



Request for an ingredient disclosure exemption under the Trade practices (consumer product information standard) (cosmetics) regulations

Instructions for filling out form

Ingredient identity and reasons for requesting exemption	
Ingredient name and CAS number (if allocated)	Please include both generic and scientific names
Product name(s)	Please list all of the products that you intend to use this ingredient in
Has the Therapeutic Goods Administration (TGA) assessed whether the product is a 'therapeutic good'?	If so, provide a copy of relevant correspondence from the TGA If not, the ACCC may need to liaise with the TGA for an opinion in this regard
Explain how the product is a 'cosmetic product' for the purposes of the regulation	A 'cosmetic product' is defined in the regulations to mean "a substance or preparation intended for placement in contact with any external part of the human body, including: (a) the mucous membranes of the oral cavity; and (b) the teeth; With a view to: (c) altering the odours of the body; or (d) changing its appearance; or (e) cleansing it; or (f) maintaining it in good condition; or (g) perfuming it; or (h) protecting it."

Is the ingredient commonly used in other cosmetic products?	If yes, please list the types of cosmetic products that this ingredient is commonly used in. Is the ingredient disclosed on these other cosmetic products?
How important is the order and conditions in which the ingredients are mixed? ¹	For example, does the claimed uniqueness arise out of the order in which the ingredients are mixed together or other conditions, (eg. temperature, PH, use of emulsifiers or processing aids) or is it due only to the presence of the ingredient?
Company information	
Are your products manufactured in Australia or overseas?	Please specify how many locations your products will be manufactured in.
If you sell your products overseas, have you sought/been granted an exemption from disclosing the ingredient by the relevant government authority in that country?	If yes, please provide details of your trade secret (confidentiality) application to the relevant international authority. Please also specify whether it was granted and when.
Efforts to develop and maintain a trade secret	
How have you limited the dissemination of information about the presence of the ingredient such that it is a trade secret?	<p>You should address the following matters:</p> <ul style="list-style-type: none"> • To what extent is the presence of the ingredient known outside your business and to employees/officers? • What measures have you taken to protect the secrecy of the presence of the ingredient? • Could the identity of the ingredient be determined by others? (Such as by analysis or research) <p>To assist your response, consider the following factors:</p> <p>(a) Who knows, or is likely to know, the identity of the ingredient? (Includes persons who have access to information about the identity of the ingredient.) Under what circumstances do they know/have access to the ingredient?</p> <p>(b) Who knows the source/preparation method of the ingredient? Is a rare or unusual source involved?</p> <p>(c) Who primarily purchases the ingredient and to what extent do they know what the ingredient is, its role in the product/s and that it is a secret ingredient?</p> <p>(d) Who primarily mixes the ingredient into the product</p>

¹ A trade secret exemption will not be granted to protect the formulation of a cosmetic product. If the uniqueness of the product is due only to the way in which the ingredients are mixed together, or the order of their mixing, protection of that information is considered to be your responsibility.

	<p>and to what extent do they know what the ingredient is, its role in the product/s and that it is a secret ingredient?</p> <p>(e) Who knows/has access to the product formulation?</p> <p>(f) Are other processing aids necessary to introduce the ingredient to the product formulation?</p>
<p>What gives the use of ingredient its value?</p>	<p>State the value to you/your company of the information regarding this ingredient, particularly whether the following applies:</p> <ul style="list-style-type: none"> • Your competitors do not know you are using this ingredient. • Use of this ingredient in cosmetics not obvious or easily ascertainable by other cosmetic producers. • It is not usually used in cosmetic products. • Its source is not known to your competitors. • Its method of preparation is unusual/ uncommon. • Disclosure of the ingredient would prejudice a trade secret. <p>Also provide an estimated monetary value (in \$AUD) to you/your organisation has spent developing the products using the ingredient?</p>
Documentation substantiating safety	
<p>Has any overseas government/accredited authority assessed this ingredient for safety and have they authorised its use in cosmetics or food?</p>	<p>Please ensure that all available supporting documentation is provided (for example references to reports, papers should include the author, date of publication and title).</p>

