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 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

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 to the proprietary ingredient, such as the supplier details. It is the supplier's responsibility to ensure that this information is available to any purchaser of the proprietary ingredient.

Any request for changes to an existing proprietary ingredient's formulation or name will be processed as notification of a new 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 (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 Ingredients table
- 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 (active pre-mixes can only contain one active ingredient)
- ☐ 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:

- ☐ Devices
- ☐ Export Only medicines
- ☐ Listed medicines for supply in Australia*
- ☐ Registered over-the-counter (OTC) medicines or Registered complementary medicines
- ☐ Prescription medicines
- ☐ 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:	
Route of administration:	

Formulation details

- 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 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.
- Quantities must be provided for all ingredients in the formulation including flavours, fragrances and printing inks.
- Quantities must total 100% or 1000mg/g. Ranges will not be accepted, exact nominal quantities must be stated.
- Use approved herbal ingredient names such as Australian Herbal Names (AHNs) or Australian Herbal Substance Names (AHSs) instead of food names (AFNs) to more accurately identify the ingredient.
- If your proprietary ingredient contains another proprietary ingredient, then the proprietary ingredient being used in your formulation must be entered into the TBS ingredient table first. A separate proprietary ingredient notification form must be submitted for each proprietary ingredient.
- If your proprietary ingredient contains another proprietary ingredient they must both have the same purpose e.g. flavour
- Do not provide any additional information about ingredients derived from animals with this notification form. These details may be requested as part of a medicine or device evaluation or review.
- For more information on ingredients derived from ruminant animals see Transmissible Spongiform Encephalopathies (TSE): TGA approach to minimising risk.

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

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

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 single consistent, meaningful unit for each quantity, for example, mg, mg/g, %. etc.
- Number each of your ingredients, particularly if providing additional pages.
- Animal or plant part details, if applicable.

	Active, Excipient or PI	Name of Ingredient	TGA ID	CAS No.	Quantity/ Unit	Plant part/preparation (if applicable)	Animal species and part/tissue (if applicable)
1	Select						
2	Select						
3	Select						
4	Select						
5	Select						
6	Select						
7	Select						
8	Select						
9	Select						
10	Select						
11	Select						
12	Select						
13	Select						
14	Select						
15	Select						