Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

TGA approved terminology for medicines

For consultation

Version 1.0, May 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- The TGA administers the *Therapeutic Goods Act* 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website <www.tga.gov.au>.

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

Version history

Version	Description of change	Author	Effective date
V1.0	Draft for consultation	OSE	May 2013

Contents

Abbreviations and acronyms

AAN	Australian Approved Name (chemical)
ABN	Approved Biological Name
ACN	Approved Cell and Tissue Name
ADN	Approved Device Name
AFN	Approved Food Name
AHN	Approved Herbal Name
AHS	Approved Herbal Substance Name
ARTG	Australian Register of Therapeutic Goods
BP	*British Pharmacopoeia*
eBS	TGA's online eBusiness Services portal
EP	*European Pharmacopoeia*
HCN	Herbal Component Name
INN	International Nonproprietary Name
IUPAC	International Union of Pure and Applied Chemistry
MIS	Medicinally interchangeable species
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TGA	Therapeutic Goods Administration
USP	*United States Pharmacopeia*
WHO	World Health Organization

1 Introduction

1.1 What is approved terminology and why is it needed?

The Therapeutic Goods Administration (TGA) develops and maintains lists of Australian approved terminology for medicines, including approved names for ingredients used in medicines. Australian approved terminology has been developed because no single internationally agreed list or primary reference covers all substances or terms used, or likely to be used, in therapeutic goods supplied in Australia.

Approved terminology for medicines covers substances (active ingredients and excipients), containers, dosage forms, routes of administration, and units of measurement. A database of approved terminology for substances is publicly accessible via the TGA eBusiness Services (eBS) website <http://www.ebs.tga.gov.au>. Approved terminology for containers, dosage forms, routes of administration, and units of measurement is listed in Section 5 of this document, as well as in code tables on the eBS website.

Use of approved terminology ensures accuracy and consistency in the information compiled in the Australian Register of Therapeutic Goods (ARTG), a comprehensive database of information about all therapeutic goods supplied in Australia or exported from Australia. The ARTG can be accessed through the TGA eBS website. Consistency in naming helps people to retrieve information from the ARTG, helps health professionals and the public to compare similar goods, and avoids the risk of confusion between goods.

Approved terminology should be used:

- when sponsors submit applications for registration, listing and export of medicines, and notification of proprietary ingredients
- in records of medicine formulations included in the ARTG
- on labels for medicines
- in Product Information, Consumer Medicine Information and other product literature where use of approved terminology is required.

1.2 What is the legislative basis for approved terminology?

The Therapeutic Goods Regulations 1990 provide for the use of approved names for ingredients used in medicines. As stated in the Regulations, a list of all approved names (the Australian Approved Names List) is published by the TGA, and is accessible via the eBS website.

Therapeutic Goods Order No. 69—General requirements for labels for medicines—specifies that approved names must be used for all ingredients on labels for medicines.

Section 23 of the *Therapeutic Goods Act 1989* 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. The product information must be in

a form approved under s. 7D of the Act and must contain the Australian approved name of each therapeutically active ingredient. The Regulations state that the Consumer Medicine Information must be consistent with the Product Information.

Therapeutic Goods Orders No. 54 and No. 54A—Standard for disinfectants and sterilants—require the use of terminology for naming these products, as published in the *TGA Approved Terminology for Medicines*.

1.3 What does this document contain?

This document:

- provides guidance on TGA policies relating to the determination of approved names for new medicine ingredients
- describes the approval process for new proposed names.

The document will be updated as required.

Correspondence with the TGA regarding the TGA Approved Terminology for Medicines, including any errors or omissions, should be directed to TGAnames@tga.gov.au.

The postal address for correspondence relating to Australian Approved Names (chemical) (AANs), Approved Biological Names (ABNs) and approved terms for containers, dosage forms, routes of administration, and units of measurement is:

AAN and ABN Committees Secretariat
Office of Scientific Evaluation
Market Authorisation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

For correspondence relating to herbal ingredients, the postal address is:

Herbal Ingredient Names Committee (HINC) Secretariat
Office of Complementary Medicines
Market Authorisation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

The remaining sections of this introduction relate to approved terminology for substances. Further information on approved terminology for other characteristics of medicines (containers, dosage forms, routes of administration, and units of measurement) is in Section 5 of this document.

1.4 What is the purpose of approved names for medicine ingredients?

Specific reasons for approving ingredient names are to:

- ensure that only one name is used to specify an ingredient, to avoid confusion
- ensure that the name clearly and unambiguously identifies the substance being named
- ensure consistency of ingredient names with international conventions (e.g. International Nonproprietary Names [INNs]) and with each other
- define the ingredient in such a way that a laboratory could determine if a substance that is used as an ingredient in a medicine meets the definition for that name.[1]

Sponsors and other users of the ingredients database should note that:

- inclusion of a name in the database does not imply any recommendation for the use of the substance in therapeutic goods
- the citation of an authority or reference (see Section 1.8) for defining a name in the database does not imply that the standard specified in that reference defines the quality of the substance, as used in a particular therapeutic good
- the database is not a list of ingredients found in products currently entered in the ARTG.

1.5 What types of substances does approved terminology apply to?

Ingredients with approved names to be used in medicines are divided into three main categories:

- chemical substances, including antibiotics
- biological substances—substances of biological origin (other than antibiotics) that are not derived from plants, algae, yeast or fungi
- herbal substances—substances of plant, algal, yeast or fungal origin.

Disinfectants and sterilants are regulated as either medical devices or therapeutic devices, depending on their classification, rather than medicines. However, legislation relating to these substances also requires the use of terminology as published in the *TGA Approved Terminology for Medicines*. Section 2 of this document (Chemical substances) includes information relating to substance names that are eligible for use in disinfectants and sterilants.

[1] This relates only to the ability to unambiguously identify the ingredient, and not to the quality of the product containing the ingredient.

1.6 What types of names are used for substances?

Table 1.1 lists the categories of names used for substances.

Table 1.1 Types of approved names used for therapeutic substances

Category	Abbreviation	Type of substance	Notes
Australian Approved Name (chemical)	AAN	Chemical	AANs are approved names for chemical substances.
Approved Biological Name	ABN	Biological	ABNs are approved names for biological substances. The ABN includes the name of the organism, and may also include the part of the organism and the preparation.
Approved Device Name	ADN	Chemical	ADNs are allocated to ingredients that are eligible for inclusion in devices.
Approved Cell and Tissue Name	ACN	Cell and tissue	ACNs are for ingredients used in products that are regulated under the regulatory framework for biologicals. They are not given to ingredients used in medicines. (Refer to <http://www.tga.gov.au/industry/biologicals-framework.htm> and the *Australian Regulatory Guidelines for Biologicals*.)
Approved Herbal Name	AHN	Herbal	An AHN is the species name (in the Latin binomial format) of a herb used in a herbal substance. The species name, the plant part and the preparation (including solvents and ratio, if applicable) are used to fully name a herbal substance.
Approved Herbal Substance Name	AHS	Herbal	AHSs are allocated to herbal ingredients that are fully characterised in a monograph of an accepted pharmacopoeia (e.g. Orange oil distilled). 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 rule that use of a particular reference to define an approved name does not mean that the substance must conform with the standard specified in the reference (see Section 1.8).

Category	Abbreviation	Type of substance	Notes
Herbal Component Name	HCN	Herbal	HCNs are used for classes of constituents in herbal ingredients. HCNs are most often needed when a herbal extract is standardised to a particular class of constituents, or where particular classes of constituents are restricted (e.g. hydroxyanthracene derivatives). An HCN is not a stand alone name and should be used only when an ingredient is expressed as a component of a herbal substance.
Approved Food Name	AFN	Food grade	AFNs are allocated to substances (e.g. orange) that are food grade. In addition to the AFN, the name of the 'preparation' of the food ingredient (e.g. orange **juice**) is usually required to form the full approved name for the substance. When an AFN is used, the ingredient can be used only as an excipient in therapeutic goods. If the substance is to be included as an active ingredient in a product, the name of the substance should be expressed in AHN format (e.g. *Citrus sinensis* fruit juice). The use of AFNs is not encouraged (see Section 4 for further information).

1.7 What other requirements apply to approved names?

Other characteristics of approved names for ingredients are listed below.

1.7.1 Ingredient requirements

Ingredients to be named must be:

- single entities or natural mixtures (e.g. complex mixtures of lipids)—approved names are not used to describe formulations that are either included in the product or used as starting materials[2]
- found in finished products (i.e. proposed, approved or cancelled medicines)—materials such as starting materials and growth media, manufacturing solvents, and

[2] Formulations may be included in the proprietary ingredients database, which is a separate list from the ingredients database.

materials included in unapproved medicines used in clinical trials or for research, are generally not included in the list of approved names.[3]

1.7.2 Trademarked names

If an ingredient name has been registered as a trademark in Australia, it cannot be an approved ingredient name (although it may be allowed as a product or trade name). It is a legal requirement that approved ingredient names are used on labels and in product information material.[4] If an active ingredient's trademarked name were approved as an Australian approved name, other sponsors would be required to include that name on their labels (e.g. Policosanol, which is the trade name for sugarcane wax alcohol), and this would breach the trademark.

1.7.3 'Inversion' of names

Historically, some ingredient names were expressed in an inverted form — for example, 'insulin — bovine' rather than 'bovine insulin'. This reflects either the naming convention used by the source reference, or previous policies. Since this can cause confusion for labelling, new ingredient names are not inverted. Irrespective of whether or not names are inverted, they will all be retrieved in appropriate searches of the ingredients database. Ingredient names must not be inverted on labels.

1.7.4 Spelling

Where it is consistent with international practice, 'ph' has been replaced by 'f' in approved names. For example, sulphacetamide is now listed as sulfacetamide.

1.7.5 Punctuation

Punctuation can be used in names, where appropriate (e.g. in names of chemicals, such as 1,3 dichloro ...). However, reducing the use of punctuation assists with database searchability.

1.7.6 Synonyms

Many ingredients are identifiable by a name (or names) other than the approved name (i.e. synonyms). Synonyms for some substances are included in the ingredients database to assist with identification. These synonyms are listed for cross-reference purposes only and **should not be used** instead of the approved names on labels of therapeutic goods sold in Australia or in applications to the TGA to enter products in the ARTG.

[3] Data relating to the animal origin of ingredients in the finished product (including products derived using starting materials or growth media of animal origin) are included in the product record (in the ARTG) for that ingredient.

[4] Refer to relevant regulatory guidelines (e.g. *Australian Regulatory Guidelines for Prescription Medicines*, *Australian Regulatory Guidelines for Over-the-Counter Medicines* and *Australian Regulatory Guidelines for Complementary Medicines*) for further guidance on legislative and other requirements for registration and listing of medicines.

1.8 What is a naming reference?

The reference refers to the publication or document that was the source of the proposed name. The reference usually includes the definition or description of the ingredient or substance. The aim of having a reference is to adequately define the name, so that a particular substance can be analysed to determine whether or not it is the substance defined by the name. In most cases, the name stated in the title of the monograph or other reference would be used for the substance.

If there is ever any confusion about the identity of an ingredient, the TGA will apply the definition from the reference for the ingredient when the name was initially approved. This reference is provided by the TGA when the name is approved, and is included in the ingredients database.

Use of a particular reference to define a name **does not** necessarily mean that it is also the approved standard or monograph that defines the quality of the substance. Refer to the *Australian Regulatory Guidelines for Prescription Medicines*, the *Australian Regulatory Guidelines for Over-the-Counter Medicines* and the *Australian Regulatory Guidelines for Complementary Medicines* for guidance on requirements for the quality of ingredients used in medicines.

References for chemical and biological names are assigned in approximate order of preference (see Sections 2.1 and 3.1). The default reference for AANs and ABNs is the INNs, maintained by the World Health Organization (WHO). The TGA uses INN terminology wherever it exists for ingredient naming. If an ingredient has an INN, sponsors will be required to justify the use of a different name. The suitability of the alternative name will be reviewed on a case-by-case basis. Salts and derivatives of INNs should also be named according to conventions described in the WHO document *International Nonproprietary Names Modified* <http://www.who.int/medicines/services/inn/INNMreview%20paperWkDoc167_Feb06_3_.pdf>.

Section 3 of the *Therapeutic Goods Act 1989* lists three pharmacopoeias that are defined as 'default standards' used to specify the quality, method of manufacture and other aspects of therapeutic goods. These are the *British Pharmacopoeia*, *European Pharmacopoeia* and *United States Pharmacopeia—National Formulary*. As well as being used to define quality aspects of medicines, these three default pharmacopoeias are often used to assist with the correct naming of ingredients approved for use in medicines.

Occasionally, some ingredient names are not included in newer versions of references. These names are retained in the ingredients database, and the specific edition of the reference used to identify the name is also documented. This is to ensure that an accurate record of all substances that are, or were, in use in Australia is maintained.

In the ingredients database, an asterisk (*) following a reference indicates that the name has been adapted from the title or entry in a reference, rather than being identical to it. There are two possible reasons for this: either the name in the reference is slightly different from the Australian approved name (e.g. hydrolysed algin as the AAN instead of hydrolyzed algin), or the ingredient itself is slightly different from the ingredient named in the reference, but that reference is considered the most appropriate reference. For example, 'cyclophosphamide' is an entry in the INN (which would be shown as the reference), whereas 'cyclophosphamide monohydrate' is based on the entry in the INN but is not an INN itself—the reference for 'cyclophosphamide monohydrate' would be INN*.

1.9 What are the TGA processes for approving names?

The TGA has established three informal committees to review applications for new approved names:

- the Australian Approved Names (AAN) Committee—reviews proposals for new AANs and ADNs, as well as new approved terms for containers, dosage forms, routes of administration and units of measurement
- the Australian Biological Names (ABN) Committee—reviews proposals for new ABNs and ACNs, as well as new approved terms for animal parts, animal origins and animal preparations
- the Herbal Ingredient Names Committee (HINC)—reviews proposals for new AHNs, AHSs, HCNs and AFNs, as well as new approved terms for plant parts and plant preparations.

These naming committees deal only with ingredient names and not trade names.

The process for review of applications for new approved names is as follows:

1. Applications are checked for completeness, including attached references. Applications that are not complete will not be processed until the necessary information specified in the application form is provided.
2. Complete applications are referred to the appropriate committee for review.
3. Committee members review the application, either in a meeting or through out-of-session papers, and make a decision.
4. If the application is successful, sponsors are notified. The TGA eBS website <http://www.ebs.tga.gov.au> is updated to include the new name. Sponsors can then submit applications for evaluation of that ingredient, or for products containing that ingredient to be entered in the ARTG, according to the appropriate processes for the type of product.
5. If the application is unsuccessful, sponsors are notified and provided with the reasons that the proposed name is unacceptable. Sponsors can request that their application be reconsidered, if they believe that they can provide justification for a different committee decision.

The three naming committees attempt to consider and decide on proposals for new ingredient names within 20 working days of their receipt by the TGA. However, these time frames may need to be extended if insufficient information is provided in the application. The TGA might also reject a name if insufficient information is provided.

1.10 How do I obtain a new approved name?

When submitting an application for evaluation of a substance that does not currently have an approved name, sponsors will need to submit a proposal for a new name prior to the application for the evaluation of that substance. Different application forms are available on the TGA website <http://www.tga.gov.au/industry/medicines-approved-terminology.htm#forms> for proposing:

- a botanical name for a herb

- a herbal substance name
- a herbal component name
- a chemical name
- a biological name

The application forms give details of what should be provided with a proposal for a new name.

Applications are likely to be processed without delay if:

- the application form is completed correctly
- the ingredient is defined by a monograph in one (or more) of the references in Sections 2 and 3, preferably an INN
- copies of the relevant monographs are attached to the application form
- the monograph defines the name with sufficient precision to enable the committee to have confidence that the ingredient can be identified; this includes any details about salts and other derivatives.

Names and supporting information will be assessed by the TGA. If considered suitable, the name will be approved and included in the ingredients database.

Sufficient information to be able to accurately identify a given ingredient will be made publicly available on the ingredients database.

Note: The TGA uses INN terminology wherever it exists for ingredient naming. If an ingredient has an INN, sponsors will be required to justify the use of a different name.

Completed forms should be sent to TGAnames@tga.gov.au or to:

AAN and ASI Committees Secretariat
Office of Scientific Evaluation
Market Authorisation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

Or for herbal ingredients

Herbal Ingredient Names Committee (HINC) Secretariat
Office of Complementary Medicines
Market Authorisation Group
Therapeutic Goods Administration
PO BOX 100
WODEN ACT 2606
AUSTRALIA

1.11 How can I access the name and reference when it is approved?

Details of all approved names and their references are available and searchable in the ingredients database via the TGA eBS website <http://www.ebs.tga.gov.au>.

1.12 Harmonisation of names

The TGA has routinely used INNs, where available, for new medicine ingredients in Australia since 2002. However, several hundred approved names that were added to the ingredients database before 2002 are synonyms of INNs, not INNs. The TGA has been working on the complex and important task of bringing these ingredients into line with INN conventions through its International Harmonisation of Ingredient Names (IHIN) project. Most of the names that require updating are AANs. The list of names proposed to be changed will be published for public consultation. To support the harmonisation process, a significant program of engagement with consumers, health professionals and industry is planned, scheduled to begin in 2013. The name changes are expected to take place in 2014. Further details are available on the TGA website.