Request for details	
Name of requestor	
Company name	
ABN	
Job title	
Postal address	
Contact number	
Email	
Ingredient identity and reasons for requestion exemption	
Ingredient name and CAS number (if allocated)	<p>Generic ingredient name:</p> <p>Scientific ingredient name:</p> <p>CAS number:</p>
Product name(s)	
Has the Therapeutic Goods Administration (TGA) assessed whther the product is a 'therapeutic good'?	<p>No</p> <p>Yes</p> <p>If yes—provide a copy of relevant correspondence from the TGA</p>
Explain how the product is a 'cosmetic product' for the purposes of the regulation	
Summary of reasons why you are requesting an exemption from listing this ingredient pursuant to Regulation 7 of the Trade Practices (Consumer Product Information Standard (Cosmetics) Regulations)	

<p>Is the ingredient commonly used in other cosmetic products?</p>	<p>No Yes If yes list products:</p>
<p>How important is the order and conditions in which the ingredients are mixed?</p>	
<p>State the period for which an exemption is sought</p>	
<p>Company information</p>	
<p>Are you a sole trader?</p>	<p>No Yes</p>
<p>Are you a national or international company?</p>	<p>National International</p>
<p>Are your products sold only in Australia or overseas or both?</p>	<p>Sold only in Australia Sold overseas Sold both in Australia and overseas</p>
<p>Where do you sell your product?</p>	<p>Direct to the public Through retail outlets Through wholesalers</p>
<p>Where are your products manufactured?</p>	<p>Australia Overseas</p>
<p>Are the products manufactured by you or a contractor?</p>	<p>Self Contractor</p>

<p>If you sell your products overseas, have you sought/been granted an exemption from disclosing the ingredient by the relevant government authority in that country?</p>	<p>No</p> <p>Yes</p> <p>If yes, provide details:</p>
<p>Efforts to develop and maintain a trade secret</p>	
<p>How have you limited the dissemination of information about the presence of the ingredient such that it is a trade secret?</p>	
<p>Has the presence of the ingredient in your product ever been disclosed to the public?</p>	<p>No</p> <p>Yes</p> <p>If yes, provide details:</p>
<p>Have you applied for or been granted patents or other protection of intellectual property?</p>	<p>No</p> <p>Yes</p> <p>If yes, provide details:</p>
<p>What gives the use of ingredient its value?</p>	
<p>What would be the effect (in monetary terms) on your company if your competitors knew:</p> <ul style="list-style-type: none"> • You were using the ingredient; or • Knew the ingredient source/preparation method 	<p>\$AUD</p>

Documentation substantiating safety	
What concentration or proportion is the ingredient used in the product(s) for which exemption is sought?	
What parts of the body the product is designed to be applied to?	
Are there any specific directions related to safe use of the product?	
What is the claimed purpose of the product?	
Has any overseas government/accredited authority assessed this ingredient for safety and have they authorised its use in cosmetics or food?	
Has dermal testing been conducted on human or animal subjects?	<p>No</p> <p>Yes</p> <p>If yes, provide test reports</p>
Is the ingredient/chemical currently listed on the Australian Inventory of Chemical Substances (AICS) or otherwise permitted for us by NICNAS?	<p>No</p> <p>Yes</p> <p>If yes, provide details:</p>
Is the ingredient listed in any of the Schedules to the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)?	<p>No</p> <p>Yes</p> <p>If yes, please list which Schedules and what restrictions or requirements are imposed by the SUSMP:</p>

<p>Have any restrictions been placed overseas on the use of the ingredient in a cosmetic product?</p>	<p>No Yes If yes, provide details:</p>
<p>Explain why you consider the inclusion of the ingredient is unlikely to be harmful to a consumer</p>	
<p>Do you provide safety instructions with the product?</p>	<p>No Yes If yes, provide a copy</p>
<p>Have you received any reports of injury/hurt from the use of the product?</p>	<p>No Yes If yes, provide details:</p>
<p>Acknowledgement and signature</p>	
<p>By signing the below form you:</p> <ol style="list-style-type: none"> 1. acknowledge that the information contained within the form is, to the best of your knowledge, accurate and complete 2. agree that in order to assess your applications, the ACCC may need to share the information you have provided with other regulators, such as the Therapeutic Goods Administration and/or the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) 	
<p>Signature of requestor</p>	
<p>Date of signature</p>	