

Application for New Chemical Notification in the Standard or Limited Notification Category



Australian Government
Department of Health and Ageing
NICNAS

Use this form to apply for a Notification of a New Industrial Chemical in the Standard or Limited Notification categories under Section 23 of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

For fees information see http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_And_Charges.asp

Notification Statement

Applicant(s) to complete. Where a joint application is made, details of all the applicants and a signed declaration from all the applicants are required.

If data is provided by a third party, either separately or accompanying the notification, a Third Party Information Lodgement Form (signed by the owner of the data) should accompany the third party data.

Please complete the form by clicking in the appropriate boxes and by writing in the relevant sections in BLOCK LETTERS. Ensure that all supporting documents and relevant fees are enclosed.

This notification statement contains:

- Two copies of the completed form.
- Test reports, chemical structure, spectra and other relevant information in **duplicate**.
- Notification Fee.

Return to: Director
NICNAS
GPO Box 58, Sydney NSW 2001 (postal address) or
Level 7, 260 Elizabeth Street, Sydney NSW 2010 (courier address)
Telephone (02) 8577 8800 / 1800 638 528 Fax (02) 8577 8888

Should you have difficulties completing this form, require further information or to provide feedback on this form, please contact the New Chemicals Program by e-mail at newchemicals@nicnas.gov.au or on the above details, or visit <http://www.nicnas.gov.au>.

Notifier Details		
Business Name:		
ACN / ABN:	NICNAS Registration Number:	
Business Address:		Postcode:
Postal Address (if same as Business Address, state AS ABOVE):		Postcode:
Contact Name:	Position:	
Phone:	Fax:	E-mail:

Authorisation to Act as Technical Contact

The technical contact is the primary contact for NICNAS and unless indicated otherwise is normally the sole contact for NICNAS with regards to requests for additional information and the giving of the assessment certificate if the contact is in Australia.

Business Name:

Business Address:

Postcode:

Postal Address (if same as Business Address, state AS ABOVE):

Postcode:

Contact Name:

Position:

Phone:

Fax:

E-mail:

I/We, the Notifier (Applicant), authorise the technical contact to act on my/our behalf in all matters pertaining to my/our application for an assessment certificate (Note: this authorisation to act can be amended or cancelled at any time by notifying NICNAS in writing) Yes No

Should correspondence between NICNAS and the technical contact be electronic where possible? Note permits/certificates will be delivered to the contact via courier. Yes No

Type of Notification

- Standard Notification (STD)
- Chemical other than polymer (>1 tonne/year)
 - Biopolymer (>1 tonne/year)
 - Synthetic polymer with Mn <1000 Da (>1 tonne/year)
 - Ultraviolet filter in a cosmetic to be applied to the skin

- Limited Notification (LTD)
- Synthetic polymer with Mn \geq 1000 Da
 - Small volume: chemical other than polymer (\leq 1 tonne/year)
 - Small volume: synthetic polymer with Mn <1000 (\leq 1 tonne/year)
 - Small volume: biopolymer (\leq 1 tonne/year)
 - Site limited: chemical other than polymer (\leq 10 tonnes/year)
 - Site limited: synthetic polymer with Mn <1000 (\leq 10 tonnes/year)
 - Site limited: biopolymer (\leq 10 tonnes/year)

Chemical Details

Chemical Name:

Marketing or Other Name(s):

CAS Number (if known):

Has this chemical been notified overseas? Yes No

If yes, by which competent authority and in what year?

Has this chemical been assessed, or is it currently being assessed by another Australian regulatory agency (e.g. TGA, APVMA)? Yes No

If yes, provide details:

Is the chemical to be used as an ultraviolet filter in a cosmetic to be applied to the skin? Yes No

If yes, please note that the application must be submitted in the Standard Notification category. In addition, the UV filters attachment form should be completed and submitted with the notification (http://www.nicnas.gov.au/Forms/New_Chemicals/STD_LTD_Notification.asp).

Is the chemical an industrial nanomaterial under the NICNAS definition? Yes No
(Note: for the working definition please consult the document, *Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials*, available from http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp) Unsure[#]

If yes or unsure, is the chemical introduced as a solid/powder or as a dispersion? (Note: if the answer to this question is yes, please consult the above nanomaterial guidance document as additional data requirements may apply). Yes No

[#]Please note that by checking this box, the chemical may be assumed to be an industrial nanomaterial for risk assessment purposes.

Exempt Information

Information that is not considered "basic information" may be claimed as confidential and if approved will not be published in the Chemical Gazette or Public Report. Some sections that may be claimed as confidential require generic text for publication.