2 Chemical substances

This section provides information on Australian approved names for:

- ingredients in medicines that are chemical substances—these substances are given Australian Approved Names (chemical) (AANs)
- ingredients in disinfectants and sterilants that are eligible for inclusion as ingredients in device goods—these substances are given Australian Approved Device Names (ADNs).

A searchable database of all approved names, including AANs, is accessible via the TGA eBusiness Services (eBS) website <http://www.ebs.tga.gov.au>.

The inclusion of an approved name in the ingredients database indicates that the name is approved as the descriptor of the substance. It **does not** indicate that the substance has been approved for use in therapeutic goods in Australia.

2.1 References

Each entry in the ingredients database shows the reference or authority that defines the chemical substance name. (See Section 1.8 for further details about references.)

Table 2.1 shows commonly used references for AANs, in order of preference. The TGA will not strictly enforce the order of preference. However, the default reference for AANs is the International Nonproprietary Names (INN), maintained by the World Health Organization (WHO), and the TGA preferentially uses INN terminology wherever it exists for ingredient naming. If a chemical substance has an INN, sponsors will be required to justify the use of a different name. The suitability of the alternative name will be reviewed on a case-by-case basis.

The references shown in Table 2.1 are the most commonly cited authorities. If the substance is not included in these publications, other references will be considered, preferably from well-recognised, peer-reviewed journals.

The reference code TGA XXXX (the XXXX signifies the year the name was approved) is a TGA reference prepared from time to time if none of the references in Table 2.1 are available or considered suitable. Further information about specific TGA references is available from the TGA.

An asterisk (*) next to a reference indicates that the name has been adapted from the title of the monograph in the reference (see Section 1.8 for further information).

Where a Chemical Abstracts Service (CAS) Registry number is given as the reference for an AAN, the Chemical Abstracts Index Name (CN) for the substance having that number may not be suitable for use as an approved name (e.g. it may be a name recommended by the International Union of Pure and Applied Chemistry [IUPAC], rather than a name more commonly used in the pharmaceutical industry). In this case, another name will be adopted.

Table 2.1 Codes for references that support names of chemical substances, in approximate order of preference

Code	Reference
INN[a]	International Nonproprietary Names
BP	British Pharmacopoeia
USP	United States Pharmacopeia
EP	European Pharmacopoeia
BAN	British Approved Names
USAN	United States Adopted Name
BPAP	British Pharmacopoeia—Appendix
MAR	Martindale: The Extra Pharmacopoeia
MI	Merck Index
FCC	Food Chemicals Codex
ANZFS	Australia New Zealand Food Standards Code
ICID	International Cosmetic Ingredient Dictionary
CAS	CAS (Chemical Abstracts Service) Registry
CI	Colour Index (Society of Dyers and Colourists)
ALL	Allured's Flavor and Fragrance Materials
CFFM	Common Fragrance and Flavor Materials
FHF	Fenaroli's Handbook of Flavor Ingredients
FIE	Fiedler Encyclopedia of Excipients
HPE	Handbook of Pharmaceutical Excipients
CG	Compositional Guideline

a INN terminology is preferred by the TGA and should be used wherever possible.

2.2 Spelling

Specific rules for spelling of chemical names are as follows:

- 'Alpha' versus 'alfa'—the correct spelling of this word in an ingredient name depends on the context. 'Alfa' is acceptable when naming active ingredients in biological medicines, to differentiate between similar ingredients. 'Alpha' is appropriate when naming a structural isomer.
- 'Sulfur' versus 'sulphur'—'sulfur' is used in names containing this word or its derivatives (e.g. sulfate, sulfonate).
- 'S' versus 'z'—words that have alternative 's' or 'z' spellings (e.g. hydrolysed, hydrolyzed) are spelt with an 's', consistent with Australian spelling convention.

2.3 Abbreviations

Abbreviations are commonly used as synonyms for some chemical substances with long names (e.g. cyclohexanedimethanol is sometimes referred to as CHDM). These abbreviations should not be used. The full chemical name should be used in preference to the abbreviation. Table 2.2 lists some examples of AANs and known abbreviations.

Table 2.2 Abbreviations for Australian approved names for chemicals

Acceptable name	Abbreviation (not to be used)
cyclohexanedimethanol	CHDM
diolamine	DEA
dimethylol dimethyl	DMDM
hydroxyethyl ethylenediamine triacetic acid	HEDTA
maleic anhydride	MA
olamine	MEA
monoisopropanolamine	MIPA
dl-pyrrolidonecarboxylic acid	PCA
propylene glycol	PG
polypropylene glycol	PPG
polyvinyl methyl ether/maleic anhydride	PVM/MA
polyvinylpyrrolidone	PVP
sulfoisophthalate	SIP
saturated methylene diphenyldiisocyanate	SMDI

Acceptable name	Abbreviation (not to be used)
trolamine	TEA
vinyl acetate	VA
vinyl pyrrolidone	VP

2.4 General guidelines

The following general guidelines are provided for names of chemical substances.

- IUPAC naming conventions should be used if there is no other preferred reference for the name (e.g. 1-[3,3-dimethylcyclohexyl]-4-penten-1-one).
- Preferably, names will be formed by joining elements of the name together to form a single word, apart from the salt, ester or glycol suffix (e.g. ethylcellulose rather than ethyl cellulose).
- Where there is no other preferred reference, the designator 'N-' will be included in the name to indicate a constituent group attached to a nitrogen.
- Where there is no INN or other common reference, stereochemical descriptors, such as 'R-' and 'S-'; 'd-', 'l-' and 'dl-'; and/or 'cis-' and 'trans-', should be included in ingredient names, where relevant, in accordance with IUPAC nomenclature. Inclusion of these terms increases the amount of information provided by the name and reduces ambiguity.
- For chemicals that include aromatic rings, the designators to be used will be 2-, 3-, 4-, rather than o-, m-, p-, or ortho-, meta-, para-. This applies only when the designators are not already defined by the reference.
- For describing the branching of alkyl groups, the designators n-, iso-, sec- and tert- should be used, unless otherwise specified in a preferred reference.

Some common INNs and their synonyms are shown in Table 2.3. The AAN for these ingredients uses the name, spelling and format shown in the 'Acceptable name' column. Sponsors who wish to deviate from these names should justify the use of the proposed alternative.

Table 2.3 Common International Nonproprietary Names

Acceptable name	Unacceptable name/spelling/format
barbital	barbitone
besilate	benzenesulfonate, besylate
betaine	betain
camsilate	camsylate
cipionate	cypionate

Acceptable name	Unacceptable name/spelling/format
closilate	closylate
dienantate	diheptanoate
dimeticone	dimethicone
diolamine	diethanolamine
edamine	ethylenediamine
edisilate	edisylate
enantate	enanthate, heptanoate
esilate	ethanesulfonate, esylate
estrogen	oestrogen
etilsulfate	ethylsulphate
isetionate	isethionate
lauril	dodecyl, lauryl
mesilate	mesylate
meticone	methicone
metilsulfate	methylsulphate
olamine	ethanolamine, monoethanolamine
napadisilate	napadisylate
napsilate	napsylate
teoclate	theoclate
tosilate	tosylate
trolamine	triethanolamine

The names for the miscellaneous groups in Table 2.4 have been determined using a similar policy as described for alcohols, aldehydes, acids, esters and acyl groups (see Section 2.5).

Table 2.4 Names for miscellaneous chemical groups

Acceptable name	Unacceptable name/spelling/format
allyl	propenyl, vinyl carbinyl
amyl	pentyl
anisate	methoxybenzoate

Acceptable name	Unacceptable name/spelling/format
anthranilate	aminobenzoate
cetyl	hexadecyl
glycerol	glycerin
nonanoate	pelargonate
nonanoyl	pelargonyl
nonanoic	pelargonic
phenylpropionate	hydrocinnamate
phenylpropionic	hydrocinnamic
phenylpropionyl	Hydrocinnamyl
xylene	Xylol

2.5 Naming of specific types of substances

2.5.1 Polymeric substances

Polymeric substances are frequently identified by a name part and a number that indicates the grade of polymer by chain length, viscosity or molecular weight. Some common examples are listed in Table 2.5. The AAN will be in this form, where appropriate. Where the references cover individual grades of a polymer, individual authorities will be quoted if they are available. Otherwise, derived names will be cited with an asterisk (see Section 1.8).

Table 2.5 Numbers used in names of polymers

Type of polymer	Numbering system
Macrogols	Average molecular weight
Dimeticones	Kinematic viscosity
Polyethylene glycols[a]	Monomer units
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

a This convention is not used for AANs

Macrogols (polyethylene glycols—PEGs)

'Macrogol' will be used as a name, rather than polyoxyl, polyoxyethylene, polyethylene glycol or PEG, unless otherwise specified in an INN. Macrogol is the term used in INNs and by the pharmaceutical industry generally, whereas PEG is used in the chemical and cosmetics industries (as shown in references such as the *International Cosmetic Ingredient Dictionary*).

Macrogols have the following general formula:

$$HOCH_2(CH_2OCH_2)_mCH_2OH$$

The convention in Australia for naming macrogols is that each macrogol name is followed by a number indicating its average molecular weight. 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).

In AANs, the size of the polymer molecule shown will conform to this format (which is also the INN format); that is, it 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 with an asterisk (e.g. ICID*). The name listed in the reference will be shown as a synonym. For example, all pure macrogols (macrogol 2000, etc.) will have references with asterisks, because the reference does not usually list the number.

Carbomers

The TGA follows the conventions of the USP in giving different names to carbomers depending on whether or not they are manufactured using benzene. The synonyms in the AAN database and/or the relevant USP references should be consulted to help determine the correct name for the substance.

2.5.2 Derivatives

Where substances are used in the form of derivatives, each individual derivative must have a name. For example, where a substance is used in the form of a salt or ester, the salt or ester must be included in the name.

- 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, derivatives should be named in accordance with INN conventions <http://www.who.int/medicines/services/inn/INNMreview%20paperWkDoc167_Feb06_3_.pdf>.

For salts, if there is no INN or other common reference and the salt can exist in only one form, there is no need to specify the molar ratio of the salt.

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

If there is no other preferred reference and there is more than one possible stoichiometry for the salt (and the stoichiometry is not specified), it is assumed to be 1:1. Common examples are sodium, potassium, magnesium, calcium, hydrochloride and hydrobromide.

- Example: monohydrochloride would be stated as hydrochloride, whereas dihydrochloride would be stated as dihydrochloride.

Sometimes, only the active component of the salt must be shown on the label. If this is the case, AANs can be approved for both the salt and the active component.

- Example: AANs exist for both amoxicillin and amoxicillin sodium, so both can be used on labels, as appropriate.

2.5.3 Starches

Starches that are naturally occurring and have not been modified are classified as herbal substances and are given Australian Herbal Substance Names (AHSs; see Section 4). These names include:

- Starch — maize
- Starch — potato
- Starch — rice
- Starch — tapioca
- Starch — wheat

Where the name of an ingredient needs to include the source of an ingredient derived from maize (corn), the name used should be maize, rather than corn. Other starches, such as starch — soluble potato, have been chemically modified and are thus classified as AANs.

2.5.4 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 list provided in Table 2.1, the currently accepted IUPAC nomenclature should be used. Where numbers are included in the name, they should be placed appropriately in the middle of the name, rather than at the start (e.g. butan-1-ol).

2.5.5 Ethanol

Some confusion has arisen over the names used to describe ethanol. The ingredients database has two entries relating to ethanol:

Ethanol — absolute	BP*
Ethanol	BP

Ethanol — absolute (reference BP*) refers to 100% ethanol, also known as Absolute or Dehydrated Alcohol, as described in the BP98 monograph 'Ethanol'.

Ethanol (reference BP) refers to either of the following:

- Ethanol (96 per cent), as described in the BP monograph of that title

· Alcohol, as described in the United States Pharmacopeia (USP) monograph of that title.

2.5.6 Anions and cations

For intravenous infusions (large-volume injections) and concentrated haemodialysis solutions, certain BP monographs require the quantities of individual ions or ion equivalents to be stated on the label. This is in addition to the statement of strength for ingredients required by Therapeutic Goods Order No. 69—General requirements for labels for medicines.

Table 2.6 lists the approved names for anions and cations.

Table 2.6 Approved names for anions and cations

Anions	Cations
acetate	ammonium
bicarbonate	calcium
bromide	citrate
carbonate	magnesium
chloride	potassium
fluoride	sodium
iodide	
lactate	
nitrate	
nitrite	
octanoate	
phosphate	
sulfate	
tartrate	

2.5.7 Amino acids and other chiral substances

Many chiral substances, such as amino acids, can exist as a single optical isomer (enantiomer) or as a mixture of isomers. The reference quoted for the name will define the isomer or mixture. In the case of amino acids, which mainly exist naturally in the l-form, the 'l-' prefix has been omitted from the approved name, even if it is included in the name shown in the reference.

The 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 policy. Inclusion of 'd-' and 'dl-' in the name improves the amount of information provided by the name and reduces ambiguity.

The designators '*R*', '*RS*' and '*S*' should not be used for chiral molecules, unless used in the reference title or required to distinguish between different chiral molecules.

2.5.8 Metals

For metals, the common name should be used; for example, 'copper' and 'iron', rather than 'cuprous' or 'cupric', and 'ferrous' or 'ferric'. Common names are more readily understood by consumers.

Where a single oxidation state occurs, that state should be included in the name (e.g. copper (I), copper (II), iron (II), iron (III)). Where mixed oxidation states occur, the names would merely be copper, iron, and so on (e.g. iron phosphate).

2.5.9 Colour names

New names for ingredients used as colours should not include the Colour Index (CI) number.

Separate names will be created for each colour and its lake (e.g. aluminium or calcium lake), as required (e.g. erythrosine and erythrosine aluminium lake).

2.5.10 Radioactive pharmaceuticals

The expression of radioactive ingredients will follow the INN format (e.g. Iometin (131I); iometopane (123I)).

2.5.11 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 major components of a mixture of fatty acids are approximately equal quantities of palmitic and stearic acids.

Where an AAN includes the term 'stearate' (e.g. erythromycin stearate, as it is referenced in the BP), the reference for that AAN should be consulted to verify the fatty acid composition(s) for that name.

2.5.12 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. Table 2.7 compares the AANs with the BP names.

Table 2.7 Australian Approved Names (chemical) and British Pharmacopoeia 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

2.5.13 Waters of hydration

The 'waters of hydration' terminology relates to the waters of crystallisation of a substance. The following approach is used:

- If a hydration state is not included in the name, the ingredient is anhydrous. This policy will be used even if the 'normal' state of the ingredient is hydrated.
- Separate names will be created for each hydration state in which the substance occurs.
- Substances that occur with a mixed hydration state will be called 'substance hydrate'.

For labelling:

- where the ingredient used in the formulation is a hydrated form and the waters of hydration are included in the approved name of the ingredient; and
- where the sponsor declares in their application the equivalent quantity of the anhydrous substance (using its approved name); then
- the approved name and quantity of the anhydrous form of the ingredient can be included on the label, provided that all other required equivalence statements are also included in the application and on the label.

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

There are some exceptions to this policy—for example, if the water is not part of the crystal structure. Some of these substances may include the word 'dried' as part of their name (e.g. 'dried magnesium sulfate'). 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').

2.6 How to propose a chemical substance name

If there is no approved name for a chemical substance in the ingredients database, the sponsor should:

- propose the name using the 'Application form for proposing a chemical name' <http://www.tga.gov.au/industry/medicines-approved-terminology.htm>
- provide evidence in support of the name—this will usually consist of a monograph or other reference that contains sufficient information to allow the name to be defined with certainty.

Refer to Section 1.10 How do I obtain a new approved name? for additional information.

Under some circumstances, a name that would otherwise be given in accordance with the above will not be adopted as an AAN or ADN. For example, a name will not be approved if it would conflict with a proprietary name used in Australia (e.g. malathion has replaced Maldison because Maldison is trademarked in Australia).

Proposals for new AANs should be sent to TGAnames@tga.gov.au, or to:

AAN Committee Secretariat
Office of Scientific Evaluation
Market Authorisation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

2.6.1 Device ingredient chemical names

Disinfectants and sterilants have recently been included as listed and registered devices in the Australian Register of Therapeutic Goods (ARTG), in accordance with Therapeutic Goods Orders No. 54 and 54A – Standards for disinfectants and sterilants. These Orders require the use of approved terminology for ingredient names in applications and on labels.

Ingredient names that have been approved for device goods only are included in the ingredients database as ADNs (see <http://www.ebs.tga.gov.au>). Note that the approval of a device ingredient name does not approve its use in medicines. For an ADN to be approved for use in medicines, further evidence must be submitted to the TGA.

