** (label AAN: heartwood, wood)
stem latex	**latex**
stem peel	**stem peel** or **stem skin**, if applicable
stem pith	**stem pith**
stem resin	**stem resin**
stem sap	refer sap
stem sapwood	**stem sapwood** (label AAN: sapwood, wood)
stem skin	**stem skin** or **stem peel**, if applicable
stem sterile	**stem**
stem vascular bundle	**stem vascular tissue** (label AAN: stem vasc.)
stem vascular tissue	**stem vascular tissue** (label AAN: stem vasc.)
stem wood	**stem wood** (label AAN: wood)
stem wood resin	**stem wood resin** (label AAN: wood resin)
stigma	**stigma** and refer silk (label AAN: flower stigma)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
stigma and style	**stigma and style**
stipe	• where of seaweed: **stem** • where of flowering plant: **stem**, **flower stalk**, or **fruit stalk**, as applicable
stipulae	**stipule**
stipule	**stipule**
stolon	**stolon**
stolon and rhizome	**rhizome and stolon** (label AAN: rhizome & stolon, rhiz. & stolon)
stolon and root	**root and stolon** (label AAN: root & stolon)
stolon and root and rhizome	**root and rhizome and stolon** (label AAN: root, rhizome & stolon)
stoma	**stoma**
strobile	• where a strobile of a flowering plant: **fruit** (label AAN: strobile, cone, if applicable) • where a strobile of a horsetail, e.g. *Equisetum*: **fruiting body** (label AAN: fruit. body, strobile)
strobilus	**flower**
stromata	**stromata**
style	**style** and refer silk (label AAN: flower style)
stylus	refer style
styrax	refer resin
succus	refer sap
synconus	**fruit**
taproot	**root** (label AAN: taproot)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
tepal	• where appearing as a petal: **petal** (label AAN: flower petal) • where appearing as a sepal: **sepal** (label AAN: flower sepal)
testa	**seed coat**
testa aril	**seed aril** (label AAN: aril)
thallus	refer whole plant
thallus blade	**blade** (label AAN: frond, if applicable)
thallus frond	**blade** (label AAN: frond)
thallus holdfast	**holdfast**
thallus stipe	**stem**
thorn	**thorn**
toadstool	refer mushroom
top	refer herb top
truewood	refer heartwood
trunk	**stem** (label AAN: trunk)
trunk bark	refer stem bark
trunk wood	refer stem wood
tuber	**tuber**
turiones	refer twig leafy young
twig	twigs without leaf, flower or fruit: **twig**
twig bark	**twig bark**
twig bark inner	**twig bark inner** (label AAN: twig bark inner, twig bark, twig bark in.)
twig bark outer	**twig bark outer** (label AAN: twig bark outer, twig bark)

Plant part	Approved name differentiation (approved names from Code Tables in bold)
twig dormant	dormant twigs with or without flower buds and/or leaf buds but without leaf, flower or fruit: **twig dormant** compare herb top
twig flowering	twigs with flowers always present, with little leaf or fruit: **twig flowering** refer twig flowering budding and herb top
twig flowering and fruiting	twigs with flowers and fruits always present with little leaf: **twig flowering and fruiting** refer twig flowering, twig fruiting, twig flowering budding and herb top
twig flowering budding	twigs with flower buds always present with little leaf, flower or fruit: **twig flowering budding**
twig fruiting	twigs with fruits always present with little leaf or flower: **twig fruiting** refer herb top
twig heartwood	**twig heartwood** (label AAN: twig wood)
twig leafy	leafy twigs where there is little flower or fruit material in the harvest: **twig leafy**
twig leafy flowering	leafy twigs with flowers always present, with little fruit: **twig leafy flowering**
twig leafy flowering and fruiting	leafy twigs with flowers and fruits always present: **twig leafy flowering and fruiting**
twig leafy fruiting	leafy twigs with fruits always present, with little flower: **twig leafy fruiting**
twig leafy young	leafy twigs where the twigs are less than a year old: **twig leafy young**
twig peel	**twig peel** or **twig skin**, if applicable
twig sapwood	**twig sapwood** (label AAN: twig wood)
twig skin	**twig skin** or **twig peel**, if applicable
twig wood	**twig wood**
twig young	refer entries under herb top