Do you wish to claim any information as confidential? (fee applies)* Yes No

Proposed Exempt Information:

- | | | |
|---|---|--|
| <input type="checkbox"/> Chemical name | <input type="checkbox"/> Molecular Weight | <input type="checkbox"/> Residual monomers/impurities |
| <input type="checkbox"/> Other names | <input type="checkbox"/> Spectral Data | <input type="checkbox"/> Manufacture/import volume |
| <input type="checkbox"/> CAS number | <input type="checkbox"/> Purity | <input type="checkbox"/> Site of manufacture/reformulation |
| <input type="checkbox"/> Molecular formula | <input type="checkbox"/> Use details | <input type="checkbox"/> Other |
| <input type="checkbox"/> Structural Formula | <input type="checkbox"/> Polymer constituents | |

Justification for claims:

Third Party Information Lodgement

Does this submission include information that is to be held confidential from the notifier and will be provided by a third party? Yes No

If yes, please identify items on the attached checklist and complete a Third Party Information Lodgement Form (http://www.nicnas.gov.au/Forms/New_Chemicals/STD_LTD_Notification.asp).

Variation of Schedule Requirements

It is possible to apply for a Variation to the Scheduled Data Requirements if you do not have all of the necessary information for the required endpoints. In such cases, please provide an indication of the likely behaviour (e.g. data on a similar chemical or calculated data) and scientific justification for the omitted endpoints. For further information on data requirements, please consult the NICNAS Handbook for Notifiers.

Does this submission include variation(s) to the Schedule requirements for any item(s)? (fee applies)* Yes No

Please identify items on the attached checklist and provide full details of the proposed variations and justification for each claim here:

Early Introduction Permit

Does this submission include an Application for Early Introduction Permit? (eligibility criteria and fees apply)* Yes No

If yes, please complete an Application for Early Introduction Permit Form (available from http://www.nicnas.gov.au/Forms/New_Chemicals/EIP.asp).

*For information regarding fees see http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_And_Charges.asp

Declaration

I declare that to the best of my knowledge all the information in this application is true, correct and complete. In relation to the notification statement and/or other documentation accompanying this application, I declare that I am entitled to use and give the Director all data in the statement.

Name:

Position:

Signature

Date:

Note: It is an offence under the Act to supply a statement that is false or misleading.

Payment Details

<input type="checkbox"/> Electronic Funds Transfer	Please quote Notification number / Registration number / Invoice number when making the payment			
	Account Name	Department of Health & Ageing Official Departmental NICNAS Special Account		
	Bank	Reserve Bank of Australia, London Circuit, Canberra ACT 2600		
	BSB Number	092-009	Account Number	11608-5
<input type="checkbox"/> Credit Card	Card Type	<input type="checkbox"/> Mastercard		<input type="checkbox"/> Visa
	Credit card no.	<input type="text"/>	<input type="text"/>	<input type="text"/>
	Amount:	\$	Expiry Date:	
	Print Name:	<input type="text"/>		
	Authorised Signature:	<input type="text"/>		
<input type="checkbox"/> Cheque	Enclosed	<input type="checkbox"/> Yes <input type="checkbox"/> No		
	Cheques are to be made payable to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in \$AUD.			
<p>Please note: If payment is being made from an overseas bank, all bank charges/fees are payable by the payee. The NICNAS SWIFT code is RSBKAU2S.</p> <p>Applications will not be processed until correct payment has been received.</p>				

NOTIFICATION CHECKLIST

This checklist is a guide to the information required to support an application for a Standard or Limited Assessment Certificate for a new chemical under Section 23 of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

For a **Standard Notification**, the parts of the Schedule to be completed are:

- chemicals other than polymers: parts **A, B and C** or
- polymers: parts **A, B, C and D**;
- Note that for an ultraviolet filter in a cosmetic to be applied to the skin, Schedule part **E** data requirements apply. In such cases the UV Filter Attachment form should be completed and submitted to NICNAS.

For a **Limited Notification**, the parts of the Schedule to be completed are:

- chemicals other than polymers: parts **A and B** or
- polymers: parts **A, B, and D**.

The scheduled items represent a minimum set of data requirements. If additional data is available to the notifier, it should be provided to NICNAS as part of the notification package. Note that with the exception of certain Schedule C items, hardcopies of all test reports should be submitted to NICNAS in duplicate. The Schedule C items for which only one hardcopy of the test report is required include acute toxicity, repeated dose toxicity and genotoxicity.

Note: the checklist is to be completed by clicking in or ticking the corresponding boxes.

Information Submitted	Click or tick each box when information has been supplied for items in the notification statement.	<input type="checkbox"/>
Proposed Variation	If a Variation to the Schedule requirements is proposed for an item, please click or tick the relevant box.	<input type="checkbox"/>
Proposed Exempt Information	If an application is sought for information to be treated as Exempt Information, click or tick the relevant box.*	<input type="checkbox"/>
Third Party Exempt Information	If an application is sought for information to be treated as exempt information <u>and</u> not be disclosed to the notifier, click or tick the relevant box.*	<input type="checkbox"/>

* For certain items classed as basic information, there is no check box for "Exempt Information". In some of these cases, it is possible to apply for exemption for certain details, such as concentration of the notified chemical in a formulation, or details of the use of the notified chemical. In these cases, a full description of the proposed exemption should be provided in the justification for claims under the Exempt Information section of the above form.

