



TGA use only

Committee session:
Date approved:
Regulatory area:
Reference:

This form, when completed, will be classified as 'For official use only'.
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<<http://www.tga.gov.au/about/tga-information-to.htm>>.

Proposed name for a chemical substance (AAN) used in therapeutic goods

Application form

Please note: This application will be considered by the TGA's Australian Approved Names (AAN) Committee. The Committee will endeavour to consider the application within 20 working days. Following consideration, the Committee may ask the application for additional information where the application is incomplete or unclear, e.g. where the substance has not been clearly defined.

Refer to [TGA approved terminology of medicines Section 1 – Chemical Substances – 1.1 Explanatory Notes](#) for information on the naming of chemical substances.

Please note that the Committee only reviews the name and definition of an ingredient. The use of an ingredient is approved by other areas of the TGA.

1. Proposed chemical substance name

2. Synonym(s)

3. Structure and/or definition: (Including waters of hydration)

4. The substance is expected to be used as:

Active ingredient: Excipient ingredient:

5. The substance is expected to be used in a:

Listed medicine

Prescription Medicine

Orphan drug? Yes No

Over the counter (OTC) medicine

Registered complementary medicine

Proprietary Ingredient Formulation

Device

Export only medicine

6. Product name (if known):

7. Route of administration:

Oral

Topical

Other (please specify)

Please specify:

8. References

This section must be completed. Please place a tick in the box next to the reference(s) containing the proposed name, and enter the reference details (edition, volume, etc.).

The reference(s) must refer to the name proposed, and a full copy of the relevant reference(s) must be provided.

TGA naming policy is to use the International Non-proprietary Name (INN) for a substance, wherever one exists. If an INN exists for a given substance, the applicant must justify the use of an alternative name. References are listed in approximate order of preference.

Note on citations: When citing a print version, provide full details including title, author details if applicable, edition, volume and pagination.

When citing an electronic version, provide full details including title, authority and platform where applicable, including version number. Specify medium accessed (for example web, CD-ROM). For internet sites, also provide the URL and date accessed.

Ref. Code		Edition, Year, Volume	Reference
<input type="checkbox"/>	INN		International Non-proprietary Names
<input type="checkbox"/>	BP		British Pharmacopoeia
<input type="checkbox"/>	BAN		British Approved Names
<input type="checkbox"/>	USP		United States Pharmacopoeia
<input type="checkbox"/>	USAN		United States Adopted Name
<input type="checkbox"/>	BPAP		British Pharmacopoeia - Appendix
<input type="checkbox"/>	EP		European Pharmacopoeia
<input type="checkbox"/>	MAR		Martindale, the Extra Pharmacopoeia
<input type="checkbox"/>	MI		Merck Index
<input type="checkbox"/>	FCC		Food Chemicals Codex
<input type="checkbox"/>	ANZFS		Australia New Zealand Food Standards Code
<input type="checkbox"/>	ICID		International Cosmetic Ingredient Dictionary
<input type="checkbox"/>	CAS		CAS Registry (Chemical Abstracts Service)
<input type="checkbox"/>	CHEM		CHEMID plus (National Library of Medicine)
<input type="checkbox"/>	CI		Colour Index (Society of Dyers and Colourists)
<input type="checkbox"/>	ALL		Allured's Flavour and Fragrance Materials
<input type="checkbox"/>	FHF		Fenaroli's Handbook of Flavour Ingredients
<input type="checkbox"/>	FIE		Fiedler Encyclopedia of Excipients
<input type="checkbox"/>	HPE		Handbook of Pharmaceutical Excipients
Other (please specify):			

9. Applicant details

Name			Sponsor: <input type="checkbox"/>	Agent: <input type="checkbox"/>
Position				
Company				
Client ID				
Address				
Telephone		Fax		
Email				

The completed form and attachments can be sent by email or post:

Email: TGANames@tga.gov.au

Post: The Secretariat
Australian Approved Names Committee
Office of Scientific Evaluation
Therapeutic Goods Administration
PO BOX 100
WODEN ACT 2602