Plant part	Approved name differentiation (approved names from Code Tables in bold)
underground parts	state parts, e.g. **root** or **rhizome** or **root and rhizome**
vascular bundles	refer vascular tissue
vascular tissue	state part, e.g. **fruit vascular tissue**, **stem vascular tissue**, **root vascular tissue** refer fibre (cells)
vine	specify part, e.g. **stem**, **herb** etc.
vine herb	refer entries under herb
vine stem	**stem** (label AAN: vine stem)
wax	state part, e.g. **leaf wax**, **fruit wax** etc. and refer to Plant Preparation code table for preparation: fresh, extract, etc.
whole plant	• where entire plant body, including any underground parts, holdfasts and reproductive structures: **whole plant** (label AAN where applicable: whole fungus, whole lichen, whole seaweed, whole moss, whole horsetail, whole liverwort, whole hornwort, whole fern) • refer to entry naming each type of plant to ensure all parts are included—loss of the fine root hairs/rhizoids is expected • where entire thallus of seaweed (blade/frond, stem (stipe) and holdfast and reproductive structures): **whole plant** • where entire hyphae (mycelia) and fruiting bodies: **whole plant** • where only aerial parts, refer herb and herb top • where mushroom-shaped part of fungus, refer fruiting body • where single celled, filamentous and colonial algae or fungi, refer cell
wood	refer: • fruit (or capsule, if applicable), fruit shell • rhizome heartwood, rhizome sapwood, rhizome wood, as applicable • root heartwood, root sapwood or root wood, as applicable • stem heartwood, stem sapwood, stem wood, as applicable • twig heartwood, twig sapwood or twig wood, as applicable
wood inner	refer heartwood

Plant part	Approved name differentiation (approved names from Code Tables in bold)
wood outer	refer sapwood
xylem	refer wood and refer vascular tissue
xylem primary	refer sapwood and refer vascular tissue
xylem secondary	refer heartwood

Appendix 2 Herbal ingredients plant preparations index

Use this Appendix to ensure you use the correct plant preparation term.

This page provides additional information on how to use (and express) the approved plant preparation names that are in the Plant Preparation Code Table.

Note: Some names listed here are not TGA approved names, but help to direct you to the most correct name.

A2.1 Information in the plant preparations index

Plant preparation type (column 1)

Plant preparations appear in alphabetical order and are commonly used names or technical terms. Refer to the description in column 2 to confirm the approved name for each preparation type, and how it should be expressed in applications and on labels.

Approved name for the preparation type (column 2)

- If an approved name is listed here (**in bold**), ensure this is used in applications and on product labels.
- You can search the Plant Preparations Code Table for the **bolded** preparation names.

Alternative term for label

In some instances, label AANs are included if you need a different term for your label.

***Note**: Some of these can only be used where there is limited space on the label.*

- Where the ingredient is extracted (other than oil and fat), the complete label AAN also includes the amount of dry/fresh raw material used to make the ingredient.
- Where the ingredient is claimed to be standardised, the complete label AAN also includes the component against which the ingredient is standardised.

If final extraction ratio and solvents are required in an application (column 3)

Use the approved name for the final extraction ratio and solvents. This is required as the second part of the approved name for extracted ingredients (other than oil and fat).

- Give the final extraction ratio (not the native extraction ratio), however a range may be acceptable. See section 7. Approved names for herbal ingredients.
- State the solvent name(s) and concentration(s).

Note

Solvent details are **only required for active ingredients**.

If equivalent dry/fresh weight is required (column 4)

The approved name for the equivalent dry or fresh weight of raw herbal material used (or needed) to make the ingredient (e.g., 'dry', 'fresh', 'juice dry' or 'juice fresh'), is required as the third part of the approved name for most extracted ingredients. This is also required if:

- a label claim is made concerning the amount of dry/fresh weight of raw herbal material needed to make the ingredient
- the statement begins with 'EQUIV.', the AHN and plant part are stated before the approved name is used.

If a component is required (column 5)

The approved name for the amount of a component in the ingredient is required as the last part of the approved name for all ingredients where a standardised plant preparation is required within the medicine application.

- Make separate statements where the amount of more than one component is to be declared.

Table A2: Herbal ingredients plant preparations index

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Decoction	**Decoction** (label AAN if label space limited: decoc.)	(1:? in 100% W)	EQUIV. AHN + part + dry/fresh	
Decoction concentrate	**Decoction concentrate** (label AAN: decoction, if label space limited: decoc.)	(?:1 in 100% W)	EQUIV. AHN + part + dry/fresh	
Decoction concentrate standardised	**Decoction concentrate standardised** (label AAN: decoction standardised, if label space limited: decoc. conc. stand., decoction stand., or decoc. stand.)	(?:1 in 100% W)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Decoction standardised	**Decoction standardised** (label AAN if label space limited: decoc. stand., decoction stand., or decoc. stand.)	(1:? in 100% W)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Distillate (where not an essential oil)	**Distillate** (label AAN if label space limited: dist.)	(1:? in 100% W)	EQUIV. AHN + part + dry/fresh	