If an ingredient name does not appear as an approved name in the ingredients database, it should be proposed using the appropriate form. In most cases, the name required will be a chemical name and the 'Application form for proposing a chemical name' should be used.

3 Biological substances

This section provides information on Australian approved names for biological substances—that is, substances of biological origin (other than antibiotics) that are not derived from plants; they are derived from human, animal or microbiological sources. These substances are given Approved Biological Names (ABNs).

Most of these ingredients are used in prescription medicines, although some are used in complementary medicines such as probiotic formulations. Under TGA terminology, ABNs do not include:

- ingredients derived from plants (that is, organisms treated as plants in the *International Code of Botanical Nomenclature*, including fungi, algae and yeast)—plant names are described in Section 4—Herbal substances
- antibiotics—antibiotics are given Australian Approved Names (chemical) (AANs) (see Section 2)
- ingredients used in products regulated under the regulatory framework for biologicals <http://www.tga.gov.au/industry/biologicals-framework.htm>, such as cell-based healthcare products—these ingredients will be given Australian Approved Cell and Tissue Names (ACNs).

A searchable database listing all approved names, including ABNs, is accessible via the TGA eBusiness Services (eBS) website <http://www.ebs.tga.gov.au>.

3.1 References

Reference codes are included against each entry in the ingredients database to indicate the reference or authority that defines the biological substance name. (See Section 1.8 for further details about references.)

Table 3.1 shows the order of preference for the most commonly used references for proposed ABNs. The TGA will not strictly enforce the order of preference. However, the default reference for ABNs is the International Nonproprietary Names (INNs), maintained by the World Health Organization (WHO), and the TGA uses INN terminology wherever it exists for ingredient naming. If a substance has an INN, sponsors will be required to justify the use of a different name. The suitability of the alternative name will be reviewed on a case-by-case basis.

If the ingredient is not included in the publications listed in Table 3.1, other material will be considered, preferably from well-recognised, peer-reviewed journals.

The reference code TGA XXXX (the XXXX signifies the year the name was approved) is a TGA reference prepared from time to time if none of the references in Table 3.1 are available or considered suitable. Further information about specific TGA references is available from the TGA.

An asterisk (*) next to a reference indicates that the name has been adapted from the title of the monograph in the reference (see Section 1.8 for further information).

Table 3.1 Codes for references supporting names of biological substances

Code	Reference
Ingredients derived from materials of human or animal origin	
INN[a]	International Nonproprietary Names
BP	British Pharmacopoeia
EP	European Pharmacopoeia
USP	United States Pharmacopeia
BAN	British Approved Names
BPAP	British Pharmacopoeia—Appendix
USAN	United States Adopted Name
HPUS	Homoeopathic Pharmacopoeia of the United States
CAS	CAS (Chemical Abstracts Service) Registry
Microorganisms and ingredients derived from microorganisms	
IJSB	International Journal of Systematic Bacteriology
BMSB	Bergey's Manual of Systematic Bacteriology
ICTV	International Committee on Taxonomy of Viruses
IF	Index of Fungi
IFG	Index Fungorum (www.indexfungorum.org)
MYC	Mycobank (www.mycobank.org)
Ingredients derived from cell lines and hybridomas	
ATCC	ATCC (American Type Culture Collection) <http://www.atcc.org>

a INN terminology is preferred by the TGA and should be used wherever possible.

In some cases, further information about the ingredient (see the following sections) should be provided with the application for an ABN and included in the name or ingredient details, to avoid ambiguity.

3.2 General guidelines

The following general guidelines are provided for names of biological substances:

- The common name, rather than the Latin binomial (species name), should be used to name organisms other than microorganisms, wherever possible. Common names (e.g. taipan) are more readily understood by consumers and others. If there is no common name for an organism, ABNs will identify organisms to species level only. The corresponding Latin binomial for the organism can be included in the ingredients database as a synonym if it is provided with the application for an ABN.
- Some animal species—cow, sheep, dog, cat, pig and horse—can also be referred to by the names bovine, ovine, canine, feline, porcine and equine, respectively. The latter form (bovine, etc.) is preferred in ABNs. The former (cow, etc.) can be included as synonyms to improve searchability of the database.
- Biodescriptors—that is, terms used to describe the source organism for biological substances that are manufactured using recombinant technology—are not included in the ABN. Specific descriptors, including biodescriptors, are often used to construct the product name in the Australian Register of Therapeutic Goods (ARTG). TGO 69 details requirements regarding the inclusion of biodescriptors, or biotechnology product descriptors, in product labelling. See Section 3.3.4 for further information about naming of biological substances derived using recombinant technology.
- Biological substances will be named as ingredients, rather than products. For example, 'pertussis vaccine' (a product) was historically an ABN. The approved name for the ingredient should be *Bordetella pertussis*.

3.3 Naming of specific types of substances

3.3.1 Microorganisms

Microorganisms should be identified to species level (and to subspecies and biovar level, where relevant) using scientifically correct and valid nomenclature. If identification of an individual strain of a microorganism is therapeutically relevant and can be justified, the strain reference can be included in the ingredient name. Information about strains can also be included as additional information for an ingredient in the ingredients database.

3.3.2 Animal parts and preparations

Where appropriate, names for biological substances will incorporate part, preparation and source details in the approved name itself, rather than as adjunct names (as is done for herbal ingredients—see Section 4). Examples of approved names for ingredients of animal origin are bovine cartilage powder and snake venom powder.

The animal source and part will only be required for entry of animal source information in the ingredients database—this is part of the information that the TGA uses 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. Animal preparations do not need to be named separately. For TSE safety, new ingredients of animal origin that are to be used in listed medicines must be pre-cleared before they can be added to the ingredients database; refer to the *Australian Regulatory Guidelines for*

Complementary Medicines <http://www.tga.gov.au/industry/cm-argcm.htm> for further details.

3.3.3 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, 'calcitonin' refers to the human protein; porcine calcitonin and salmon calcitonin will be named as such.

3.3.4 Ingredients derived from a recombinant source

If a biological substance is derived from a recombinant source, the recombinant ingredient name will be used (e.g. nonacog alfa). Approved biotechnology product descriptors are listed in the code tables (accessible on the TGA eBS website <http://www.ebs.tga.gov.au>). The appropriate descriptor should be selected from the list and included in the application form for a new ABN. See TGO 69 regarding requirements for the inclusion of biodescriptors, or biotechnology product descriptors, in product labelling.

3.4 How to propose a biological substance name

If an ingredient meets the criteria of being a biological substance but is not listed in the ingredients database, the sponsor should:

- propose a new name using the 'Application form for proposing a biological name (ABN) or term' <http://www.tga.gov.au/industry/medicines-approved-terminology.htm>
- provide evidence in support of the name—this will usually consist of a monograph or other reference that contains sufficient information to allow the name to be defined with certainty.

Refer to section 1.10 How do I obtain a new approved name? for additional information.

Proposals for new ABNs should be sent to TGAnames@tga.gov.au, or to:

ABN Committee Secretariat
Office of Scientific Evaluation
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

4 Herbal substances

This section provides information on Australian approved names for herbal substances. These names should be used when required for herbal substances in applications to enter medicines in the Australian Register of Therapeutic Goods (ARTG) (referred to as 'product applications' in this section) and on product labels.

Herbal substances are preparations of plants, and other organisms that are treated as plants in the *International Code of Botanical Nomenclature*, such as fungi, algae and yeast.

A searchable database of all Australian approved names is accessible via the TGA eBusiness Services (eBS) website <http://www.ebs.tga.gov.au>.

4.1 Construction of approved names for herbal substances

Herbal ingredient names are created by identifying the **herb (plant) species**, the **plant part(s)** and the **preparation**. The complete approved name for the herbal substance might need to include an approved name or code for each of these pieces of information. In other cases, a single approved name is used for the herbal substance. As explained in Section 1, different codes are used for different types of approved names for herbal substances—for example, a herb species approved name is an 'AHN' (Approved Herbal Name), and a food approved name is an 'AFN' (Australian Food Name). Where there is a single ingredient that is defined by a pharmacopoeia, this is an 'AHS' (Australian Herbal Substance Name).

There are three methods for making a complete approved name for a herbal substance, as follows:

1) AHN + plant part code + plant preparation code
   - Examples:

     '*Thymus serpyllum*' + 'herb' + 'dry'

     '*Frangula purshiana*' + 'stem bark' + 'tincture 1:5 in 35% E:W'

     '*Pulsatilla vulgaris*' + 'whole plant' + '6X'
   - Extracted herbal preparations are generally named using this format.

2) AHS
   - Example:

     'Orange Oil', as specified in the *British Pharmacopoeia* (BP).

3) AFN + food preparation code
   - Examples:

     'apple' + 'powder'

     'apple' + 'juice fresh'

The following sections describe these three methods for making an approved name for a herbal substance, as well as the naming of medicinally interchangeable substances.

4.2 Naming using AHN + plant part code + plant preparation code

4.2.1 AHN

The AHN is the botanical name of a plant species—for example, *Abies balsamea*. In the botanical name, the first word is the genus name and the second word is the species name (specific epithet); both words together (the Latin binomial) are needed to name the plant species. By international convention, the botanical name is written in italics, with the first letter of the genus name capitalised.

Where no AHN has been approved for a plant, a sponsor should propose one. Please refer to section 4.11 How to propose a herbal substance name for guidance on the correct procedure to follow to obtain a new AHN.

Approval of a new AHN does not imply approval of that plant for use in medicines. Refer to the *Australian Regulatory Guidelines for Complementary Medicines* <http://www.tga.gov.au/industry/cm-argcm.htm> for guidance on legislative and other requirements for registration and listing of medicines.

4.2.2 Plant part code

Plant part codes must be botanically correct and, where possible, also generally recognised terms.

Plant part codes are listed in the 'Plant part' code table on the eBS website. The herbal substances plant parts list in Appendix 1 provides guidance on the appropriate use of plant part codes. Some plant part names that have not been adopted by the TGA as plant part codes are also included in column 1 of the list for information.

Where no plant part code has been approved, please contact the TGA for advice and, where appropriate, for a plant part code to be created.

Selecting the plant part code

The name of the plant part should be obtained from the raw material supplier. Although the herbal substances plant parts list contains about 160 different plant part codes, most ingredients are made from one of the following parts:

- whole plant[5]
- herb[5]
- herb top[5]
- herb flowering[5]
- herb top flowering[5]

[5] The meaning of the term is interpreted more broadly by the TGA than under a strict botanical definition. An explanation of the meaning is given under 'Definitions of plant part terms' in Section 4.2.2.

- leaf[5]
- flower[5]
- fruit[5]
- seed[5]
- stem
- twig
- root[5]
- rhizome
- root and rhizome
- stem bark
- root bark
- stem wood
- root wood

For plant parts that are not listed above, check column 1 in the herbal substances plant parts list:

- If the plant part is in column 1 and
  - there is only one plant part code in column 2, use that term
  - there are two or more plant part codes in column 2, select the correct term; if column 2 says 'refer ...' look up each of the cross-reference entries and then select the correct term.
- If the supplier's name for the part is not in column 1, contact the TGA to find out if this is a new plant part.

Ensure that the term selected accurately describes the part(s) used and that all parts named are present in every batch of the product.

Using the plant part code

Product applications

The appropriate term in bold in column 2 must be used in product applications. Approved names for products listed in the ARTG are usually brief or abbreviated, and the word order is always the same (e.g. 'herb top fl.').

Product labels

Any appropriate term in column 3 or a term in bold in column 2 may be used on product labels. Although label AANs need to be generally recognised and botanically correct terms, they can differ from the approved name used in the ARTG in the following ways:

- Special names may be used, provided that they are correct. 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').
- Word order can be changed and words can be written in full to achieve plain English (e.g. 'flowering herb top').
- Simplifications may be approved in column 3 (e.g. 'flowering tops').

Further information on product labels is provided below (under 'Additional information on labels').

Combinations of plant parts

It is only acceptable to use more than one plant part where there is an approved code for that combination—for example, 'root & rhizome', 'whole plant' and 'herb fruiting'. In this case, every part in that combination should be used in every batch of the product. **It is the sponsor's responsibility to ensure that the product has a consistent medicinal activity.** This can mean that, where combinations of parts are approved, each part should be used in similar proportions in each batch.

Where there is **not** a code for a certain combination of plant parts (e.g. 'leaf & root'), two **separate ingredients** must be named. For example:

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

Applications can be made for two or more plant parts of a certain herb species to be allowed to be interchanged (see 'Changing the plant part', below, and Section 4.5).

Changing the plant part

In general, a change in the plant part(s) constitutes the use of a different ingredient, creating a **separate and distinct** good under s. 16 of the *Therapeutic Goods Act 1989*. This will influence the type of request needed to vary an entry to a listed complementary medicine (see the *Australian Regulatory Guidelines for Complementary Medicines* <http://www.tga.gov.au/industry/cm-argcm.htm>).

An alteration in the **expression** of the plant part, where there is no change in the part(s) used, is not a change of ingredient.

If the sponsor can demonstrate that a change in plant part is botanically minor and medicinally insignificant, the TGA may consider accepting the new herbal substance as an interchangeable ingredient (see Section 4.5). Since this type of interchangeable ingredient does not involve any change in the herb species, a less detailed submission than that described in Section 4.5 could be sufficient.

Definitions of plant part terms

Explanations of the meanings of TGA standard terms for plant parts are provided below.

'**Flower**' refers both to flowers alone and to whole inflorescences, including branching flower stalks.

- Where present, leafy bracts may be included.
- Where leaves and stems are also included, use '**herb flowering**' or '**herb top flowering**'.

'**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 leaves and stems are also included, use '**herb fruiting**' or '**herb top fruiting**'.
- Refer to the herbal substances plant parts list for guidance on the correct optional use, on labels, of terms such as '**pod**', '**capsule**', '**nut**' and '**berry**'.
- Fruits that contain very little tissue other than the seeds are described in some pharmacopoeias as a fruit and in others as seeds. For the 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**', and on labels as either 'fruit' or 'seed'. Fruits that are usually described in pharmacopoeias as seeds should be named as '**seed**'—for example:
  - single-seeded caryopsis, such as in the Graminae/Poaceae (grass) family, which includes wheat, rice, oats and corn
  - four-seeded carcerulus schizocarps, such as in the Labiatae/Lamiaceae family, which includes mint and basil, and the Boraginaceae family, which includes comfrey and borage
  - many-seeded lomentum schizocarps, such as pea pods that fragment
  - single-seeded achenes, such as in buttercup
  - cypselas with no pappus, such as in some Compositae/Asteraceae.
- 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**' in the product application, with the option of '**berry**' on the label.

Fungi: Use '**mushroom**' to refer to the mushroom-shaped spore-bearing bodies of basidiomycetes, and use '**fruiting body**' to refer to all other types of spore-bearing bodies of fungi.

'**Herb**' refers to 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.

- Where the plant is immature, consider using '**sprout**' and '**herb young**'.
- Where flowers are always present and fruits are rarely present, use '**herb flowering**'.
- Where fruits are always present and flowers are rarely present, use '**herb fruiting**'.
- Where flowers and fruits are always present, use '**herb flowering fruiting**'.

'**Herb top**' refers to the terminal ends of the branches when only vegetative parts are present at harvesting—that is, the reproductive structures of flowers and fruits are not present.

- Where the plant is a tree or woody shrub, use '**leaf & twig**'.
- Where flowers are always present and fruits are rarely present, use '**herb top flowering**'.
- Where fruits are always present and flowers are rarely present, use '**herb top fruiting**'.

- Where flowers and fruits are always present, use '**herb top flowering fruiting**'.

'**Leaf**' refers to the leaf blade, leaf stalk, axillary bud and stipules. In compound leaves, the branching stalks between leaflets are included. 'Leaf' may also be used to describe the leaf like structures of simple plants such as mosses.

- Where stems, branch ends, flowers or fruit are included, refer to '**herb**', '**herb top**' and related terms.
- Where the leaf has a specialised form, more accurate terms should be used—for example, '**clove**' and '**bulb**'.
- For seaweeds, use '**thallus blade**' in product applications and '**blade**' or '**frond**' on labels.

'**Root**' refers to all or most of the rooting system, such as fibrous roots and tap roots with any lateral roots and nodules.

- Where only some of the rooting system is used, consider '**root lateral**', '**root aerial**' or '**root nodule**'.
- Where an underground stem is also used, name each part (e.g. '**root & rhizhome**').

'**Stem**' refers to the central stem(s) and the branches.

- Where the stem has a specialised form, more accurate terms should be used—for example, '**corm**', '**rhizome**', '**stolon**' or '**tuber**'.
- Where other plant parts are included, refer to '**herb**', '**herb top**', '**whole plant**' and related terms.

'**Whole plant**' refers to the entire plant body, such as aerial and underground plant parts; for fungi, it refers to hyphae (mycelia) and fruiting bodies; and for seaweeds, it refers to the entire thallus (i.e. holdfast, stipe, blades/fronds and reproductive structures).

- Where only aerial parts are used, refer to '**herb**', '**herb top**' and related terms.

