



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>.

Notification of a new proprietary ingredient

This form is for suppliers of ingredient mixtures, such as flavours or fragrances, who want to include their mixture in the [Proprietary Ingredients Table](#).

All published proprietary ingredients are given a unique ID.

Applicants for new therapeutic goods can then refer to the proprietary ingredient ID in their therapeutic good formulation, rather than having to submit a full list of ingredients.

The names of ingredients contained within proprietary ingredients, other than flavours, fragrances or colours, will be visible to the public via the public ARTG summary of the medicine.

For more information see [Notification of a new proprietary ingredient](#).

Instructions

1. Complete all questions in this form, incomplete forms will not be processed.
2. Email the completed form to TGANames@tga.gov.au
3. Processing your form usually takes 20-30 working days.
4. We will email you the unique ID number for use in therapeutic goods applications and a supplier summary of the formulation details once processed.

Your obligations

If the formulation of this proprietary ingredient changes, you must tell TGANames@tga.gov.au and they will issue you a new unique number for the new formulation.

Proprietary ingredients cannot be changed without generating a new identification number unless you can prove an error at the time of the initial notification.

Help completing this form

For help in completing this form, email TGANames@tga.gov.au or call 02 6232 8465.

Proprietary ingredient name

- Max 150 characters
- No punctuation or special characters
- Must be unique and not existing
- Must not include the word 'natural' unless your formulation complies with the [TGA guidance for the use of this term](#)

Proprietary ingredient name	
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Supplier details

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

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

Manufacturer details

The manufacturer can also be the supplier.

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

Manufacturer name:	
Manufacturer site address:	
Manufacturer Client ID:	

Proprietary Ingredient type

This proprietary ingredient is intended for use as a (choose **one**):

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

Proposed product use

The product your proprietary ingredient will be used in (select all that apply):

- [Biologicals](#)
- [Device](#) (select for hard surface disinfectants)
- [Export Only medicines](#)
- [Registered over-the-counter medicines](#) or [Registered complementary medicines](#) (select for sanitisers)
- [Prescription medicines](#)
- [Listed and assessed listed medicines](#)*

* All ingredients proposed for use in listed medicines **must** be included in the [Therapeutic Goods \(Permissible Ingredients\) Determination](#) and approved for use in listed medicines.

If your formulation includes ingredients not in the Determination, your proprietary ingredient will not be given availability for use in listed medicines.

Formulation checklist

Complete this checklist before submitting your notification.

Note: If your application is incomplete or missing required information, it will not be processed.

I declare:

- supplier and manufacturer details have been completed.
- a single Proprietary Ingredient Type has been selected.
- all ingredients in the formulation are Australian Approved Names. If you cannot find an ingredient, you will need to submit a [new ingredient name proposal form](#) and have it approved before you can submit your proprietary ingredient notification.
- all ingredients in the formulation are available for use in the selected proposed product use. For example, if you have ticked Registered over-the-counter medicines, all ingredients must be available for use in over-the-counter medicines.
- Australian Food Names are not used. Only Australian Herbal Names (AHN) or Australian Herbal Substance Names (AHS) can be used.
- this formulation contains at least 2 ingredients. Two ingredients are the minimum allowed in a proprietary ingredient formulation.
- TGA ID numbers have been provided for all ingredients. You can find these numbers in the [TGA Business Services Ingredients Table](#).
- quantities have been provided for all ingredients totalling 100% or 1000mg/g. We do not accept a range unless the intended use is flavour or fragrance.
- ethanol quantity is provided. The quantity of ethanol is required for all proprietary ingredients, even if only trace amounts.
- maltodextrin source is provided if relevant. If your formulation includes maltodextrin, you must specify the source.
- plant part and preparation details have been provided if relevant. For each Australian Herbal Name, you must provide the [plant part](#) and [plant preparation](#).
- animal species and part/tissue have been provided if relevant. For all animal-derived ingredients you must provide the animal species and part/tissue.
- the intended use of any proprietary ingredient contained within this formulation is the same as the intended use for this proprietary ingredient.
- all ingredients in the formulation and required details have been entered into the formulation details table below or in the PI formulation Excel template.

Formulation details

Total number of ingredients	
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Note: If your formulation contains more than 55 ingredients, download and complete the [PI formulation Excel template](#), and submit with this notification.

TGA ID	Name of Ingredient	CAS No.	Quantity / Unit	Maltodextrin source	Plant part & preparation for AHNs	Animal species & tissue for ABNs
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
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27.						
28.						

TGA ID	Name of Ingredient	CAS No.	Quantity / Unit	Maltodextrin source	Plant part & preparation for AHNs	Animal species & tissue for ABNs
29.						
30.						
31.						
32.						
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