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Distillate concentrate (where not an essential oil)	**Distillate concentrate** (label AAN: distillate, if label space limited: dist.)	(?:1 in 100% W)	EQUIV. AHN + part + dry/fresh	
Dry	**Dry**		Required if label claim: EQUIV. AHN + part + fresh	
Dry standardised	**Dry standardised** (label AAN if label space limited: dry stand.)		Required if label claim: EQUIV. AHN + part + fresh	EQUIV. stand. comp. AAN/ HCN
Essence, i.e. 'flower essence'	**Essence** (label AAN: flower essence)	(1:? in solvents)	Required if not highly dilute: EQUIV. AHN + part + dry/fresh (optional if highly dilute)	
Extract	refer oil, fat, wax, resin, oleoresin and balsam. If an extract of a fat, resin, oleoresin or balsam, ensure this term is part of the plant part, and use 'extract etc.' as the plant preparation			
Extract dry	**Extract dry** (label AAN: extract, if label space limited: ext. dry)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	
Extract dry concentrate	**Extract dry concentrate** (label AAN: extract, if label space limited: ext. dry conc.)	(?:1 in solvents)	EQUIV. AHN + part + dry/fresh	

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Extract dry concentrate standardised	**Extract dry concentrate standardised** (label AAN: extract standardised, if label space limited: ext. dry conc. stand., extract stand., or ext. stand.)	(?:1 in solvents)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Extract dry standardised	**Extract dry standardised** (label AAN: extract standardised, if label space limited: ext. dry stand., extract stand., or ext. stand.)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Extract liquid	**Extract liquid** (label AAN: extract, if label space limited: ext. liq.)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	
Extract liquid concentrate	**Extract liquid concentrate** (label AAN: extract, if label space limited: ext. liq. conc.)	(?:1 in solvents)	EQUIV. AHN + part + dry/fresh	
Extract liquid concentrate standardised	**Extract liquid concentrate** standardised (label AAN: extract standardised, if label space limited: ext. liq. conc. stand., extract stand., or ext. stand.)	(?:1 in solvents)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Extract liquid standardised	**Extract liquid standardised** (label AAN: extract standardised, if label space limited: ext. liq. stand., extract stand., or ext. stand.)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Extract oil infused	refer 'oil infused'			

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Extract soft	**Extract soft** (label AAN: extract, if label space limited: ext. soft)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	
Extract soft concentrate	**Extract soft concentrate** (label AAN: extract, if label space limited: ext. soft conc.)	(?:1 in 100% W)	EQUIV. AHN + part + dry/fresh	
Extract soft concentrate standardised	**Extract soft concentrate standardised** (label AAN: extract standardised, if label space limited: ext. soft conc. stand., extract stand., or ext. stand.)	(?:1 in 100% W)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Extract soft standardised	**Extract soft standardised** (label AAN: extract standardised, if label space limited: extract stand., or ext. stand.)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Fat	**Fat** If an extract of a fat, ensure 'fat' is part of the plant part and use 'extract' etc. as the plant preparation		Required if label claim, otherwise optional: EQUIV. AHN + part + dry/fresh	
Fresh	**Fresh** (label AAN: 'fresh' may be omitted if the plant part includes any of the following terms: balsam, gum, latex, oleoresin, resin, sap, wax)		Required if label claim: EQUIV. AHN + part + dry	

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Homoeopathic potency: refer Homeopathic Pharmacopoeia of the United States (HPUS)	**X ... decimal (1 in 10) dilutions (or equiv.) counted as in HPUS, where first dilution of mother tincture = 2X** (label AAN decimal (1/10) dilutions: n X centessimal (1 in 100) dilutions: n counted as in US/French/ German homoeopathic pharmacopoeia)			
Infusion	**Infusion**	(1:? in 100% W)	EQUIV. AHN + part + dry/fresh	
Infusion standardised	**Infusion standardised** (label AAN if label space limited: infusion stand.)	(1:? in 100% W)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Juice concentrate	**Juice concentrate** (label AAN if label space limited: juice conc.)		EQUIV. AHN + part + juice dry/fresh	
Juice concentrate standardised	**Juice concentrate standardised** (label AAN if label space limited: juice concentrate stand., or juice conc. stand.)		EQUIV. AHN + part + juice dry/fresh	EQUIV. stand. comp. AAN/HCN
Juice dry	**Juice dry** (label AAN: juice powder)		Required if label claim: EQUIV. AHN + part + juice fresh	
Juice dry standardised	**Juice dry standardised** (label AAN: juice powder standardised, if label space limited: juice dry stand., or juice powder stand.)		Required if label claim: EQUIV. AHN + part + juice fresh	EQUIV. stand. comp. AAN/HCN

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Juice fresh	**Juice fresh** (label AAN: juice)		Required if label claim: EQUIV. AHN + part + juice dry	
Juice fresh standardised	**Juice fresh standardised** (label AAN: juice standardised, if label space limited: juice fresh stand., or juice stand.)		Required if label claim: EQUIV. AHN + part + juice dry	EQUIV. stand. comp. AAN/HCN
Juice powder	**Juice dry** (label AAN: juice powder)		Required if label claim: EQUIV. AHN + part + juice fresh	
Juice powder standardised	**Juice dry standardised** (label AAN: juice dry standardised, juice powder standardised, if label space limited: juice dry stand. or juice powder stand.)		Required if label claim: EQUIV. AHN + part + juice fresh	EQUIV. stand. comp. AAN/HCN
Latex	Where it is part of the plant part; select the preparation, e.g. 'fresh', 'extract...'			
Oil essential	**Oil essential** (label AAN if label space limited: oil ess. or oil)		Required if label claim, otherwise optional: EQUIV. AHN + part + dry/fresh	

