Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only

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 a **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

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.

Evaluation of a proprietary ingredient is NOT part of this notification process. Proprietary ingredients may be reviewed or evaluated when used in therapeutic goods. The role of the 'Notification of a New Proprietary Ingredient' form is to allow the capture of complex formulation details and other relevant information within the TGA Business Services (TBS) system. Applications for new goods can then use the allocated proprietary ingredient number to upload a complex formulation in a single step.

It is the supplier's responsibility to ensure that complete and accurate formulation details are provided in this form.

To ensure that our records are accurate, suppliers must inform the TGA of any change in the formulation, proprietary ingredient name, supplier or supplier details. It is the supplier's responsibility to ensure that this information is available to any purchaser of the proprietary ingredient.

Once a proprietary ingredient has been included in the formulation of any products on the ARTG, its name and formulation cannot be changed. The only exception to this is where a proven error occurred at the time of notifying the proprietary ingredient.

Proprietary ingredient name

Please enter the proposed ingredient name:

The proprietary ingredient name must **NOT**:

- be an existing name in the TGA Business Services Proprietary Ingredients table
- exceed 150 characters
- include punctuation or other symbols

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):

- ☐ Active pre-mix
- ☐ Adhesive
- ☐ Capsule shell formulation
- ☐ Coating material
- ☐ Colour
- ☐ Cream (Ointment) base

- ☐ Excipient mix
- ☐ Flavour
- ☐ Fragrance
- ☐ Ink
- ☐ Oral base
- ☐ Preservative mix
- ☐ Sweetener

Proposed use

This proprietary ingredient is proposed for use in:

- ☐ Export Only medicines
- ☐ Listed medicines for supply in Australia*
- ☐ Registered over-the-counter (OTC) medicines or Registered complementary medicines
- ☐ Prescription medicines
- ☐ Devices
- ☐ Unknown at the time of notification**

*Please ensure the formulation complies with the Therapeutic Goods (Permissible Ingredients) Determination for listed medicine ingredients. Compliance is not assessed as part of the proprietary ingredient notification process; however, failure to comply may result in applications for listing of medicines that contain the proprietary ingredient failing validation at the time of submission.

**Where the 'unknown at the time of notification' box is checked, and there are ingredients used in the formulation that are not included in the Determination, the proprietary ingredient will not be given listed medicine availability.

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

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

Product name:	
Sponsor name:	
Submission number:	
Route of administration:	

Formulation details

Total number of ingredients contained in this proprietary ingredient formulation: ☐

- Only use approved ingredient names as they appear in the TGA Business Services (TBS) Ingredients table. If you cannot find an ingredient, you will need to submit a form to propose a new ingredient name. Do not use words such as 'Natural' as an additional descriptor in conjunction with the Australian Approved Name (AAN) for an ingredient name in your formulation.
- The formulation must contain at least two (2) ingredients.
- Only certain colours are permitted for use in therapeutic goods. Information on colours is available on the TGA Colourings used in medicines for topical and oral use webpage.
- With the exception of flavours, fragrances and printing inks, quantities must be provided for all ingredients in the formulation. Quantities must total 100% or 1000mg/g.
- No changes are permitted to the Proprietary Ingredient (PI) name or the formulation after it has been included in an ARTG entry.

Are there any proprietary ingredients used in your formulation? Yes ☐ No ☐

Other proprietary ingredients within your formulation must be entered into the TGA Business Services Proprietary Ingredients Table before you submit this form. If not already entered, a separate Notification of a new proprietary ingredient form for each proprietary ingredient must be submitted. Please note that any proprietary ingredient used within another proprietary ingredient formulation must have the same purpose as the primary formulation. For example, if a proprietary ingredient is used as 'fragrance', any proprietary ingredient included in its formulation must also have the purpose 'fragrance'.

Complete each column of the table below with all ingredient details. Include:

- All active, excipient and other proprietary ingredients (Attach additional pages as required).
- A meaningful unit for each quantity, for example, mg, mg/g, %., etc.
- A single consistent quantity or unit type.

	Active, Excipient or PI	Name of Ingredient	TGA ID	CAS No.	Quantity/ Unit
1.	Select from list				
2.	Select from list				
3.	Select from list				
4.	Select from list				

	Active, Excipient or PI	Name of Ingredient	TGA ID	CAS No.	Quantity/ Unit
5.	Select from list				
6.	Select from list				
7.	Select from list				
8.	Select from list				
9.	Select from list				
10.	Select from list				
11.	Select from list				
12.	Select from list				
13.	Select from list				
14.	Select from list				
15.	Select from list				
16.	Select from list				
17.	Select from list				
18.	Select from list				
19.	Select from list				
20.	Select from list				

Are any ingredients in your formulation derived from animals? Yes ☐ No ☐

If **yes** provide details below:

	Name of ingredient	Animal species (list all relevant)	Animal part/tissue (list all relevant)
1.			
2.			
3.			
4.			
5.			
6.			

- **DO NOT** include any additional material on ingredients derived from animals with this notification form.
- Ingredients derived from animals may be evaluated when used as part of the formulation of a medicine or device application.
- For more information on ingredients derived from ruminant animals see Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising risk.