4.2.3 Plant preparation code

Plant preparation codes are listed in the 'Plant preparation' code table on the eBS website. The herbal substances plant preparations list in Appendix 2 provides guidance on the appropriate use of plant preparation codes. The list has four columns of terms for use in product applications and a column containing simple terms that can be used on labels.

Where the preparation is a type of extract (other than an oil), the complete plant preparation code identifies whether the raw material used to make the extract is 'fresh' or 'dry'.

Some plant preparation names that have not been adopted by the TGA as plant preparation codes are also included in column 1 of the herbal substances plant preparations list for information.

Where no plant preparation code has been approved, please contact the TGA for advice and, where appropriate, for a plant preparation code to be created.

Product applications

In product applications, plant preparation codes can be a single term, such as 'fresh', 'dry', 'powder' and 'oil essential'. However, the complete plant preparation name for non-oil extracts has three or four parts:

- the type of preparation—for example, 'ext. dry conc.'
- the extraction ratio and solvent details—for example, '(3:1 in 55% E:W [ethanol in water])'; excipient ingredients are named completely without solvent details
- the type of raw material[6] used—for example, 'dry' or 'fresh' (preceded by 'EQUIV.', the AHN and the plant part code); 'EQUIV.' means 'equivalent to'
- where standardised, the name of the component against which the preparation is standardised; the name is an Australian Approved Name (chemical) (AAN), preceded by 'EQUIV.' (e.g. 'EQUIV. hypericin') or an HCN preceded by 'EQUIV.' and the AHN—for example, 'EQUIV. hyperforin (of *Hypericum perforatum*)'.

These four parts are described in detail in subsequent sections.

Product labels

On product labels, plant preparation codes are much simpler. The label AAN for the preparation type is often a single word (e.g. 'extract'). The raw material used is usually identified without repeating the herb species or plant part names. It is often possible to avoid repetition of ingredients by using an introductory line, such as 'Contains extracts equivalent to dried:'. It is recommended that neither the extraction ratio nor the solvent details are included on product labels.

Where the above guidelines have been followed and label space is still limited, certain abbreviations are approved to name the preparation type on labels. Abbreviations should be selected in the order shown in the herbal substances plant preparations list in Appendix 2 (e.g. 'extract stand.' should be used in preference to 'ext. stand.').

Characteristics of plant preparation codes used in product applications and on product labels are described in the following text.

Selecting the plant preparation code

Details of the plant preparation should be obtained from the raw material supplier. Ensure that the term selected accurately describes the preparation used and that only the preparation named is used in each batch of the product.

Find the preparation type (e.g. 'tincture' or 'oil fixed') in column 1 of the herbal substances plant preparations list.

The abbreviations in Table 4.1 should be used in product applications and may be used to name ingredients on labels.

[6] Where additional label claims are made, the product application may need to include additional statements of fresh or dry weight equivalence and of component content.

Table 4.1 Abbreviations for plant preparation codes

Preparation type	Abbreviation
concentrated	conc.
decoction	decoc.[a]
dissolved	diss.
distillate	dist.
essential	ess. [a]
extract	ext. [a]
fixed	fix. [a]
infused	inf. [a]
liquid	liq.
standardised	stand.
tincture	tinct. [a]

a On labels, abbreviate only where space is restricted.

Extraction ratio

Where the ingredient is extracted, the final extraction ratio is usually required. This will be indicated in column 2 of the herbal substances plant preparations list. For preparations that are 'concentrates', the final extraction ratio should be expressed in the form 'x:1' and a dilute preparation as '1:x', as described below.

The concentration of preparations such as tinctures, extracts, spagyrics, infusions and decoctions should be given as the ratio of the weight of the herbal material used to the quantity of the final preparation of the ingredient. For example, where 2 kg of dry plant material is used to make 1 L of extract, the extraction ratio is 2:1.

Units for quantities of the raw herbal material and the final preparation to derive the extraction ratio are shown in Table 4.2.

Table 4.2 Units used to derive extraction ratio

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

Dry herbal material

In most cases, the herbal material is dried before further stages in commercial manufacture. The extraction ratio is assumed to express the dry weight of the raw material. Examples are shown in Table 4.3.

Table 4.3 Examples of extraction ratios for dry herbal material

Extraction ratio	Meaning	Examples
1:10	1 part of dry herb is used to make 10 parts of preparation	1 g of dry herb is used to make 10 mL of tincture
1:1	1 part of dry herb is used to make 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	3 parts of dry herb is used to make 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

Fresh herbal material

Where fresh herbal material is used as the starting material, the extraction ratio is stated in terms of the fresh weight of herbal material used. Examples are shown in Table 4.4.

Table 4.4 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

Range in extraction ratio

In some circumstances, approval may be given for a single ingredient to encompass a limited range of extraction ratios. In such cases, there should be no change in the herb species, plant part(s), type and concentration of solvents, type of diluents used or equivalent dry/fresh weight. The quantity of the diluent may vary, and this should be indicated as a range when quantifying the product excipients, as shown in Table 4.5.

Table 4.5 Examples of ranges in extraction ratios

Extraction ratio	Meaning
1:8–10	1 part of dry herb is used to make 8 to 10 parts of preparation
fresh 2–3:1	2 to 3 parts of fresh herb is used to make 1 part of a concentrated preparation

Solvent

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. These will be indicated in column 3 of the herbal substances plant preparations list. For preparations that are infusions or decoctions (defined below, under 'Definitions of plant preparation terms'), the solvent is always water and this need not 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'.

Product applications

In product applications, the name and relative proportion of solvent(s) used in extraction should be stated for active ingredients. The solvent details should be written in the brackets following the extraction ratio—for example, (5:1 in 45% E:W). Any residual solvents should also be named and quantified as excipients.

If there is inadequate space to describe the solvent(s) within the 'name' line of the product application, this information should be attached as a signed statement, clearly identifying the ingredient(s) to which the solvent(s) relate.

Product labels

Solvent details need not be given on labels. Approval is required to disclose any excipients on the label, including residual solvents. Disclosure of product alcohol content on labels is recommended, and approval is given routinely.

Solvent abbreviations

The solvent name abbreviations shown in Table 4.6 may be used only in conjunction with the extraction ratio; where no abbreviation is given, an AAN should be used. Note that some of these solvents are potentially dangerous, and must be completely eliminated from the final herbal substance.

Table 4.6 Solvent abbreviations for use with extraction ratio

Solvent	Abbreviation
acetone	acet
alcohol	OH
aqueous (water)	W
benzene	benz
carbon dioxide	CO_2
ethanol	E
ether—solvent	ether
glycerol (glycerin)	glyc
methyl ethyl ketone	MEK
propylene	pr-gl
toluene	tol
water—potable	W
water—purified	W

The relative solvent concentrations should be stated as percentages, as shown in Table 4.7.

Table 4.7 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 of approved names for extraction ratios and solvents are given in Table 4.8.

Table 4.8 Examples of approved names for 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

Quantifying herbal substances

Product applications

Product applications should state, on separate lines, the quantity or strength of:

- the preparation in the product
- the equivalent dry or fresh weight of the herbal raw material, where the substance is an extract, tincture, spagyric, infusion or decoction
- the standardised active component, where applicable

Product labels

It is not necessary to quantify the preparation, raw material or active component on the product label.

Units

Metric units should be used, as follows:

- With discrete dosage forms, give the quantity per dosage unit—for example, '250 mg' per tablet, '1.1 mL' per capsule.
- With non-discrete dosage forms, give the strength per mg or mL—for example, '250 mg/g' of powder, '300 microlitre/mL' of liquid.
- Where there is only one ingredient in the product, use '1 g/g' or '1 mL/mL'.

Calculating the equivalent dry/fresh weight

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 mg
- quantity of dry extract in mg gives dry/fresh weight in mg

Examples are shown in Table 4.9.

Table 4.9 Examples of calculation of equivalent dry/fresh weight from extraction ratio

Name		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

Where a range of extraction ratios has been approved, an extract would be expressed as in the example in Table 4.10 for the product application.

Table 4.10 Example of calculation of equivalent dry/fresh weight from range of extraction ratios

Name		Extraction ratio	Quantity of extract/tincture	Equivalent dry/fresh weight
Frangula purshiana stem bark ext. liq. conc. (3–2:1 in 45% E:W)	EQUIV. *Frangula purshiana* stem bark dry	3–2:1	400–600 mg	1.2 g[a]

a Note that the equivalent dry weight is 1.2 g per dosage unit, for both 400 mg of (3:1) extract and 600 mg of (2:1) extract.

Raw material name

Where the ingredient is a non-oil extract or a juice concentrate, the type of raw material used to make the ingredient should be named as indicated in column 4 of the herbal substances plant preparations list. Choose the appropriate term from 'dry', 'fresh', 'juice dry' or 'juice fresh'.

The type of raw material used is part of the plant preparation code, and the quantity used is a measure of the strength of the ingredient.

This information is given as a separate statement, which repeats the AHN and plant part code—for example, 'EQUIV. *Lavandula angustifolia* subsp. *angustifolia* herb top fl. fresh'.

Some sponsors choose to make a product claim about the amount of dry or fresh weight of raw herbal material that would be needed to make the ingredient. For instance, where an ingredient is made from dry herbal material, an equivalent fresh weight claim could be made (or vice versa). Similarly, the name of an oil ingredient usually does not need to include either a dry or a fresh weight equivalence statement, but the sponsor could choose to make claims about one or both of these. In these cases, the claims should be included in the product application statement of the herbal ingredient, using the same format as in the example above.

Using the plant preparation code

Product applications

In product applications, the plant preparation code is built up using the appropriate term in column 2 of the herbal substances plant preparations list, followed by the information from columns 3, 4 and 5. For example, 'powder' could be the complete plant preparation code. In contrast, where a standardised extract is used, the complete plant preparation code could be:

- *Arctostaphylos uva-ursi* ext. dry conc. stand. (6:1 in 35% E:W)
  ... EQUIV. x mg dry
  ... EQUIV. x mg arbutin

Product labels

On product labels, the plant preparation code is built up using the appropriate term in column 6, followed by the information indicated only in columns 4 and 5. In the first example, 'powder' would also be the complete plant preparation label AAN. In the second example, the plant preparation code could be:

- *Arctostaphylos uva-ursi* extract standardised
  EQUIV. x mg dry
  EQUIV. x mg arbutin

On labels, the herb species name and plant part need not be repeated, and the word order may be changed to achieve plain English. The above example could become:

- 'Contains *Arctostaphylos uva-ursi* extract equiv. to dry leaf x mg standardised to contain x mg arbutin',[7] or

- 'Contains standardised extracts equivalent to dried:
  Arctostaphylos uva-ursi leaf x mg
  (EQUIV. arbutin x mg)'.

Combinations of plant preparations

It is usually **not** acceptable to combine plant preparations.

However, where there is no cell structure to affect bioavailability, 'dry' and 'powder' preparations are considered to be the same preparation. For example:

- the AHS 'Acacia' refers to either dry or powdered preparations of the gum

- 'juice dry' refers to dry or powdered juice

- 'extract dry' refers to dry or powdered extracts

[7] As one of several ingredients

Changing the plant preparation

In general, a change in the plant preparation constitutes the use of a different ingredient, creating a **separate and distinct** good under s. 16 of the *Therapeutic Goods Act 1989*. This will influence the type of application required for making changes to listed medicines (see the *Australian Regulatory Guidelines for Complementary Medicines* <http://www.tga.gov.au/industry/cm-argcm.htm>).

Where the ARTG record names a range in extraction ratios, extracts made from the same herb species and the same plant part, extracted with the same solvent(s) and with the solvents in the same relative concentration, may be used interchangeably, provided that:

- if not standardised, the equivalent dry or fresh weight of the raw material herb used is the same; or
- if standardised, the quantity of the standardised component is the same.

Definitions of plant preparation terms

Common plant preparation types are defined below. In these definitions, 'herbal material' refers to the fresh or dry plant part(s) used as raw material.

'**Decoction**' refers to an aqueous extract obtained by boiling the herbal material—usually hard plant parts, such as roots, bark and woody fruits—and decanting, straining or filtering to separate the fluid. (Compare with 'infusion'.) Ethanol and glycerol are often used as preservatives.

'**Dry**' preparation refers to a preparation in which the herbal material is dried but not powdered. The material is often cut and crushed (comminuted), but remains identifiable under close visual inspection.

'**Extract**' refers to a preparation that contains herbal material obtained by dissolving the components in suitable solvent(s). Extracts are usually concentrated by evaporating some or all of the solvent, with or without subsequent dilution with an inert solid, to achieve the desired concentration. (Compare with 'tincture'.)

- A '**concentrated extract**' is prepared from more than 1 part of the dry herbal material for each 1 part of extract—for example, more than 1 g of dry herb is used to make each 1 mL of liquid extract or each 1 g of dry or soft extract.
- A '**dry extract**' is prepared by evaporating a liquid extract to dryness. The dried extract is often adjusted to the desired strength by dilution with an inert diluent such as lactose, starch or, where the dry extractive is liquefied by contact with air (deliquescent), the absorbent diluent, calcium phosphate.
- A '**liquid extract**' is prepared by either (a) maceration or percolation of the herbal material with suitable solvent(s) and separation of the fluid fraction, often by straining and filtering, or (b) addition of liquid diluent(s) to a soft or dry extract. In the case of (a), the liquid extract is usually concentrated to the desired strength by evaporating some of the solvent.
- A '**soft extract**' is prepared by evaporating the solvent from a liquid extract until a soft mass is obtained.

'**Infusion**' refers to an aqueous extract obtained by pouring water onto herbal material and allowing it to stand before decanting, straining and filtering. Usually, boiling water is used on herbal material that does not include hard or wood parts, and the mixture stands

for 10–15 minutes. (Compare with a 'decoction'.) Ethanol and glycerol are often used as preservatives.

'**Juice**' refers to a liquid obtained from plant parts with a high water content, by mechanical methods such as pressing.

'**Oil**' refers to a compound substance that is liquid at 20°C, insoluble or only slightly soluble in water, soluble in organic solvents, and prepared by pressing, distillation, extraction or other methods as defined in the Therapeutic Goods Regulations 1990.

- An '**essential oil**' is largely or completely composed of volatile oils, and is usually obtained via one or more distillations with steam, water alone, or water with alcohol. The essential oils of *Citrus* peels are obtained by pressing. *Citrus* juice 'essence' oils are distilled. Essential oil 'absolutes' are prepared by extraction in a non-polar solvent and a second extraction in alcohol. Volatile herbal oils are complex mixtures of hydrocarbons and oxidation products of hydrocarbons; they gradually evaporate at room temperature and are often aromatic.
- A '**fixed oil**' is non-volatile and is usually prepared from herbal material, such as seeds, by pressing or by extraction with a non-polar solvent such as hexane. Fixed oils are composed of lipids or lipid-soluble carbohydrates and are prone to becoming rancid on oxidation.
- An '**infused oil**' is initially absorbed from the herbal material, such as petals, into an oil or fat base, then recovered through successive extractions in alcohol to obtain a complex mixture, including oils, resins and oleoresins. Several methods may be used, including infusion into thin layers of oil to obtain a pomade (enfleurage), infusion into volatile oil carried in a current of warm air (pneumatic) and digestion in melted fat.

'**Powder**' refers to a preparation in which the herbal material is dried and ground to a powder. Seed flour is a powder. No plant fragments remain identifiable by visual inspection.

'**Spagyric**' refers to a combination of preparations made from the same herbal material, where the preparations are usually two or more of the following:

- essential oil
- tincture or extract, or a distillate of an extract or tincture
- spagyric ash—the ash obtained from combustion of a herbal residue following removal of active components through processes such as extraction and distillation; the whole ash or the water-soluble fraction of the ash is then combined with the products from each stage of preparation.

'**Tincture**' refers to an alcoholic or aqueous–alcoholic solution of herbal material, and is obtained by percolation or maceration of the herbal material in alcohol or a water–alcohol mixture. Usually, 1 part of the dry herbal material is used to make 4 or more parts of the tincture. Tinctures are sometimes obtained by dilution of a liquid, soft or dry extract. In contrast, 'extracts' are more concentrated, and 'infusions' and 'decoctions' are extracted in water.

4.3 Naming using AHS

The AHS is the only type of herbal ingredient name that is a complete approved name for the substance. Where it is appropriate to use an AHS, there is no need to add further details about the plant part and plant preparation. Although every AHS is linked to a monograph reference (e.g. BP93), this reference is not part of the AHS. For clarity, the first letter of each word in an AHS should be in capital letters.

Examples of AHSs are 'Angelica Root Oil', 'Benzoin Sumatra' and 'Garlic Bulb Powder'.

The ingredients database contains the full list of AHSs.

4.3.1 Selecting the AHS

An AHS may only be used to name an ingredient if the following three conditions are met:

- An AHS can only be accepted where the herbal material is derived from an Approved Herbal name (AHN) that is permitted for use in listed medicines.
- The ingredient is made from the herbal raw material specified in the 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.
- The 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. An oil is usually identified by physical characteristics such as optical rotation and specific density, chromatographic pattern and chemical identification tests.