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Oil fixed	**Oil fixed** (label AAN if label space limited: oil)		Required if label claim, otherwise optional: EQUIV. AHN + part + dry/fresh	
Oil infused	**Oil infused** (label AAN if label space limited: oil inf. or oil) CAUTION: Quantify the active ingredient oil alone (do not include the quantity of solvent oil used) Where the solvent oil(s) are also in the product, name and quantify these excipient(s) separately		Required if label claim, otherwise optional: EQUIV. AHN + part + dry/fresh	
Oleoresin	If an extract of an oleoresin, ensure 'oleoresin' is part of the plant part, and use 'extract etc.' as the plant preparation			
Potency	Refer homoeopathic potency			
Powder	**Powder**		Required if label claim: EQUIV. AHN + part + fresh	
Powder standardised	**Powder standardised** (label AAN if label space limited: powder stand.)		Required if label claim: EQUIV. AHN + part + fresh	EQUIV. stand. comp. AAN/HCN
Resin	Resin is part of the plant part; select the preparation, e.g. 'fresh', 'extract…'			

Plant preparation	Approved name differentiation (approved names in bold)	If final extraction ratio and solvents required	If equivalent dry/fresh weight required	If component required
Sap	Sap and sap balsam are part of the plant parts; select the preparation, e.g. 'fresh', 'extract ...'			
Spagyric	**Spagyric**	(1:?): prep 1 (?:? in solvents) & prep 2 ... etc.	EQUIV. AHN + part + dry/fresh	
Spagyric concentrate	**Spagyric concentrate** (label AAN: spagyric, if label space limited: spagyric conc.)	(?:1): prep 1 (?:? in solvents) & prep 2 ... etc.	EQUIV. AHN + part + dry/fresh	
Spagyric concentrate standardised	**Spagyric concentrate standardised** (label AAN: spagyric standardised, if label space limited: spagyric conc. stand. or spagyric stand.)	(?:1): prep 1 (?:? in solvents) & prep 2 ... etc.	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Spagyric standardised	**Spagyric standardised** (label AAN: spagyric standardised, if label space limited: spagyric stand.)	(1:?): prep 1 (?:? in solvents) & prep 2 ... etc.	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN
Tincture	**Tincture** (label AAN if label space limited: tinct.)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	
Tincture standardised	**Tincture standardised** (label AAN: if label space limited: tinct. stand.)	(1:? in solvents)	EQUIV. AHN + part + dry/fresh	EQUIV. stand. comp. AAN/HCN

Appendix 3 Where to find the approved terminology

A list of TGA approved terminology can be found in the Ingredients Table and Code Tables on the TGA Business Services website (TBS). The TBS website provides publicly visible information relating to ingredient names and approved terminology and does not require a login.

A3.1 Ingredients Table

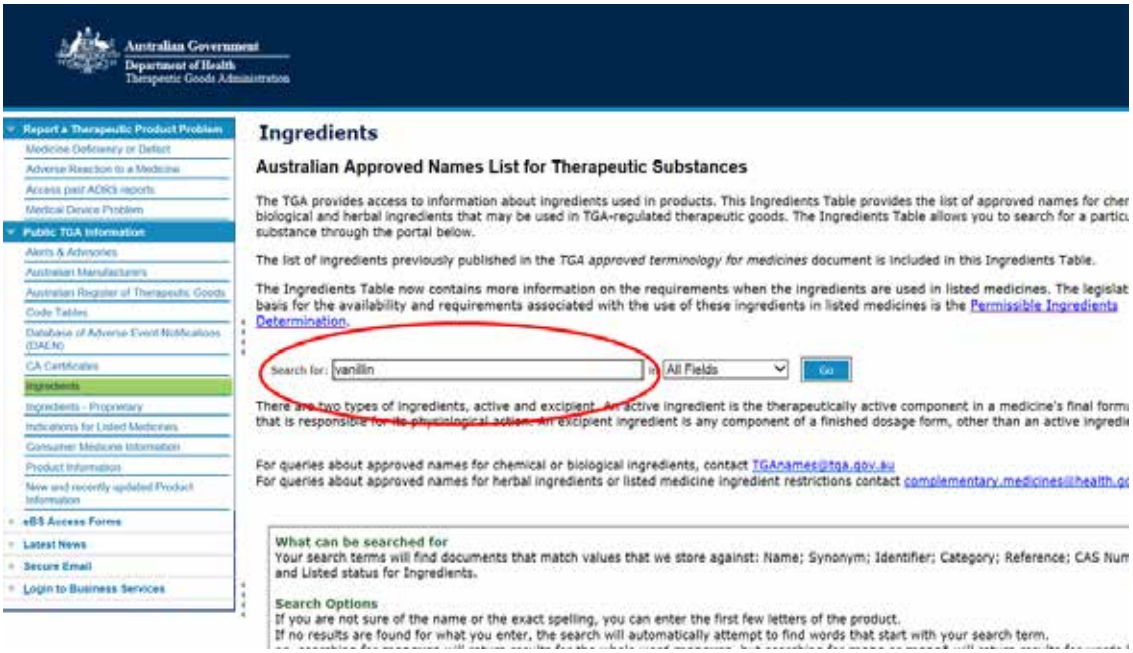
The Ingredients Table provides the list of approved names for substances used in therapeutic products, including:

- active ingredients,
- excipients,
- components or 'equivalents' of ingredients,
- cells and tissues.

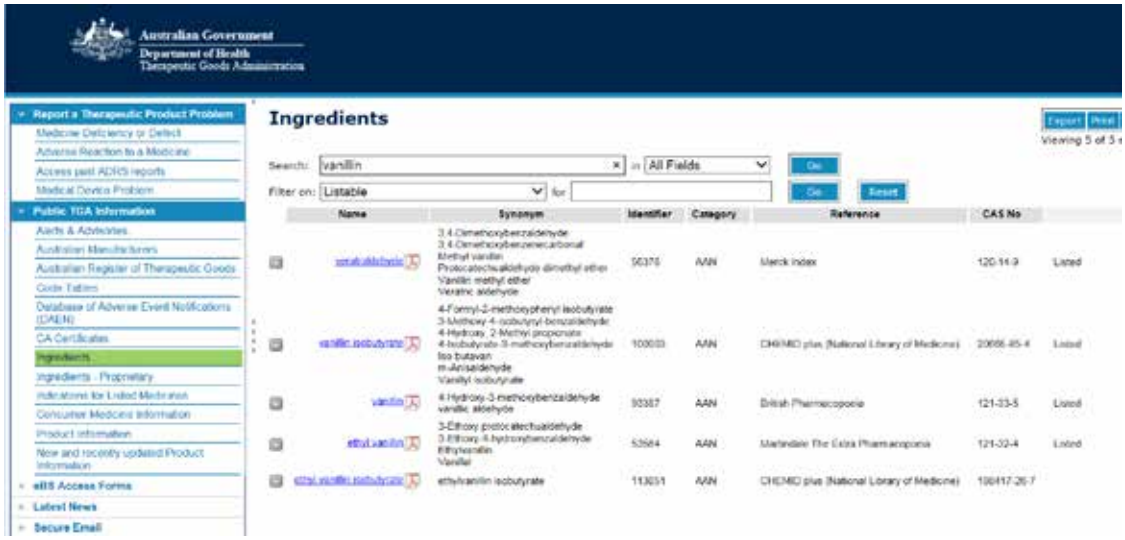
A3.1.1 How to search the Ingredients Table

1. To search for ingredients in the Ingredients Table, go to the TGA Business Services website. Select the link to the Ingredients Table located in the left menu under ***Public TGA Information,*** then select ***Ingredients.***

2. To search for an ingredient, enter an ingredient name in the search bar. For example, 'vanillin' and press the 'GO' button.



3. If an ingredient name exists, search results similar to this example will be displayed. If no search results are returned, try searching for the CAS number. If there are still no results, you will need to follow the process for proposing a new ingredient name.



4. To view the details of a particular ingredient, select the name of an ingredient (highlighted in blue). An ingredient summary will then be displayed, similar to this example.

Australian Government
Department of Health
Therapeutic Goods Administration

Ingredient Summary

Ingredient Name	vanillin
Ingredient ID	93387
Category	Australian Approved Name
Synonyms	vanillic aldehyde 4-Hydroxy-3-methoxybenzaldehyde
CAS Number	121-33-5
Availability	Available for use as an Active Ingredient in: Biologicals, Export Only, Over the Counter, Prescription Medicines Available for use as an Excipient Ingredient in: Biologicals, Devices, Export Only, Listed Medicines, Over the Counter, Prescription Medicines Not available as an Equivalent Ingredient in any application *Please note: Only the name and definition of a substance have been reviewed to allow it to be included in the ingredient repository. The approval for use of the ingredient in therapeutic goods is a decision made by the relevant TGA regulatory area. This approval process may require submission of further information, for example safety data for the ingredient or for the finished goods, to meet legislative and regulatory requirements.*
Additional Information	

Naming Reference

Reference	Edition/Year/Volume	Page Number(s)	Accessed Online
British Pharmacopoeia	93		No

