



This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.



If your proprietary ingredient contains an **herbal extract** as an **active ingredient**, DO NOT complete this notification form.

Please complete the [Notification of selective non-disclosure of Active Herbal Extract details](#).

Notification of a new proprietary ingredient

This form allows the TGA to enter formulation details and other relevant information into the Proprietary Ingredient Table in TGA Business Services. Once processed, a unique name and number is generated for each proprietary ingredient mixture. This number can then be used in therapeutic goods applications.

Email your completed form to: TGAnames@tga.gov.au

For more assistance in completing this form, email [TGA Names](#) or call 02 6232 8465.

[Proprietary ingredient](#) notifications are usually processed within 20-30 working days.

Proprietary ingredient name (maximum 150 characters)

Please enter the proposed ingredient name



The proprietary ingredient name must **NOT**:

- be an existing name in the TGA Business Services Proprietary Ingredient Table
- include punctuation or other symbols
- contain the word 'natural' unless you can demonstrate that your formulation complies with the [TGA guidance for the use of this term](#)

Supplier details

Supplier name:		Client ID:	
Supplier address:			
Contact officer name:			
Contact officer email:			

If you do not have a client ID, complete an [Organisation details](#) form and submit to eBS@tga.gov.au.

Manufacturer details

Manufacturer name:	
Manufacturer site address:	
Client ID:	

If the manufacturer does not have a client ID, complete an [Organisation details](#) form and submit to eBS@tga.gov.au.

Type of proprietary ingredient

This proprietary ingredient is intended for use as a (tick one of the following):

Containing a therapeutically active ingredient:

- Active pre-mix (active pre-mixes can only contain one active ingredient)

Excipient only:

- Adhesive
- Capsule shell formulation
- Coating material
- Colour
- Cream (Ointment) base
- Excipient mix
- Flavour
- Fragrance
- Ink
- Oral base
- Preservative mix
- Sweetener

Proposed use

Once processed, your proprietary ingredient name and PI number will be visible in TGA electronic application systems for different types of therapeutic goods.

Select which TGA electronic application system(s) you wish to make your proprietary ingredient visible in:

- [Devices](#) (the formulation will be given excipient availability within TGA electronic systems)
- [Export Only](#) medicines
- [Listed medicines](#) (including assessed listed medicines) for supply in Australia *
- Registered [over-the-counter \(OTC\) medicines](#) or Registered [complementary medicines](#)
- [Prescription medicines](#)
- [Biologicals](#)



* If a proprietary ingredient mixture is proposed to be used in a listed medicine all ingredients within the formulation **must** be included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) and meet those requirements.

For example, coumarin can only be used in a listed medicine as a homoeopathic active ingredient or as an excipient in limited concentrations in specific types of medicines.

Is this proprietary ingredient notification made in association with a medicine, biological or device application? Yes No

If **yes**, complete the following information:

Product name:

Sponsor name:

Route of administration:

Formulation details

Use the table on the next page to provide information about the ingredients in your formulation (attach additional pages as required).

Only use approved ingredient names and TGA ID numbers as they appear in the [TGA Business Services \(TBS\) Ingredients Table](#) to identify your ingredients. If you cannot find the ingredient, you will need to submit a form to propose a new ingredient name.

For herbal ingredients:

- Use Australian Herbal Names (AHN) or Australian Herbal Substance Names (AHS) instead of food names (AFN) to more accurately identify the ingredient.
- When using an AHN, provide [plant part](#) and [plant preparation](#) details to fully describe your ingredient.
- For animal-derived ingredients (such as gelatin), provide animal species and part/tissue.



Provide quantities for all ingredients in the formulation:

- Include a single consistent, meaningful unit for each quantity, for example, mg, mg/g, %. etc.
- State exact nominal quantities (ranges will only be accepted for flavour, fragrance and printing ink formulations).
- Quantities must total 100% or 1000mg/g.

If your formulation contains an ingredient mixture from the Proprietary Ingredient Table:

- If you know the component ingredients within the mixture you can enter these ingredients individually in the table below.
- If you do not wish to enter the ingredients individually and instead wish to enter the PI mixture into your formulation, make sure the 'purpose' of this mixture is the same as the overall purpose of your mixture (e.g. a flavour within a flavour). Otherwise your PI may not validate within TGA electronic systems.

Total number of ingredients contained in this proprietary ingredient formulation (minimum 2):

Is maltodextrin in your formulation No Yes please specify the source:

	Active, Excipient or PI	Name of Ingredient	TGA ID	CAS No.	Quantity / Unit	Plant part / preparation (for AHN ingredients)	Animal species and part / tissue (for ABN ingredients)
1.	Excipient						
2.	Excipient						
3.	Excipient						
4.	Excipient						
5.	Excipient						
6.	Excipient						
7.	Excipient						
8.	Excipient						
9.	Excipient						
10.	Excipient						
11.	Excipient						
12.	Excipient						
13.	Excipient						
14.	Excipient						
15.	Excipient						
16.	Excipient						
17.	Excipient						
18.	Excipient						
19.	Excipient						
20.	Excipient						
21.	Excipient						
22.	Excipient						
23.	Excipient						
24.	Excipient						