If no AHS exists for a particular preparation of a particular part of a herb, in most cases, the substance can be named using the 'AHN + plant part code + plant preparation code' format, rather than the AHS; in these instances, the ingredient need not meet the description or standards of the monograph. However, **where there is an appropriate monograph in the current edition of a default pharmacopoeia, the herbal substance MUST comply with both the description and the standards set out in the monograph and the AHS should be used**.

Where no AHS has been approved for a herbal substance, sponsors may choose to propose one based on a suitable default pharmacopoeial monograph.

4.3.2 Using the AHS

Product applications

In product applications, the AHS should be stated exactly as it appears in the ingredients database.

Product labels

On product labels, the word order of the AHS may be altered if necessary to achieve plain English.

- Example: Where the product application would state 'Aloes Barbados Dry', the label may instead state 'Barbados Aloes Dry' or 'Dry Barbados Aloes'.

4.3.3 AHS reference monographs

Wherever possible, a relevant monograph in one of the default pharmacopoeias (including their supplements) listed in ss. 3 and 10 of the *Therapeutic Goods Act 1989* serves as the standard for substances used in medicines, including AHSs. See Section 1.8 for further information on default pharmacopoeias.

Where there is no relevant monograph in the default pharmacopoeia, an earlier edition or another suitable pharmacopoeial reference may be used. To be suitable as a basis for naming AHSs, pharmacopoeias should:

- provide a description of the source material and method of preparation
- give detailed identification characteristics of the substance
- be written in English and be readily accessible in Australia
- preferably, have been published in a recent edition.

4.4 Naming using AFN + food preparation code

In most cases, the name of a plant food excipient is composed of the main food name (AFN) and an approved food preparation code that is allowed to be used with an AFN (see below)—for example, 'walnut oil'.

It is unlikely that new AFNs will be approved, because this format of naming herbal substances has been superseded; however, sponsors will be able to use the names that already exist in this format. Use of Latin binomials is preferred to use of AFNs.

4.4.1 AFN

AFNs:

- may only be used to name ingredients that are included as food excipients—they are unsuitable for naming active ingredients because of their broad definition and the absence of a pharmacopoeial monograph to describe the identification characteristics of each substance
- refer only to edible substances fit for human consumption as food.

AFNs name the herb species (one or more) that may be used to obtain the edible food substance, the plant part(s) and, in some cases, the preparation. They have the following characteristics:

- Where the genus is named without a particular species being indicated, any species (one or more) in that genus may be used. Where 'hybrids' are included, these may be any hybrid cultivars that have at least one parent species named in the AFN description—for example, *Brassica oleraceae* var. botrytis (cauliflower).
- Sometimes the food preparation name is included in the AFN—for example, 'walnut **oil**' and 'apple **cider vinegar**'. In these cases, the preparation name should not be repeated.
- Where the preparation is not specified in the AFN, a food preparation code needs to be added to complete the name—for example, apple (AFN) + fresh (food preparation code) = apple fresh.
- To help distinguish them from AHSs, AFNs do not have capitals.

4.4.2 Food preparation code

Only certain preparations—fresh, dry and powdered plant material, and fresh, dry and concentrated juices—may be named with most AFNs. Juice preparations may only be named where the fresh plant part has a high water content.

Only the following food preparation names are approved codes:

- dry
- fresh
- juice dry
- juice fresh
- juice concentrate
- oil
- powder

For example, the AFN 'apple', defined as 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)

Other food preparations may be named with an AFN only where there is a particular AFN for that preparation. For example, both 'walnut oil' and 'walnut' are AFNs. Note that 'walnut oil' is a complete approved name, whereas 'walnut' must be completed with the food preparation code. AFNs are not, in general, adopted for extracted preparations other than oils.

On product labels, where appropriate, there are some acceptable alternatives for terms in names of food excipients. You may:

- substitute 'flour' (e.g. wheat flour) or 'meal' (e.g. almond meal) for 'powder'
- substitute 'dried' for 'dry'
- substitute 'juice powder' for 'juice dry'
- write the plant part in the plural (e.g. 'flowers')
- vary the word order to achieve plain English

4.5 Medicinally interchangeable species

The TGA recognises some groups of medicinally interchangeable species (MISs). In these groups, any one herbal species or any combination of the herbal species in the MIS group may be used to make the ingredient. Each batch of the product may be made using a different selection from the approved MISs.

- Example: In the *Drosera* MIS group, '*Drosera rotundifolia* MIS whole plant fresh' indicates that, in any batch, the fresh whole plant of any one or any combination of the following four sundews may be used: *D. rotundifolia*, *D. intermedia*, *D. anglica* and *D. ramentacia*.

The name of an ingredient with a MIS name is in the format: herb species AHN (from the MIS group) + 'MIS' + plant part code + plant preparation code.

- Example: If the powder of the flowering herb is used from the *Thymus* MIS group, complete approved names include '*Thymus vulgaris* MIS herb fl. powder' and '*Thymus zygis* MIS herb fl. powder'.

4.6 Common names

The use of common names of herbal species is generally not permitted for approved names because a common name cannot be used to positively identify the correct herb species. However, a limited range of common names are allowed, where they help to distinguish between several closely related species, subspecies, varieties and cultivars (e.g. *Brassica oleracea*, whose cultivars include cabbage, broccoli and cauliflower); common names are listed as synonyms in the ingredients database.

On labels that require use of approved names, sponsors may use a common name in addition to the complete approved name. In such circumstances, the common name should be selected from those in the ingredients database. It should correctly represent that species and reflect common usage and understanding in Australia—for example, *Polygala senega* (Senega), *Azadirachta indica* (Neem).

4.7 Component HCN or AAN

Where an ingredient is claimed to be standardised, the component used as the marker for standardisation must be stated as part of the complete plant preparation code. The quantity of that chemical component is a measure of the strength of the ingredient. The component is named with an HCN or AAN (from the ingredients database).

This information is given as a separate statement—for example, 'EQUIV. echinocoside'.

Some sponsors choose to make a product claim about the amount of one or more components in a herbal ingredient that is not standardised. These claims should be included in the product application statement of the herbal ingredient, using the same format as in the example above. However, in this case, the preparation should not be claimed to be standardised or include 'stand.' in the name.

4.8 Additional information on labels

On product labels, sponsors may include extra information about herbal ingredients (that is, in addition to the complete approved name), including plant parts and plant preparations, provided that all the information required under the labelling order (Therapeutic Goods Order No. 69—General requirements for labels for medicines) is present, and the additional information is both correct and unlikely to mislead consumers.

Where the additional label information indicates that the ingredient is unusual in some way, this information should also be stated in the product application. For example:

- if a label claim is made that the *Echinacea* is 'biodynamically grown' or that only 'mature' rhizome is used, this should also be stated as part of the ingredient name in the product application
- if a label claim is made that the dry preparation is 'freeze dried', this should also be stated as part of the ingredient name in the product application.

Where the additional label information does not indicate that the ingredient is unusual in any way for the particular herb species, this information need not be stated in the product application. For example, if a label claim is made that the ingredient is made from the 'flowering rosette herb' of *Taraxacum officinale* (dandelion) or the 'vine stem' of *Lonicera japonica*, the usual names, 'herb fl.' and 'stem', are sufficient to name the plant parts in the product application.

Considerations for additional label claims include the following:

- A **common name** may be used, but should
  - correctly represent either the herbal substance (e.g. borage oil, starflower oil) or the herb species (e.g. black cohosh, willow)
  - reflect common usage and understanding in Australia.
- An additional HCN:
  - may be used where it is a correct synonym of the HCN used (e.g. xanthophyll [lutein])
  - may be used where it is an approved label HCN (e.g. 'lignans' for 'lignans calculated as secoisolariciresinol diglucoside [of *Linum usitatissimum* seed]')
  - may **not** be used where the component is quantified on the label or in the indications.

4.9 Herbal components names list

Approved names for components of herbal ingredients (HCNs) can be found on the eBS website. These names should be used in product applications and on labels where names are required to identify marker components of standardised herbal ingredients and where claims are made about the strength or concentration of components in herbal ingredients. HCNs are not stand-alone names and should only be used in conjunction with an AHN that has been approved for use in medicines.

Both AANs and HCNs may be used to name components that are part of herbal ingredients.

HCNs can name:

- single chemicals, such as 'cascaroside A'
- groups of chemicals, such as 'cascarosides calculated as cascaroside A', 'proanthocyanadins calculated as ptocyanadin B1 (of *Vaccinium macrocarpon*)', 'hydroxyanthracene derivatives calculated as cascaroside A' and 'hydroxyanthracene glycosides calculated as cascaroside A'.

HCNs and AANs should only be used to name a component of a herbal ingredient if the component complies with the physical and chemical identification characteristics set out in the reference monograph. Where a group of chemicals is named, it is common for the monograph to set out the relative proportion of component chemicals.

4.10 Eligibility of herbal substances for entry in the Australian Register of Therapeutic Goods

This section provides key points about the status of herbal ingredients in the ARTG.

4.10.1 Registrable substances under the Therapeutic Goods Regulations

Some herbal substances are not eligible for inclusion as active ingredients in a listed product because they are named in the Therapeutic Goods Regulations, Schedule 4, Part 4. If an excipient role is proposed for such ingredients, they would usually be considered unsafe for inclusion in a listed product.

Some herbal substances are excluded from the Regulations, Schedule 4, Part 4, at certain very low recommended daily doses and so may be included in listed products. This is usually where the recommended daily dose is equivalent to 1 mg or less of the dry raw herbal material used to make the ingredient.

4.10.2 Registrable (scheduled) substances

Some herbal substances are not eligible for inclusion as an active or excipient ingredient in a listed product because they are included in one of the schedules to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

Some herbal substances are excluded from the SUSMP (or its appendices) if the ingredient is in a very low concentration in the product; the substance may then be included as an ingredient in a listed product. Most often, this is where the scheduled herbal substance or component is in a concentration equal to or less than 10 micrograms of the substance per gram or millilitre of the product (i.e. 10 mg per kg or L). This is equivalent to, or more dilute than, a 5X homoeopathic potency, measured according to the *Homoeopathic Pharmacopoeia of the United States*. For more information, refer to the relevant sections of the SUSMP.[8]

Some homoeopathic ingredients that are not included in schedules in the SUSMP may be included in listed products as homoeopathic preparations where the active ingredient is homoeopathically prepared and is more dilute than a 1000-fold dilution of a mother

[8] <http://www.tga.gov.au/industry/scheduling-poisons-standard.htm>

tincture. For more information, refer to the Therapeutic Goods Regulations, Schedule 4, Part 1.

4.10.3 Homoeopathic substances

Some herbal substances may not, in general, be used in therapeutic goods as a result of the herbal substance or a component being included in Appendix C of the SUSMP (substances that are prohibited from sale, supply and use because of their danger to health).

These herbal substances may possibly be included in listed and registered products where the preparation is of acceptable preparation and dilution—that is, where the herbal substance is prepared homoeopathically and is a 12X or a greater dilution when measured according to the *Homoeopathic Pharmacopeia of the Unites States* (i.e. usually equal to or more dilute than 1 nanogram of the ingredient per gram or millilitre of the product).

4.11 How to propose a herbal substance name

The expression of herbal ingredients in complementary medicine applications involves several types of approved names and codes, as shown in Table 4.11.

Table 4.11 Types of approved names and codes used for herbal ingredients

	Type of approved name or code	Examples
1	AHN	*Vaccinium macrocarpon*, *Polygala senega*
2	Plant part code	fruit, seed
3	Plant preparation code	extract soft, powder
4	AHS	Orange Oil; Psyllium Husk Dry
5	AFN	cabbage, mustard seed oil
6	HCN	anthocyanosides, catechin (of *Vitis vinifera*)
7	AAN[a]	Citrus bioflavonoids extract, Zeaxanthin

a That defines an active component

Proposals for the first six types of names or codes are the responsibility of the Herbal Ingredient Names Committee (HINC). Proposals for active component AANs are considered by the Australian Approved Names Committee.

Applicants for a new herbal substance name must complete an application form (with supporting documentation attached) for the proposal of a new AHS <http://www.tga.gov.au/industry/cm-forms-ahs.htm>, AHN <http://www.tga.gov.au/industry/cm-forms-ahn.htm>, or HCN <http://www.tga.gov.au/industry/cm-forms-hcn.htm>.

There are no application forms for proposing new AFNs, plant part codes or plant preparation codes. A sponsor intending to apply for any of these should contact the HINC Secretariat at:

HINC Secretariat
Office of Complementary Medicines
Market Authorisation Group
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606
AUSTRALIA

5 Approved terms for containers, dosage forms, routes of administration, and units of measurement

Australian approved terms have been created to describe the way a medicine is presented as a product—these terms cover container types, dosage forms, routes of administration and units of measurement. Designating Australian approved terms ensures consistency in the use of these terms across all medicine products.

Current approved terms, with detailed definitions, can be accessed in the code tables on the TGA eBusiness Services (eBS) website <http://www.ebs.tga.gov.au>. When making an application to the TGA for a particular product, sponsors should use an approved term relevant to the presentation of the product. If they wish to use a term that is not in one of the code table lists, they should contact the TGA for advice.

Many types of dosage forms, routes of administration and units of measurement can only be used in registered medicines, and are not suitable for use in listed medicines. The following sections list terms that are applicable for use in listed medicines.

5.1 Container types

The terms listed in the 'Container code' table on the eBS website are used to describe containers that hold medicines (immediate containers). The full list of approved terms to describe container types, with definitions, is in the 'Container Code' code table on the eBS website; all of these terms can be used to describe registered medicines. The following approved terms for container types can be used in listed medicines.

Definitions of container types in the code tables are for guidance only; they are intended to be independent of the material used to make the container and the size of the container, although the examples may refer to specific materials. Formal definitions are not provided for container types whose names have a well-understood meaning.

Approved terms for container types for use in listed medicines are:

- aerosol can
- aerosol can—metered dose
- aerosol—pump actuated
- aerosol—pump actuated metered dose
- ampoule
- bag
- blister pack
- bottle
- bottle, with integral pump—manual actuated
- carton
- cartridge
- compact
- dial dispenser pack
- dispenser pack
- inhaler—dry powder
- jar/can
- puffer pack
- sachet
- shrink wrap
- spray—elasticity driven
- strip pack
- tea bag
- tube
- wrapping

5.2 Dosage forms

The full list of approved terms to describe dosage forms, with full definitions, is in the 'Dosage forms' code table on the eBS web site; all of these terms can be used to describe registered medicines. The following approved terms for dosage forms can be used in listed medicines:

- application
- bar, soap
- block
- capsule, enteric
- capsule, hard
- capsule, modified release
- capsule, soft
- capsule, soft enteric
- collodion
- cream
- drug delivery system, transdermal
- ear drops, emulsion
- ear drops, powder for
- ear drops, solution
- ear drops, suspension
- enema
- essential oil
- extract
- extract, concentrated
- extract, dry
- extract, liquid
- extract, soft
- gel
- granules
- granules, effervescent
- granules, enteric coated

- granules, modified release
- gum, chewing
- herb, dried
- inhalation
- inhalation, conventional
- inhalation, powder for
- inhalation, pressurised
- insufflations
- liniment
- liquid, multipurpose
- lotion
- lotion, powder for
- lozenge
- mouthwash
- nasal drops, emulsion
- nasal drops, powder for
- nasal drops, solution
- nasal drops, suspension
- ointment
- oral liquid
- oral liquid, emulsion
- oral liquid, powder for
- oral liquid, solution
- oral liquid, suspension
- pad, impregnated
- paint
- paint, concentrated
- paint, powder for
- paste
- pastille
- patch, dermal
- pessary
- pessary, compressed
- pessary, modified release
- pessary, moulded
- pessary, shell
- pill
- powder
- powder, dusting
- powder, oral
- slice
- solution
- solution, powder for
- spray
- spray, nasal
- spray, pressurised
- spray, solution
- spray, suspension
- stick
- stick, lip
- suppository
- suppository, compressed
- suppository, moulded
- suppository, shell
- suspension
- suspension, powder for
- tablet, chewable
- tablet, dispersible
- tablet, effervescent
- tablet, enteric coated
- tablet, film coated
- tablet, gelatin coated

- tablet, modified release
- tablet, multilayer
- tablet, orally disintegrating
- tablet, soluble
- tablet, sugar coated
- tablet, uncoated
- tea

Some approved terms to describe dosage forms are also known by other names (synonyms). Common synonyms are listed in Table 5.1. These synonyms are not to be used to describe the dosage form for registered or listed medicines.