Restrictions

Restriction	Applies To

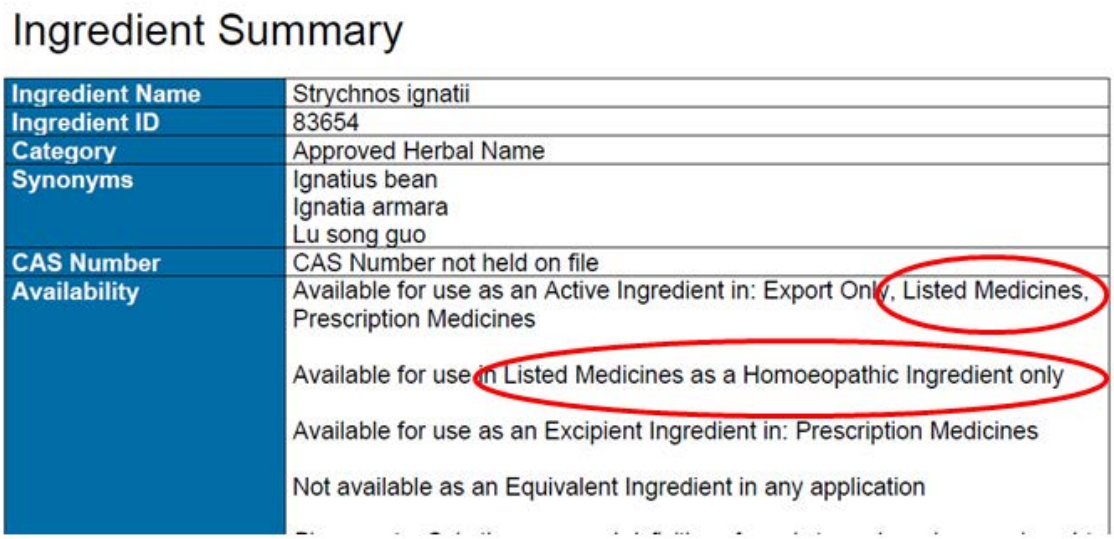
A3.1.2 How to interpret an ingredient summary

The ingredient summary provides a publicly visible summary of an ingredient and provides the approved role of the ingredient (active or excipient). The ingredient summary generally lists the following information:

- *Ingredient name* – TGA approved ingredient name
- *Ingredient ID* –ingredient identifier assigned by the TGA
- *Category* – approved ingredient and tissue name categories, e.g. AAN, ABN, ACN etc.
- *Synonyms* – other names by which the ingredient is known by (included to assist with search functionality; where applicable)
- *CAS number* – ingredient identifier assigned by the Chemical Abstract Service (CAS); (where possible)
- *Naming reference* – publication that served as the source of the ingredient name, e.g. INN, British Pharmacopoeia, monograph)
- *Restrictions* – any restrictions that might apply to use or labelling of the ingredient, e.g. to be used topically, only to be used as an active homeopathic ingredient
- *Availability* – product types and roles the ingredient is permitted for use in e.g. listed medicines, prescription medicines etc.

The ingredient availability section must be read in totality, as additional restrictions on availability can apply. For example, this screenshot shows that '*Strychnos ignatii*':

- is available for use as an active ingredient in export only, prescription medicines and listed medicines; and
- that listed medicine availability is permitted only when the ingredient is used as a homoeopathic ingredient.



Ingredient Summary

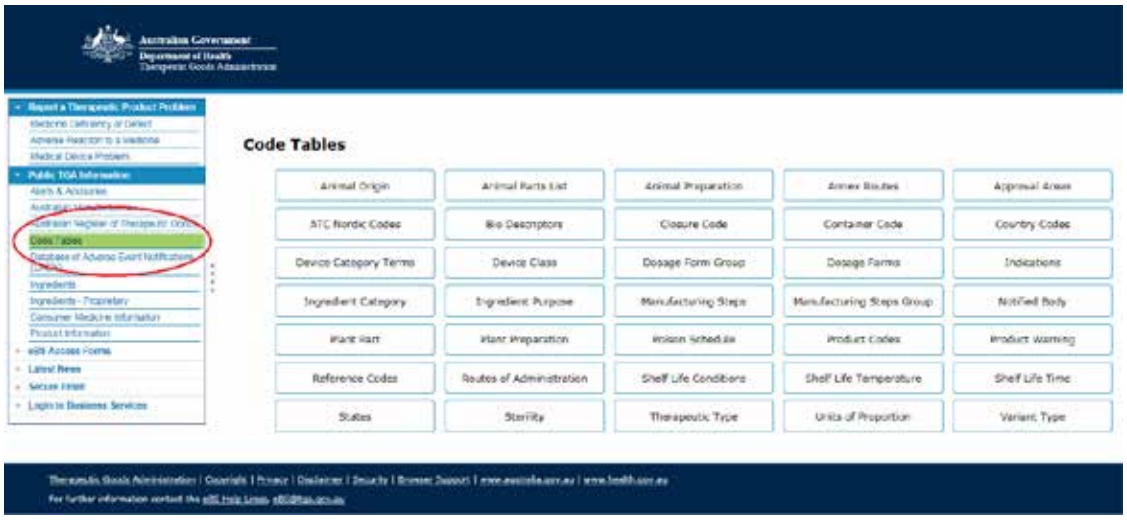
Ingredient Name	Strychnos ignatii
Ingredient ID	83654
Category	Approved Herbal Name
Synonyms	Ignatius bean Ignatia armara Lu song guo
CAS Number	CAS Number not held on file
Availability	Available for use as an Active Ingredient in: Export Only, Listed Medicines, Prescription Medicines Available for use in Listed Medicines as a Homoeopathic Ingredient only Available for use as an Excipient Ingredient in: Prescription Medicines Not available as an Equivalent Ingredient in any application

A3.2 Code Tables

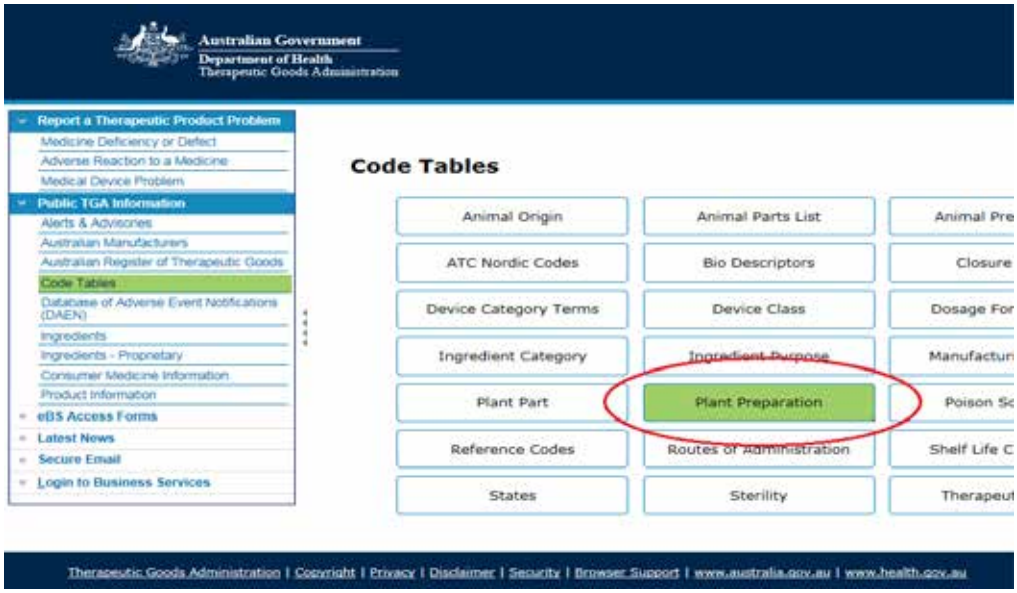
The Code Tables provide terminology for use in applications for therapeutic goods and on product labels, where relevant. The Code Tables provide a consistent and standardised method for naming and specifying therapeutic products including: dosage forms, plant preparation etc. For a full list of Code Table terminology, refer to the Code Tables homepage.

A3.2.1 How to search the Code Tables

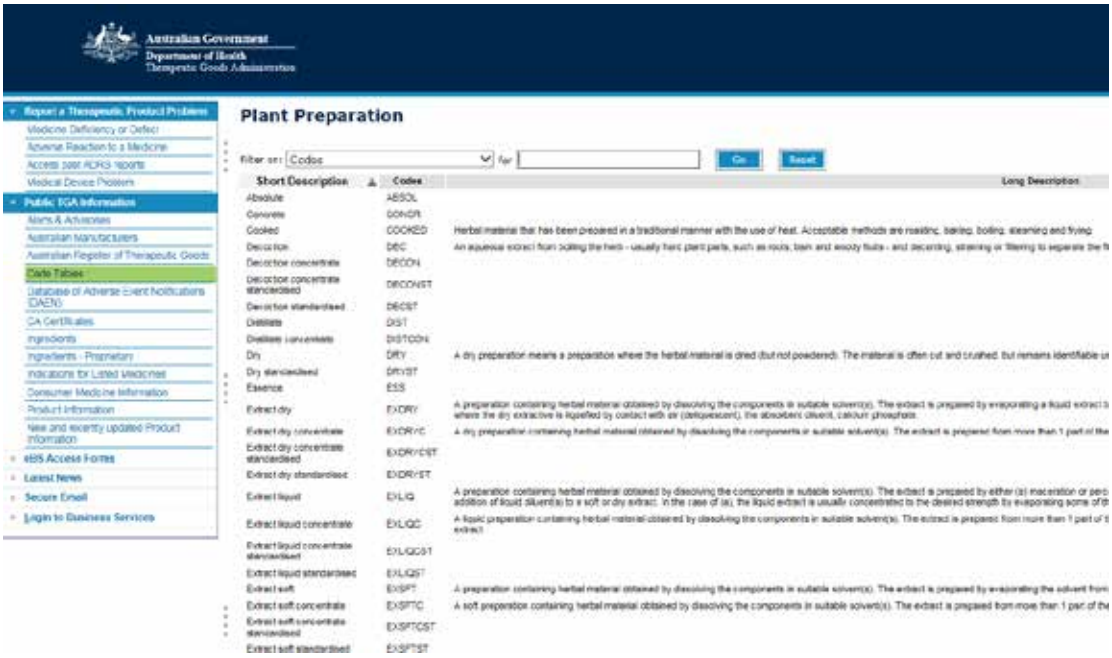
1. The Code Tables are located on the TGA Business Services website and can be found in the left menu under ***Public TGA Information***, then select ***Code Tables***.