Table 5.1 Synonyms for dosage forms

Approved dosage form	Synonym (not to be used)
Cement, medicated	Cement, bone Cement, dental
Dressing, medicated	Dressing, impregnated
Drug delivery system, ocular	Sac, eye
Drug delivery system, transdermal	Patch, transdermal
Ear drops Eye drops Eye and ear drops Nasal drops	Drops
Gel	Jelly
Inhalation, pressurised	Aerosol for inhalation, metered dose
Oral liquid	Drops, oral Mixture Syrup
Paste	Poultice
Pessary, shell	Capsule, vaginal
Spray, pressurised	Aerosol
Suppository, shell	Capsule, rectal
Various dosage forms (e.g. oral liquid, application)	Tincture

5.3 Routes of administration

The full list of approved terms to describe routes of administration, with full definitions, is in the 'Routes of administration' code table on the eBS website. All of these terms can be used to describe registered medicines. The following approved terms for routes of administration can be used for listed medicines:

- buccal
- dental
- inhalation
- mucosal
- nasal
- oral
- oral application
- otic
- rectal
- sublingual
- topical
- transdermal
- vaginal

5.4 Units of measurement

The full list of approved terms to describe units of measurement is in the 'Units of proportion' code table on the eBS website. All of these terms can be used to describe registered medicines. The approved terms for units of measurement, with their definitions, that can be used in listed medicines are shown in Table 5.2.

Table 5.2 Approved terms for units of measurement

Unit	Description
Mass	
g	gram
g/g	grams per gram
mg	milligram
mg/g	milligrams per gram
microgram	microgram
microgram/g	micrograms per gram
ng	nanogram
ng/g	nanograms per gram
picogram	picogram

Unit	Description
picogram/g	picograms per gram
Volume	
L	litre
microlitre	microlitre
microlitre/g	microlitres per gram
mL	millilitre
mL/g	millilitres per gram
nanolitre	nanolitre
Concentration	
g/mL	grams per millilitre
mg/L	milligrams per litre
microgram/mL	micrograms per millilitre
ng/mL	nanograms per millilitre
picogram/mL	picograms per millilitre
microlitre/mL	microlitres per millilitre
mL/mL	millilitres per millilitre
nanolitre/mL	nanolitres per millilitre
Terms involving international units	
IU	international unit
IU/g	international units per gram
IU/mg	international units per milligram
IU/microgram	international units per microgram
IU/mL	international units per millilitre
Terms involving microbiological culture units	
billion CFU	billion colony forming units
billion CFU/g	billion colony forming units per gram

Unit	Description
billion CFU/mL	billion colony forming units per millilitre
billion organisms	billion organisms
billion organisms/g	billion organisms per gram
billion organisms/mL	billion organisms per millilitre
CFU	colony forming unit
CFU/g	colony forming units per gram
CFU/mL	colony forming units per millilitre
million CFU	million colony forming units
million CFU/g	million colony forming units per gram
million CFU/mL	million colony forming units per millilitre
million organisms	million organisms
million organisms/g	million organisms per gram
million organisms/mL	million organisms per millilitre
thousand CFU	thousand colony forming units
thousand CFU/g	thousand colony forming units per gram
thousand CFU/mL	thousand colony forming units per millitre
thousand organisms	thousand organisms
thousand organisms/g	thousand organisms per gram
thousand organisms/mL	thousand organisms per millilitre
Terms involving biological units	
ALU	acid lactase unit
ALU/g	acid lactase units per gram
CU	cellulase unit
CU/g	cellulase units per gram
DU/g	dextrinising units per gram
HUT	haemoglobin unit on the tyrosine basis
HUT/g	haemoglobin units on the tyrosine basis per gram

Unit	Description
LipU	lipase unit
LipU/g	lipase units per gram
RE	retinol equivalent
RE/g	retinol equivalents per gram
RE/microgram	retinol equivalents per microgram
RE/milligram	retinol equivalents per milligram
RE/millilitre	retinol equivalents per millilitre
thousand ALU	thousand acid lactase units
thousand ALU/g	thousand acid lactase units per gram
thousand CU	thousand cellulase units
thousand CU/g	thousand cellulase units per gram
thousand DU	thousand alpha-amylase dextrinising units
thousand DU/g	thousand alpha-amylase dextrinising units per gram
thousand LipU	thousand lipase units
thousand LipU/g	thousand lipase units per gram
thousand HUT	thousand haemoglobin units on the tyrosine basis
thousand HUT/g	thousand haemoglobin units on the tyrosine basis per gram
Miscellaneous units	
DU	dose unspecified
USP Unit	United States Pharmacopeial Unit
X	1/10 dilution

Appendix 1 Herbal substances plant parts list

The 'Plant part' code table on the eBS website provides approved names for plant parts. These names should be used where plant part terms are required to complete the approved name for a herbal substance in product applications and on product labels. The herbal substances plant parts list (Table A1.3) provides additional information about how to use the different plant part codes.

The list is presented in three columns, as indicated in Table A1.1. Table A1.2 explains the symbols used in the list.

Table A1.1 Structure and content of herbal substances plant parts list

Column	Content	Comment
1	Common usage and technical terms for plant parts, in alphabetical order	May or may not be suitable for use; refer to columns 2 and 3
2	Terms (in bold) for use in product applications or on product labels	Where more than one plant part code is suggested, select the appropriate term for the plant part used to make the ingredient
3	Terms for use on product labels	These terms are an optional alternative for labels only

Table A1.2 Key to the herbal substances plant parts list

Character	Meaning	Comments
refer	Refer to the term shown for more information	Caution is needed: alternative terms are suggested and usually include the correct code, but this is not always the case
~	Only use the term if it is applicable	For example, 'leaf or ~frond' in column 3 means that 'leaf' would usually be the appropriate code but that, in cases where the leaf is also termed a frond (such as in ferns), the label could state either 'leaf' or 'frond'
/	The term may be formed using any one of the given words	For example, 'seed skin/~bran' indicates that 'seed skin' and, in some circumstances, 'seed bran' are both acceptable codes

Character	Meaning	Comments
*	The meaning of the approved name is broader than the strict botanical definition	See comments under 'Definitions of plant part terms' in Section 4.2.2 of this document

Table A1.3 Herbal substances plant parts list

Plant part	Approved name: product application and label	Abbreviation for label
achene	**seed**	
aerial parts	refer ~herb, herb top (contrast with 'whole plant')	
aerial root	**root aerial**	aerial root, root
albedo (*Citrus* fruit)	white layer of fruit peel (mesocarp): **fruit peel inner**	fruit peel inner
adroecium	**stamen**	flower stamen
anther	**anther**	flower anther
antheridium	refer fruiting body	
archegonium	refer fruiting body	
aril	**seed aril**	aril
arillus	refer aril	
ascocarp	refer fruiting body	
balsam	• refer ~oil, ~oleoresin, ~resin, ~gum, ~gum-oleoresin • where not as above: add plant part from which balsam was derived e.g. **~gum/~sap/~stem balsam** and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~extract, etc.	
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**	rhiz. bark root bark bark twig bark
bark inner	state part, e.g. refer rhizhome/root/stem/twig	

Plant part	Approved name: product application and label	Abbreviation for label
	bark inner	
bark living	refer bark inner	
bark outer	state part, e.g. refer rhizhome/root/stem/twig bark outer	
bark dead	refer bark outer	
basidiocarp	refer mushroom entry under fruiting body	
bean	refer bean seed and bean pod	
bean pod	• with bean seeds: **fruit** • without bean seeds: **fruit pericarp**	pod, bean pod, fruit/legume pod [as above]
bean seed	**seed**	
berry	• where soft fruit of flowering plants: **fruit** 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** • where seed has a fleshy layer around the embryo, e.g. *Zanthoxylum*: **seed**	berry* berry
blade	• where leaf-like blade of seaweeds: **blade** • 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**	~frond
blossom	**flower**	
bough	refer branch	
bracket fungus	refer fungus	
bract	**bract** or **~seed husk**	flower bract
bran	**seed bran**	bran
branch	**branch, ~stem** or **~stem wood**	
branch terminal	• refer twig entries under 'herb top' • **branch terminal**	branch, terminal branch
branch terminal leafy	• refer twig entries under 'herb top' • **branch terminal leafy**	leafy branch leafy terminal branch

Plant part	Approved name: product application and label	Abbreviation for label
Bryophyte	refer: moss, liverwort, hornwort	
bud	**~leaf bud, ~flower bud**	~flower bud
bulb	**bulb**	
bulbus	refer bulb	
calyx	**sepal**	flower sepal
capsule	• where a moss capsule (sporangium): **fruiting 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** Do not use the label AAN 'capsule' for legume pods, follicle pods, siliqua and silicula	Capsule capsule
carcerulus	refer seed	
caryopsis	refer under 'fruit/seed'	
catkin	**flower**	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**	[may be left blank]
cellulose	refer fibre – dietary	
cereal grain	refer under 'fruit/seed'	
clove	**clove**	
cone	**fruit**	cone, ~strobile
corm	**corm**	
corolla	**flower petal**	petal
cortex	• where peelings, refer peel, ~fruit peel, ~skin, ~bark, ~bark outer • where parenchyma, refer: ~root pith, ~stem pith	
cotyledons	refer cotyledon	
cotyledon	**leaf cotyledon**	cotyledon

Plant part	Approved name: product application and label	Abbreviation for label
cremocarp	refer fruit/seed	
cypsela	**fruit**	
drupe	**fruit**	
embryo	**seed germ**	
embryon	refer shoot	
embryonic shoot	refer shoot	
endocarp	refer entry under 'fruit'	
endosperm	**seed endosperm**	~seed starch
endospermum	refer endosperm	
epidermis	refer skin, ~fruit skin entry under 'fruit'	
exocarp	refer entry under 'fruit'	
exocarpus	refer exocarp entry under 'fruit'	
fasciculus	refer vascular tissue	
fat	state part, e.g. ~seed, **~fruit flesh** and refer Herbal Substances Plant Preparations list 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**	leaf
fibre	• where dietary fibre or fibre cells, refer ~fruit/~stem/~root/ fibre, ~seed fibre, ~seed bran • where fibre cells: **~fruit skin fibre, ~root pith fibre, ~stem bark fibre,** etc. • where vascular tissue, refer vascular tissue	
fibrous root	with or without root hairs: **root**	fibrous root
filament	refer ~cell, ~leaf (needle), stamen filament, ~hyphae (of fungi), ~spine, ~thorn	
flavedo (*Citrus* fruit)	white layer of fruit peel (mesocarp): **fruit peel outer**	
flesh	refer: ~fruit flesh, ~root pith, ~stem pith, ~seed	

Plant part	Approved name: product application and label	Abbreviation for label
	endosperm	
flos	refer flower	
flower	• where whole flowers: **flower** • where a cluster of flowers (inflorescence) with included flower stalks (pedicels and peduncles) and any leafy bracts: **flower** COMPARE WITH 'HERB FL.' AND 'HERB TOP FL.' • where only a part of the flower, consider: - **flower stalk** (pedicel, peduncle, rachis, rachilla) - **bract** - **flower receptacle** - **sepal** - **petal** - tepal appearing as a sepal: **flower sepal** - tepal appearing as a petal: **flower petal** - **stamen** - **stamen filament** - **anther** - pollen collected by mechanical means: **pollen** - pollen collected by bees: use the Australian approved biological substance name 'Pollen' to name the substance - **ovary** - **style** - **stigma**	 flower stalk flower bract flower receptacle sepal, flower sepal petal, flower petal sepal, flower sepal petal, flower petal stamen, flower stamen flower filament anther, flower anther ovary, flower ovary style, flower style stigma, flower stigma
flower bud	**flower bud**	flower bud
flower bud resin	**flower bud resin**	flower bud resin
flower receptacle	**flower receptacle**	flower receptacle
flower stalk	**flower stalk**	flower stalk
flowering head	**flower**	flowering head
flowering herb	refer entries under 'herb'	
flowering herb top	refer entries under 'herb top'	
flower rachilla	refer flower stalk entry under 'flower'	
flower rachis	refer flower stalk entry under 'flower'	
flowering top	refer entries under 'herb top'	
flowering twig	refer entries under 'herb top'	

Plant part	Approved name: product application and label	Abbreviation for label
folium	refer leaf	
follicle	**fruit**	fruit pod, pod
folliculus	refer follicle	
frond	• where leaf of ferns: **leaf** • where leaf-like part of seaweeds: **blade** • where seaweed blade and stem (stipe): **herb** • where seaweed blade, stem (stipe) and holdfast: **whole plant**	frond ~frond whole seaweed
frucificatio	refer fruiting body	
fructus	refer fruit	
fruit	• where a fruiting (reproductive) body of an algae, seaweed, fungus, lichen, liverwort, moss, hornwort, fern, refer fruiting body • where the whole fruit including the seeds, the surrounding soft/leathery/hard fruit tissue and any individual fruit stalks: **fruit** COMPARE WITH 'HERB FR.' AND 'HERB TOP FR.'. **Refer also: berry, capsule, cone, follicle, hip, nut, pod, strobile** • 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, consider: • **fruit stalk** (pedicel, peduncle, rachis, rachilla) • **fruit pericarp** - all fruit tissue except seeds, e.g. legume pods without the seeds (pericarp = exocarp + mesocarp + endocarp) • fruit epidermis: refer fruit skin • **fruit exocarp** - outer layer of fruit (exocarp) - **also refer ~fruit** skin/peel/rind/hull • **fruit skin** - exocarp/epidermis, e.g. peach skin, tomato skin • **fruit peel** - exocarp only: refer fruit skin - exocarp + mesocarp, e.g. orange peel - other tissue, e.g. apple peel • **fruit peel outer** - endocarp, e.g. coloured layer (flavedo) of *Citrus* (oranges, lemons, etc.) • **fruit peel inner** - mesocarp, e.g. white layer (albedo) of *Citrus* (oranges, lemons, etc.)	fruit ~fruit/~legume pod ~pea/~bean pod, ~pod ~fruit rind ~fruit rind outer fruit peel inner fruit rind in./inner

Plant part	Approved name: product application and label	Abbreviation for label
	• **fruit hull** - outer tough/leathery layer of fruit (exocarp), e.g. leathery walnut hull outside walnut shell - where hard/stony layer of fruit, refer fruit shell entry (above) - where sepals (often papery/leafy) remaining around fruit: **sepal** - where bracts (often papery) from around seed: **seed husk**	~walnut hull sepal
fruit (continued)	• **fruit shell** - outer <u>hard</u> layer of fruit (i.e. pericarp is hard/stony, not tough/leathery), e.g. hazel nut shell - inner hard/stony layer around seed (e.g. endocarp in a drupe), e.g. walnut and almond shells - where inner hard/stony shell (as above) with enclosed seed: **seed & fruit shell** • **fruit flesh** - exocarp and mesocarp, e.g. pitted cherry - mesocarp, e.g. peeled and stoned peach - endocarp, e.g. juice cells of orange - various tissues, e.g. peeled pineapple, peeled apple • **fruit pith** - mesocarp, e.g. granadilla flesh - central pithy tissue that seeds attach around (placenta) - refer ~fruit flesh (above) - refer ~fruit peel in. (above) • **fruit mesocarp** - mesocarp - refer fruit ~flesh/~peel in./~pith • **fruit endocarp** - endocarp - refer ~fruit shell • **fruit without juice** • **fruit vasc.** - nutrient-conducting tissue (xylem and phloem), sometimes stringy, e.g .bean pod strings • **seed** - refer seed and ~fruit/seed	shell shell seed & shell fruit vascular tissue
fruit endocarp	refer entry under 'fruit'	
fruit epidermis	refer fruit skin entry under 'fruit'	
fruit exocarp	refer entry under 'fruit'	
fruit fibre	**fruit fibre**	

Plant part	Approved name: product application and label	Abbreviation for label
fruit flesh	refer entry under 'fruit'	
fruit hull	refer entry under 'fruit'	
fruit husk	refer ~seed husk or ~fruit rind entry under 'fruit'	
fruit mesocarp	refer entry under 'fruit'	
fruit oleoresin	**fruit oleoresin**	
fruit pedicel	refer fruit stalk entry under 'fruit'	
fruit peduncle	refer fruit stalk entry under 'fruit'	
fruit peel	refer entry under 'fruit'	
fruit peel outer	refer entry under 'fruit'	
fruit peel inner	refer entry under 'fruit'	
fruit pericarp	refer entry under 'fruit'	
fruit pith	refer entry under 'fruit'	
fruit pitted	refer fruit flesh entry under 'fruit'	
fruit pulp	• refer ~fruit flesh entry under 'fruit', ~fruit • **~fruit without juice**	
fruit rachis	refer fruit stalk entry under 'fruit'	
fruit rachilla	refer fruit stalk entry under 'fruit'	
fruit resin	**fruit resin**	
fruit rind	refer fruit peel entry under 'fruit'	
fruit rind outer	refer fruit peel outer entry under 'fruit'	
fruit rind inner	refer fruit peel in. entry under 'fruit'	
fruit seed	refer seed and fruit/seed entry below	
fruit/seed	where 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 (see below): **(1)** 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*	