2. To view a particular terminology category, go to the Code Tables homepage. Then select a specific category, for example, 'plant preparation'.



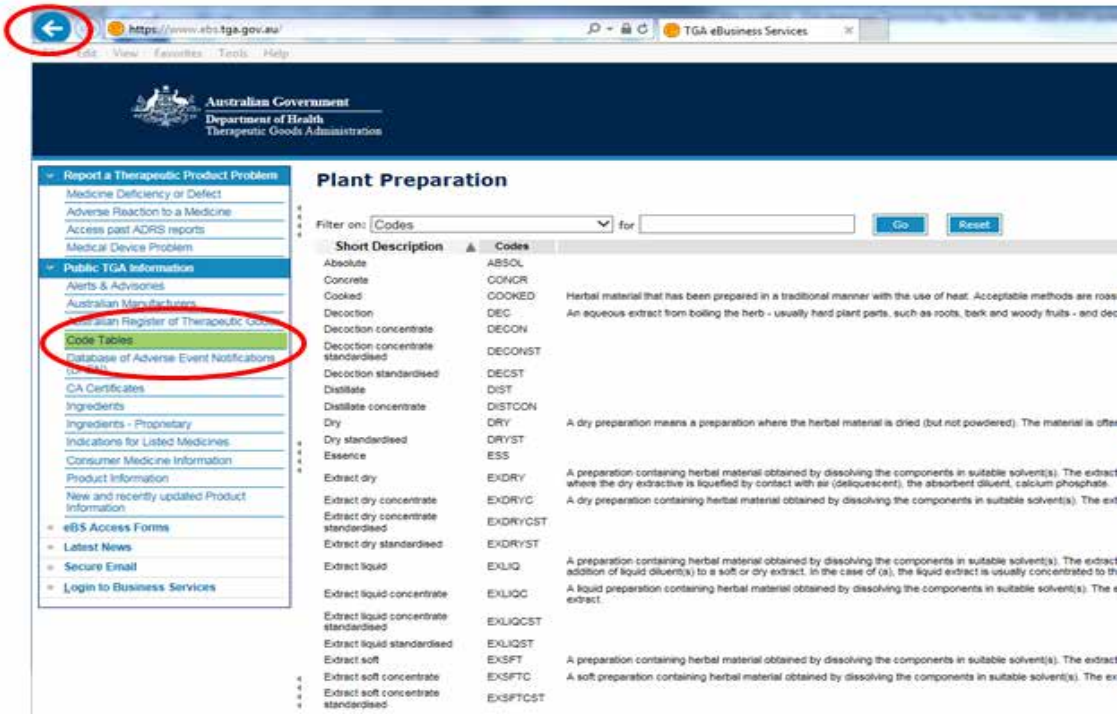
3. A summary of approved terminology will be displayed, similar to this example for 'plant preparation'.



Each result will generally list the following:

- *Short Description* – full name of the approved terminology
- *Codes* – terminology abbreviation
- *Long Description* – A description of the approved terminology (where possible)

4. To navigate back to the Code Tables homepage, you can select the back button in the top left hand corner. Alternatively, go to the left menu, then under ***Public TGA Information***, select ***Code Tables***.



Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA	July 1999
V2.0	Updated	TGA	June 2016
V3.0	Title of document changed to *TGA Approved Terminology for Therapeutic Goods* Addition of new information about: • approved cell and tissue names information - part 5 • what is approved terminology – part 1 • where to find approved terminology and how to search the Ingredients Table and Code Tables – Appendix 3 Clarification to reflect current processes regarding: • Herbal Component Names (HCNs) • Legal basis for using approved terminology • Herbal naming references Removal of information found in other documents, including some medicine labelling guidance. Minor formatting and structural changes. Corrections to minor errors.	TGA	November 2019
V3.1	Clarifying definition of Approved Herbal Name to include algae, yeast or fungi.	TGA	March 2020

Therapeutic Goods Administration

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https://www.tga.gov.au

Reference/Publication #D19-5801437