Plant part	Approved name: product application and label	Abbreviation for label
	(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 **(2)** dry single-seeded caryopsis of the Graminae/Poaceae grass family, including *Avena* (oats), *Oryza* (rice), *Secale* (rye), *Triticum* (wheat), *Zea* (corn, maize): **seed** **(3)** four-seeded carcerulus schizocarps, e.g. Labiatae/Lamiaceae family (*Mentha* (mints), *Ocimum* (basil), etc.) and Boraginaceae family (*Borago* (borage), etc.): **seed**	
fruit/seed (continued)	**(4)** single-seeded achenes, e.g. *Ranunculus* (buttercup): **seed** **(5)** cypselas with no pappus, e.g. some Compositae/Asteracea: **seed** **(6)** many-seeded lomentum schizocarps, e.g. pea pods that fragment: **seed**	
fruit seedless	refer fruit pericarp entry under 'fruit'	
fruit shell	refer entry under 'fruit'	
fruit skeleton	refer fruit vasc. entry under 'fruit'	
fruit skin	refer entry under 'fruit'	
fruit skin fibre	**fruit skin fibre**	
fruit stalk	refer entry under 'fruit'	
fruit stone	• where stone only, refer fruit shell entry under 'fruit' • where stone and seed, refer nut entry under 'fruit'	
fruit vascular bundles	refer fruit vasc. entry under 'fruit'	
fruit vascular tissue	refer fruit vasc. entry under 'fruit'	
fruit wax	refer wax	
fruit without juice	refer fruit pulp	
fruiting body	• COMPARE WITH 'FRUIT' • where a strobile of a horsetail, e.g. *Equisetum*: **fruiting body**	strobile, cone

Plant part	Approved name: product application and label	Abbreviation for label
	• where a fern spore cluster (sporangium): **fruiting body** • where a fruiting body of a moss, liverwort or hornwort (sporangium, archegonium or antheridium): **fruiting body** • where a fruiting body of a fungus, with a mushroom (or toadstool) shape (basidiocarp): **mushroom** • where the cap of a mushroom: **mushroom cap** • where the stem of a mushroom: **mushroom stem** • where a fruiting body of a fungus, not with a mushroom shape (~acsocarp): **fruiting body** • where a fruiting body of a lichen: **fruiting body** • where an algae/seaweed fruiting body (sporangium or gametangium): **fruiting body**	spore body fruiting body ~spore body ~capsule [of moss] ~toadstool ~toadstool cap ~toadstool stem fruiting body ~puff ball ~bracket fungus fruiting body fruiting body ~spore body
fruiting herb	refer entries under 'herb'	
fruiting herb top	refer entries under 'herb'	
fruiting top	refer entries under 'herb top'	
fruiting twig	refer entries under 'herb top'	
fungus	refer whole plant, cell, hyphae, spore, fruiting body (basidiocarp or ascocarp, etc.—e.g. mushroom, puff ball, bracket fungus)	
gall	**gall**	
galla	refer gall	
gallnut	**gall**	
gemma	refer bud	
germ	**seed germ**	
glume	**bract** or **~seed husk**	
gourd	**fruit**	gourd
grain (of cereal)	refer under 'fruit/seed'	
grain bract	**seed husk**	
grain glume	**seed husk**	
grain husk	**seed husk**	

Plant part	Approved name: product application and label	Abbreviation for label
gram	where seeds of legume plants, e.g. beans: **seed**	
gum	**gum** and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~extract, etc.	
gum balsam	• refer ~oil, ~oleoresin, ~resin, ~gum, ~gum oleoresin • where not as above: **gum balsam** and refer Herbal Substances Plant Preparations list for preparation: ~fresh, ~extract, etc.	
gum oleoresin	**gum oleoresin** and refer Herbal Substances Plant Preparations list for the preparations: ~fresh, ~extract, etc.	
gummi	refer gum	
gynoecium	**ovary**	ovary, flower ovary
heartwood	refer ~root heartwood, ~stem heartwood	
herb	• stems with attached leaves where there is little flower or fruit material in the harvest (not with root or rhizome): **herb** • COMPARE WITH 'HERB TOP' AND 'WHOLE PLANT' • as for 'herb', but immature plant before flowers or other reproductive structures form: **herb young** • as for 'herb', but flowers always present, with little fruits: **herb flowering** • as for 'herb', but fruits always present, with little flowers: **herb fruiting** • as for 'herb', but both flowers and fruits always present: **herb flowering and fruiting** • germinating seed with first leaves: **sprout** • immature stem offshoots of mature plant: **shoot** • where fern frond without spores: **leaf** • where fern frond with spores: **leaf fertile** • where seaweed thallus without holdfast: **herb** • where seaweed thallus with holdfast: **whole plant** • also refer ~fungus, ~cell	flowering herb fruiting herb flowering and fruiting herb frond leaf, frond whole seaweed
herb flowering	refer entries under 'herb'	
herb flowering and fruiting	refer entries under 'herb'	
herb fruiting	refer entries under 'herb'	
herb top	• terminal ends of stems/branches with	

Plant part	Approved name: product application and label	Abbreviation for label
	attached leaves where there is little flower or fruit material in the harvest (not with root or rhizome): **herb top** • also refer to terms including 'twig' (below) • COMPARE WITH 'HERB' AND 'WHOLE PLANT' • as for 'herb top', but immature plant before flowers or other reproductive structures form and before stems become woody: **herb top young** • as for 'herb top', but flowers always present, with little fruit: **herb top fllowering** • as for 'herb top', but fruits always present, with little flower: **herb top fruiting** • as for 'herb top', but both flowers and fruits always present: **herb top flowering and fruiting** • terminal ends of immature stems with leaves emerging as offshoots of a mature plant: **shoot top** • leafy twigs where there is little flower or fruit material in the harvest: **twig leafy** • leafy twigs where the twigs are less than a year old: **twig leafy young** • leafy twigs with flowers always present, with little fruit: **twig leafy flowering**	herb top flowering herb top fruiting herb top flowering & fruiting herb top shoot leafy twig flowering leafy twig
herb top (continued)	• leafy twigs with fruits always present, with little flower: **twig leafy fruiting** • leafy twigs with flowers and fruits always present: **twig leafy flowering and fruiting** • twigs without leaf, flower or fruit: **twig** • dormant twigs with or without flower buds and/or leaf buds but without leaf, flower or fruit: **twig dormant** • twigs with flowers always present, with little leaf or fruit: **twig flowering** • twigs with flower buds always present with little leaf, flower or fruit: **twig flower bud** • twigs with fruits always present with little leaf or flower: **twig fruiting** • twigs with flowers and fruits always present with little leaf: **twig flowering and fruiting** **branch terminal** **branch terminal leafy**	fruiting leafy twig flowering & fruiting leafy twig twig flowering twig budding twig fruiting twig flowering & fruiting twig
herb top flowering	refer entries under 'herb top'	
herb top fruiting	refer entries under 'herb top'	
herb top flowering	refer entries under 'herb top'	
herb top young	refer entries under 'herb top'	
herb young	refer entries under 'herb'	

Plant part	Approved name: product application and label	Abbreviation for label
herba	refer entries under 'herb' and 'herb top'	
hesperidium (*Citrus*)	**fruit**	
hip (of *Rosa)*	• where whole fruit including seeds: **fruit** • where fruit without seeds: **fruit pericarp**	rose hip 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 entry under 'fruit'	
husk	• **~seed husk** • refer ~fruit peel entry under 'fruit'	
hyphae (of fungi)	**hyphae**	
hypocotyl	**hypocotyl**	
inflorescence	refer entries under 'flower'	
inflorescentia	refer entries under 'flower'	
juice	state part, e.g. **~leaf/~fruit/~stem** and refer Herbal Substances Plant Preparations list for preparation, e.g. juice ~fresh/~dry/~conc.	
juice cells (of *Citrus*)	• **fruit flesh** or **~fruit juice** (see Herbal Substances Plant Preparations list for 'juice') • where fruit pulp without juice: **~fruit without juice**	
kernel	**seed**	kernel
kernel shell	refer fruit shell entry under 'fruit'	
kino	state part, e.g. **~root wood kino**	
lamina	**leaf blade**	
lateral root	**root lateral**	lateral root, root
latex	state part, i.e. **latex**, and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~powder, ~extract, etc.	

Plant part	Approved name: product application and label	Abbreviation for label
leaf	• where true leaf, including leaf blade and stalk of simple leaf, or leaflets and stalks in compound leaf, with any stipules and axilliary buds: **leaf** • where leaf-like blade/frond of seaweed: **blade** • where leaf-like stems with tiny or absent leaves, e.g. *Equisetum* (horsetail): **stem**	~frond (of fern) ~needle (eg pine) ~frond
leaf and stem	refer entries under 'herb' and 'herb top'	
leaf and twig	refer entries under 'herb top'	
leaf blade	• where broad portion of leaf (lamina): **leaf blade** • where leaf-like blade of seaweeds: **blade**	~frond
leaf bud	**leaf bud**	
leaf bud resin	**leaf bud resin**	
leaf cotyledon	**leaf cotyledon**	cotyledon
leaf inner	**leaf inner** (e.g. of *Aloe*: leaf in. juice fresh/extract, etc.)	inner leaf, leaf
leaf inner juice	**leaf inner juice** (e.g. of *Aloe:* leaf in. juice extract, etc.)	
leaf outer	**leaf outer**	
leaf rachilla	**leaf rachilla**	
leaf rachis	**leaf rachis**	
leaf radical	**leaf radical**	leaf
leaf resin	**leaf resin**	
leaf stalk	**leaf stalk** (petiole, rachis or rachilla)	
leaf skeleton	**leaf vasc.**	leaf skeleton
leaf vascular bundles	**leaf vasc.**	leaf vascular tissue
leaf vascular tissue	**leaf vasc.**	leaf vascular tissue
leaf wax	refer wax	
leaf young	**leaf young**	leaf
leaflet	**leaf**	leaflet
legume pod	• with pea/bean seeds: **fruit**	pod, ~pea/~bean pod fruit/legume pod

Plant part	Approved name: product application and label	Abbreviation for label
	• without pea/bean seeds: **fruit pericarp**	[as above]
legume seed	**seed**	~pea/~bean seed
legumen	refer legume pod	
lichen	refer whole plant, fruiting body, spore, etc.	
lignin	refer fibre – dietary	
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 entry under 'fruit'	
mesocarpium	refer mesocarp entry under 'fruit'	
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** where fruiting body of fungus, not with a mushroom shape (~ascocarp): **fruiting body**	~toadstool fruiting body ~puff ball ~bracket fungus
mushroom cap	**mushroom cap**	~toadstool cap
mushroom stem	**mushroom stem**	~toadstool stem
mycelium (of fungi)	**hyphae** or refer cell	
needle (of conifer)	**leaf**	needle
nodus	refer node	
node	**node**	
nodule	**root nodule**	
nodule and root	**root & root nodule**	
nut	• where seeds/kernels only: **seed**	~kernel

Plant part	Approved name: product application and label	Abbreviation for label
	• 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** • where seed and inner shell from a fruit (drupe) with the outer soft or leathery layer removed, e.g. walnuts, almonds: **seed & fruit shell**	nut seed & shell
nut shell	refer fruit shell entry under 'fruit'	
nux	refer nut	
oil	state part, e.g. **~seed/~herb/~flower** and refer Herbal Substances Plant Preparations list for preparation, i.e. oil ~fixed/~ess./~infused	
oleoresin	state part, e.g. **~gum/~fruit/~stem bark oleoresin** and refer Herbal Substances Plant Preparations list for preparation, e.g. ~fresh/~extract	
ovary	**ovary**	flower ovary
ovary stigma	**stigma**	flower stigma
ovary style	**style**	flower style
parenchyma	refer pith	
pea	**seed**	pea
pea pod	• with pea seeds: **fruit** • without pea seeds: **fruit pericarp**	pod, pea pod, fruit/legume pod [as above]
pedicel	**~flower stalk, ~fruit stalk**	
pedicellus	refer pedicel	
peduncle	**~flower stalk, ~fruit stalk**	
peel	• state part, e.g. ~fruit/~root/~rhizhome/~stem/~twig peel • refer also ~skin, ~fruit peel, ~bark, ~bark outer	
pepo	**fruit**	
petal	**petal**	flower petal
petiole	**leaf stalk**	
pericarp	refer entry under 'fruit'	

Plant part	Approved name: product application and label	Abbreviation for label
pericarpium	refer pericarp entry under 'fruit'	
phloem	refer bark and refer vascular tissue	
pinna	**leaf**	
pinnule	**leaf**	
pith	• state part, e.g. **~stem/~root pith** • refer fruit pith entry under 'fruit'	
placenta	refer ~fruit flesh and ~fruit pith entries under 'fruit'	
plant	refer entries under 'herb', 'herb top' and 'whole plant'	
plant immatura	refer herb young entry under 'herb'	
plantula	**sprout**	
plumula	refer plumule	
plumule	**plumule**	
pod	• where fruit is a legume (pea or bean pod), follicle, siliqua or silicula AND includes seeds: **fruit** • where fruit is as above, without seeds: **fruit pericarp** • where fruit is not as above, with seeds: **fruit** where fruit is not as above, without seeds: **fruit pericarp**	fruit pod, pod, ~pea/~bean pod, ~legume pod, ~follicle pod [as above] fruit pod, pod
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**	
Pteridophyte	refer fern, horsetail (e.g. *Equisetum*), lycopod (e.g. *Lycopodium*)	
puff ball	**fruiting body**	fruiting body puff ball
pulp	refer ~fruit pulp, ~stem pith	
pulse	where seeds of legume plants, e.g. beans: **seed**	bean seed

Plant part	Approved name: product application and label	Abbreviation for label
rachis	**~leaf/~fruit/~flower stalk**	
rachilla	**~leaf/~fruit/~flower stalk**	
radix	refer root	
ramulus	refer twig entries under 'herb top' and refer stem	
ramu	refer twig entries under 'herb top' and refer stem	
receptacle	**flower receptacle**	flower receptacle
recetaculum	refer receptacle	
resina	refer resin	
resin	state part, e.g. **~flower bud/~stem/~stem bark resin** and refer Herbal Substances Plant Preparations list for preparation: ~fresh, ~extract, etc.	
rhizoid	refer root	
rhizoma	refer rhizome	
rhizome	**rhizhome**	
rhizome and root	**root and rhizhome**	root and rhizome
rhizome and stolon	**rhizome and stolon**	root and stolon
rhizome and root and stolon	**root and rhizome and stolon**	root, rhizome and stolon
rhizome bark	**rhizome bark**	rhizome bark
rhizome bark inner	**rhizome bark inner**	rhizome bark rhiz. bark
rhizome bark outer	**rhizome bark outer**	rhizome bark rhiz. bark
rhizome heartwood	**rhizome heartwood**	rhizome wood rhiz. wood
rhizome peel	**rhizome peel/~skin**	
rhizome sapwood	**rhizome sapwood**	rhizome wood rhiz. wood
rhizome skin	**rhizome skin/~peel**	

Plant part	Approved name: product application and label	Abbreviation for label
rhizome wood	**rhizome wood**	rhizome wood
rind	refer ~peel, ~fruit peel, ~skin, ~bark, ~bark outer	
root	• where true roots with/without root hairs: **root** • where root-like rhizoids: **root**	~tap root ~fibrous root rhizoid
root aerial	**root aer.**	aerial root
root and nodule	**root and root nodule**	
root and stolon	**root and stolon**	
root and rhizome	**root and rhizhome**	root and rhizome
root and rhizome and stolon	**root and rhizome and stolon**	root, rhizome and stolon
root bark	**root bark**	
root bark inner	**root bark inner**	root bark
root bark outer	**root bark outer**	root bark
root epidermis	**root skin**	
root fibre	**root fibre**	
root heartwood	**root heartwood**	root wood
root lateral	**root lat.**	lateral root
root nodule	**root nodule**	
root pith	**root pith**	
root peel	**root peel/~skin**	
root sapwood	**root sapwood**	root wood
root skin	**root skin/~peel**	
root wood	**root wood**	
root wood inner	**root heartwood**	root wood
root wood outer	**root sapwood**	root wood
root vascular bundles	**root vasc.**	root vascular tissue

Plant part	Approved name: product application and label	Abbreviation for label
root vascular tissue	**root vasc.**	root vascular tissue
samara	**fruit**	
sap	**sap** and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~powder, ~extract, etc.	
sap balsam	• refer ~oil, ~oleoresin, ~resin, ~gum, ~gum oleoresin • where not as above: **sap balsam** and refer Herbal Substances Plant Preparations list for preparation: ~fresh, ~extract, etc.	
sapwood	refer ~root/~stem/~twig/~rhizome sapwood	
sawdust	refer wood	
scape	**scape**	
scapus	refer scape	
schizocarp	refer fruit/seed	
schlerenchyma	refer fibre	
sclerotium	**fruiting body**	spore body
scobis	refer sawdust	
seaweed	refer whole plant, holdfast, stem (stipe), blade (~frond), fruiting body (gametangium, sporangium)	
seed	**seed** refer also fruit/seed	
seed aril	**seed aril**	aril
seed bran	**seed bran**	
seed coat	**seed coat**	
seed coat aril	**seed aril**	aril
seed embryo	**seed germ**	
seed endosperm	**seed endosperm**	seed endosperm ~seed starch
seed epidermis	**seed skin/~bran**	
seed fibre	**seed fibre**	

Plant part	Approved name: product application and label	Abbreviation for label
seed/fruit	refer fruit/seed	
seed germ	seed germ	
seed germinating	refer sprout entry under 'herb'	
seed husk	**seed husk**	
seed mucilage	**seed mucilage**	
seed shell	refer fruit shell entry under 'fruit'	
seed skin	**seed skin/~bran**	
seed sprout	refer sprout entry under 'herb'	
semen	refer seed	
sepal	**sepal**	flower sepal
shell	refer fruit shell entry under 'fruit'	
shoot	• refer entries under 'herb' and 'herb top' • where only the stem: **stem**	
silicula	**fruit**	fruit pod, pod
siliqua	**fruit**	fruit pod, pod
silk (of corn, *Zea)*	**style** or **stigma** (both are correct)	flower style, flower stigma
skin	• state part, e.g. fruit/~root/~rhizhome/~stem/~twig skin refer also ~peel, ~fruit peel, ~bark, ~bark outer	
sorosis	**fruit**	
spina	refer ~spine, ~thorn	
spine	**spine**	
spora	refer spore	
sporangium	refer fruiting body	
spore	**spore**	
sprout	refer entries under 'herb' and 'herb top'	
stalk	refer stem, stolon, twig entries under 'herb top', leaf stalk (petiole), flower/fruit stalk (pedicel, peduncle), leaf/flower/fruit rachi and rachilla	

Plant part	Approved name: product application and label	Abbreviation for label
stamen	**stamen**	flower stamen
stamen anther	**anther**	flower anther
stamen filament	**stamen filament**	flower filament
staminis	refer flower stamen	
stem	• where stem growth form not specialised: **stem** • where stem growth form specialised, refer rhizome, stolon, corm, tuber, bulb (includes leaves), etc. • where leaf-like stems with tiny or absent leaves, e.g. *Equisetum* (horsetail): **stem**	~vine stem
stem and leaf	• refer entries under '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 • where not as above: **stem balsam** and refer Herbal Substances Plant Preparations list for preparation: ~fresh, ~extract, etc.	
stem bark	stem includes branches and twigs: **stem bark**	bark
stem bark fibre	**stem bark fibre**	bark fibre
stem bark inner	**stem bark inner**	inner bark, bark
stem bark oleoresin	**stem bark oleoresin**	bark oleoresin
stem bark outer	**stem bark outer**	outer bark, bark
stem bark resin	**stem bark resin**	bark resin
stem epidermis	**stem skin**	
stem fibre	**stem fibre**	
stem gum	**gum** and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~extract, etc.	
stem heartwood	**stem heartwood**	heartwood, wood
stem latex	**latex**	
stem peel	**stem peel/~skin**	
stem pith	**stem pith**	

Plant part	Approved name: product application and label	Abbreviation for label
stem resin	**stem resin**	
stem sap	**sap** and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~powder, ~extract, etc.	
stem sapwood	**stem sapwood**	sapwood, wood
stem skin	**stem skin/~peel**	
stem sterile	**stem**	
stem vascular bundle	**stem vasc.**	stem vascular tissue
stem vascular tissue	**stem vasc.**	stem vascular tissue
stem wood	**stem wood**	wood
stem wood resin	**stem wood resin**	wood resin
stigma	**stigma** and refer silk	flower stigma
stipe	• where of seaweed: **stem** • where of flowering plant: **~stem** or **~flower/fruit stalk**	
stipule	**stipule**	
stipulae	refer stipule	
stolon	**stolon**	
stolon and rhizome	**rhizome and stolon**	rhizome and stolon
stolon and root	**root and stolon**	root and stolon
stolon and root and rhizome	**root and rhizome and stolon**	root, rhizome and stolon
strobile	• where a strobile of a flowering plant: **fruit** • where a strobile of a horsetail, e.g. *Equisetum:* **fruiting body**	strobile, ~cone strobile
strobilus	**flower**	
style	**style** and refer silk	flower style
stylus	refer style	
styrax	refer resin	
succus	refer sap	

Plant part	Approved name: product application and label	Abbreviation for label
synconus	**fruit**	
taproot	• where the taproot, with lateral root and some root hair, as harvested: **root** • where the taproot only, with all harvested lateral root and root hair removed: **taproot**	taproot
tepal	• where appearing as a petal: **petal** • where appearing as a sepal: **sepal**	flower petal flower sepal
testa	**seed coat**	
testa aril	**seed aril**	aril
thallus	refer whole plant	
thallus blade	**blade**	~frond
thallus frond	**blade**	frond
thallus holdfast	**holdfast**	
thallus stipe	**stem**	
thorn	**thorn**	
toadstool	refer mushroom entry under 'fruiting body'	
top	refer entries under 'herb top'	
truewood	refer heartwood	
trunk	**stem**	trunk
trunk bark	refer stem bark	
trunk wood	refer stem wood	
tuber	**tuber**	
tuliones	refer leafy twig young under 'herb top'	
twig	refer entries under 'herb top'	
twig bark	**twig bark**	
twig bark inner	**twig bark inner**	twig bark inner twig bark
twig bark outer	**twig bark outer**	twig bark outer twig bark
twig dormant	refer entries under 'herb top'	

Plant part	Approved name: product application and label	Abbreviation for label
twig flowering	refer entries under 'herb top'	
twig fruiting	refer entries under 'herb top'	
twig heartwood	**twig heartwood**	twig wood
twig leafy	refer entries under 'herb top'	
twig peel	**twig peel/~skin**	
twig sapwood	**twig sapwood**	twig wood
twig skin	**twig skin/~peel**	
twig wood	**twig wood**	
twig young	refer entries under 'herb top'	
underground parts	state parts, e.g. **root** or **rhizome** or **root and rhizhome**	
vascular bundles	refer vascular tissue	
vascular tissue	• state part, .eg. **~fruit vascular tissue, ~stem vascular tissue, ~root vascular tissue** • refer fibre – cells	
vine	specify part, e.g. ~stem, ~herb	
vine herb	refer entries under 'herb'	
vine stem	**stem**	vine stem
wax	state part, e.g. **~leaf/~fruit wax** and refer Herbal Substances Plant Preparations list for the preparation: ~fresh, ~extract, etc.	
whole plant	• where entire plant body, including any underground parts, holdfasts and reproductive structures: **whole plant** [refer to entry naming each type of plant to ensure all parts are included—loss of the fine root hairs/rhizoids is expected] • where only aerial parts, refer entries under 'herb' and 'herb top' • where mushroom-shaped part of fungus, refer fruiting body • where single celled, filamentous and colonial algae or fungi, refer cell	~whole fungus ~whole lichen ~whole seaweed ~whole moss ~whole horsetail ~whole liverwort ~whole hornwort ~whole fern
wood	• refer fruit, ~capsule • refer fruit shell entry under 'fruit'	

Plant part	Approved name: product application and label	Abbreviation for label
	• refer rhizome ~heartwood/~sapwood/wood • refer root ~heartwood/~sapwood/wood • refer stem ~heartwood/~sapwood/wood • refer twig ~heartwood/~sapwood/wood	
wood inner	refer heartwood	
wood outer	refer sapwood	
xylem	refer wood and refer vascular tissue	
xylem primary	refer sapwood and refer vascular tissue	
xylem secondary	refer heartwood	
xylem	refer xylem	

Appendix 2 Herbal substances plant preparations list

The 'Plant preparation' code table on the eBS website provides approved names for plant preparations. These names should be used where plant preparation terms are required to complete the approved name for a herbal substance in product applications and on product labels. The herbal substances plant preparations list (Table A2.3) provides additional information about how to use the various plant preparation codes.

The list is presented in six columns, as indicated in Table A2.1. Table A2.2 explains the symbols used in the list.

Table A2.1 Structure and content of herbal substances plant preparations list

Column	Content	Comment
1	Common usage and technical terms for plant preparations, arranged in alphabetical order	Do NOT use
2	Approved name (for use in product applications) for preparation type	• Label terms are found in column 6
3	Approved name (for use in product applications) for the final extraction ratio and solvents	• 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). A range may be acceptable. See 'Extraction ratio' in Section 4.2.3. • State the solvent name(s) and concentration(s) (see 'Solvent' in Section 4.2.3). • Solvent details are only required for active ingredients

Column	Content	Comment
4	Approved name (for use in product applications) for the equivalent dry or fresh weight of raw herbal material used or needed to make the ingredient: 'dry', 'fresh', 'juice dry' or 'juice fresh'	• Required as the third part of the approved name for most[a] **extracted ingredients** to state the amount of dry/fresh weight of raw herbal material actually used to make the ingredient (see 'Quantifying herbal substances' in Section 4.2.3) • Also required if a label claim is made concerning the amount of dry/fresh weight of raw herbal material needed to make the ingredient • If the statement begins with 'EQUIV.', the AHN and plant part code are stated before the approved name is used
5	Approved name (for use in product applications) for the amount of a component in the ingredient.	• Required as the last part of the approved name for all standardised ingredients • CAUTION: contact the TGA before claiming standardisation of either the ingredient or the product • Also required if a label claim is made concerning the amount of a component in the ingredient • Make separate statements where the amount of more than one component is claimed
6	Label AAN: preparation type	• The equivalent approved name for product applications is in column 2 • Where the ingredient is extracted (other than oil and fat), the complete label AAN also includes the dry/fresh raw material used to make the ingredient—refer column 4 • Where the ingredient is claimed to be standardised, the complete label AAN also includes the component against which the ingredient is standardised—refer column 5

a Optional for oil, fat and highly dilute so-called flower essences

Table A2.2 Key to the herbal substances plant preparations list

Character	Meaning	Comments
~	Only use the term if it is applicable	For example, '~dry/fresh' means that the appropriate term of the ones given should be selected for use
/	The term may be formed using any one of the given words	For example, 'juice ~dry/~fresh' indicates that 'juice dry' and 'juice fresh' are both approved codes
*	Caution: contact the TGA if intending to claim standardisation	'stand.' may be omitted from the label if no claim is made
#	Solvent details are not required where the ingredient is an excipient	
^	Only use where label space is limiting	

Table A2.3 Herbal substances plant preparations list

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Balsam may be included in the term for plant part; select the preparation, e.g. 'fresh', 'extract ...'					
Decoction	decoc.	(1:? in 100% W)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• decoction • decoc.^
Decoction concentrate	decoc. conc.	(?:1 in 100% W)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• decoction • decoc.^

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Decoction concentrate standardised*	decoc. conc. stand.	(?:1 in 100% W)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• decoction standardised* • decoction stand.*^ • decoc. stand.*^
Decoction standardised*	decoc. stand.	(1:? in 100% W)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• decoction standardised* • decoction stand.*^ • decoc. stand.*^
Distillate (where not an essential oil)	distillate	(1:? in 100% W)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• distillate • dist.^
Distillate concentrate (where not an essential oil)	distillate conc.	(?:1 in 100% W)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• distillate • dist.^
Dry	dry	–	Required if label claim: EQUIV. AHN + part + fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• dry
Dry standardised*	dry stand.	–	Required if label claim: EQUIV. AHN + part + fresh	EQUIV. stand. comp. ~AAN/~HCN	• dry standardised* • dry stand.*^
Essence, i.e. 'flower essence'	essence	(1:? in solvents)	Required if not highly dilute: EQUIV. AHN + part + ~dry/~fresh	–	• essence • flower essence
Essence, oil: refer oil essential					

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Extract: also refer oil, fat, wax, resin, oleoresin and balsam. If an extract of a fat, wax resin, oleoresin or balsam, ensure this term is part of the plant part, and use 'extract etc.' as the plant preparation					
Extract dry	ext. dry	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• extract
Extract dry concentrate	ext. dry conc.	(?:1 in solvents)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• extract
Extract dry concentrate standardised*	ext. dry conc. stand.	(?:1 in solvents)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• extract standardised* • extract stand.*^ • ext. stand.*^
Extract dry standardised*	ext. dry stand.	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• extract standardised* • extract stand.*^ • ext. stand.*^
Extract liquid	ext. liq.	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• extract
Extract liquid concentrate	ext. liq. conc.	(?:1 in solvents)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• extract

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Extract liquid concentrate standardised*	ext. liq. conc. stand.	(?:1 in solvents)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• extract standardised* • extract stand.*^ • ext. stand.*^
Extract liquid standardised*	ext. liq. stand.	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• extract standardised* • extract stand.*^ • ext. stand.*^
Extract oil infused: refer oil infused					
Extract soft	ext. soft	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• extract
Extract soft concentrate	ext. soft conc.	(?:1 in 100% W)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• extract
Extract soft concentrate standardised*	ext. soft conc. stand.	(?:1 in 100% W)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• extract standardised* • extract stand.*^ • ext. stand.*^
Extract soft standardised*	ext. soft stand.	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• extract standardised* • extract stand.*^ • ext. stand.*^
Fat: if an extract of a fat, ensure 'fat' is part of the plant part and use 'extract etc.' as the plant preparation	fat	–	Required if label claim: EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• fat

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Fresh	fresh	–	Required if label claim: EQUIV. AHN + part + dry	Required if label claim: EQUIV. component ~AAN/~HCN	• fresh—may be omitted if the plant part code includes any of the following terms: balsam, gum, latex, oleoresin, resin, sap, wax
Flower essence: refer essence					
Gum, 'gum balsam' and 'gum oleoresin': these are part of the plant part; select the preparation, e.g. 'fresh', 'extract ...'					
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	–	–	–	• 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	Required if label claim: EQUIV. component ~AAN/~HCN	• infusion
Infusion standardised*	infusion stand.	(1:? in 100% W)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• infusion standardised* • infusion stand.*^
Juice concentrate	juice conc.	–	EQUIV. AHN + part + juice ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• juice concentrate • juice conc.^

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Juice concentrate standardised*	juice conc. stand.	–	EQUIV. AHN + part + juice ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• juice concentrate standardised* • juice concentrate stand.*^ • juice conc. stand.*^
Juice dry	juice dry	–	Required if label claim: EQUIV. AHN + part + juice fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• juice dry • juice powder
Juice dry standardised*	juice dry stand.	–	Required if label claim: EQUIV. AHN + part + juice fresh	EQUIV. stand. comp. ~AAN/~HCN	• juice dry standardised* • juice powder standardised* • juice dry stand.*^ • juice powder stand.*^
Juice fresh	juice fresh	–	Required if label claim: EQUIV. AHN + part + juice dry	Required if label claim: EQUIV. component ~AAN/~HCN	• juice fresh • juice
Juice fresh standardised*	juice fresh stand.	–	Required if label claim: EQUIV. AHN + part + juice dry	EQUIV. stand. comp. ~AAN/~HCN	• juice fresh standardised* • juice standardised* • juice fresh stand.*^ • juice stand.*^
Juice powder	juice dry	–	Required if label claim: EQUIV. AHN + part + juice fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• juice dry • juice powder

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Juice powder standardised*	juice dry stand.	–	Required if label claim: EQUIV. AHN + part + juice fresh	EQUIV. stand. comp. ~AAN/~HCN	• juice dry standardised* • juice powder standardised* • juice dry stand.*^ • juice powder stand.*^
Latex: is part of the plant part; select the preparation, e.g. 'fresh', 'extract...'					
Oil essential	oil ess.	–	Required if label claim: EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• oil essential • oil ess.^ • oil^
Oil fixed	oil fixed	–	Required if label claim: EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• oil fixed • oil^
Oil infused CAUTION: quantify the active ingredient oil alone (do not include the quantity of solvent oil used)	oil inf. CAUTION where the solvent oil(s) are also in the product, name and quantify these excipient(s) separately	–	Required if label claim: EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• oil infused • oil inf.^ • oil
Oleoresin: if an extract of an oleoresin, ensure 'oleoresin' is part of the plant part, and use 'extract etc.' as the plant preparation					

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Potency: refer homoeopathic potency					
Powder	powder	–	Required if label claim: EQUIV. AHN + part + fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• powder
Powder standardised*	powder stand.	–	Required if label claim: EQUIV. AHN + part + fresh	EQUIV. stand. comp. ~AAN/~HCN	• powder standardised* • powder stand.*^
Resin: is part of the plant part; select the preparation, e.g. 'fresh', 'extract…'					
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	Required if label claim: EQUIV. component ~AAN/~HCN	• spagyric
Spagyric concentrate	spagyric conc.	(?:1): prep 1 (?:? in solvents) & prep 2 ... etc	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• spagyric
Spagyric concentrate standardised*	spagyric conc. stand.	(?:1): prep 1 (?:? in solvents) & prep 2 ... etc	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• spagyric standardised* • spagyric stand.*^

Plant preparation	Preparation type	If final extraction ratio and solvents# required	If equivalent dry/fresh weight required	If component required	Abbreviation for label
Spagyric standardised*	spagyric stand.	(1:?): prep 1 (?:? in solvents) & prep 2 ... etc	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• spagyric standardised* • spagyric stand.*^
Tincture	tinct.	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	Required if label claim: EQUIV. component ~AAN/~HCN	• tincture • tinct.^
Tincture standardised*	tinct. stand.	(1:? in solvents)	EQUIV. AHN + part + ~dry/~fresh	EQUIV. stand. comp. ~AAN/~HCN	• tincture standardised* • tinct. stand.*^

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6232 8605
www.tga.gov.au

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