Schedule A: Summary of Notification

	Information Submitted
1. Type of Notification	<input type="checkbox"/>
2. Summary of Health and Environmental Effects	<input type="checkbox"/>
3. Summary of how chemical meets definition of hazardous substance	<input type="checkbox"/>
4. Details of any notification made in another country	<input type="checkbox"/>
5. Bibliography	<input type="checkbox"/>

Schedule B: Identity, Properties and Uses

	Information Submitted	Proposed Variation	Proposed Exempt Information	Third Party Exempt Information
1. Identity of Chemical				
(a) Chemical Name(s)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(b) Other Name(s)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(c) Marketing Name	<input type="checkbox"/>			
(d) CAS Number	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(e) Molecular Formula	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Structural Formula	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(f) Molecular Weight	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(g) Spectral Data	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
2. Composition				
(a) Purity	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(b) Identity of Toxic or Hazardous Impurities	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
% Weight of Toxic or Hazardous Impurities	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(c) Non-hazardous Impurities (>1%)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
(d) Identity of Additives/Adjuvants	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
% Weight of Additives/Adjuvants	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
3. Use	<input type="checkbox"/>			
4. Physical State and Appearance	<input type="checkbox"/>			
5. Manufacture/Import Volume	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
6. Occupational Health and Safety				
(a) Occupational Exposure Data				
Category of Workers	<input type="checkbox"/>			
Nature of Work Done	<input type="checkbox"/>			
Prevention of Worker Exposure	<input type="checkbox"/>			
Education and Training	<input type="checkbox"/>			
Work-Related Injuries/Diseases	<input type="checkbox"/>			
Other Occupational Hazards	<input type="checkbox"/>			
(b) Health Conditions	<input type="checkbox"/>			
(c) Occupational Health Monitoring				
Atmospheric Monitoring	<input type="checkbox"/>			
Biological Monitoring	<input type="checkbox"/>			
(d) Observation on Human Exposure	<input type="checkbox"/>			
7. Environmental Impact				
(a) Manufacturing/Reformulation Process				
Identity of Sites	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Process Description	<input type="checkbox"/>			
Release at Each Site	<input type="checkbox"/>			
(b) Release to Environment for Each Use	<input type="checkbox"/>			
(c) Transport and Storage	<input type="checkbox"/>			
(d) Disposal	<input type="checkbox"/>			
8. Public Exposure	<input type="checkbox"/>			

	Information Submitted	Proposed Variation	Proposed Exempt Information	Third Party Exempt Information
9. Physical and Chemical Data				
(a) Melting Point/Boiling Point	<input type="checkbox"/>	<input type="checkbox"/>		
(b) Specific Gravity/Density	<input type="checkbox"/>	<input type="checkbox"/>		
(c) Vapour Pressure	<input type="checkbox"/>	<input type="checkbox"/>		
(d) Water Solubility	<input type="checkbox"/>	<input type="checkbox"/>		
(e) Hydrolysis as a Function of pH	<input type="checkbox"/>	<input type="checkbox"/>		
(f) Partition Co-efficient	<input type="checkbox"/>	<input type="checkbox"/>		
(g) Absorption/Desorption	<input type="checkbox"/>	<input type="checkbox"/>		
(h) Dissociation Constant	<input type="checkbox"/>	<input type="checkbox"/>		
(i) Particle Size	<input type="checkbox"/>	<input type="checkbox"/>		
(j) Flash Point	<input type="checkbox"/>	<input type="checkbox"/>		
(k) Flammability	<input type="checkbox"/>	<input type="checkbox"/>		
(l) Autoignition Temperature	<input type="checkbox"/>	<input type="checkbox"/>		
(m) Explosive Properties	<input type="checkbox"/>	<input type="checkbox"/>		
(n) Reactivity	<input type="checkbox"/>	<input type="checkbox"/>		
Oxidising Properties	<input type="checkbox"/>	<input type="checkbox"/>		
10. Methods of Detection and Determination	<input type="checkbox"/>			
11. Label	<input type="checkbox"/>			
12. MSDS	<input type="checkbox"/>			
13. Emergency Procedures				
Occupational Emergency Procedures	<input type="checkbox"/>			
Environmental Emergency Procedures	<input type="checkbox"/>			

Schedule C: Toxicology Information

Acute Toxicity				
(a) Acute Oral Toxicity	<input type="checkbox"/>	<input type="checkbox"/>		
(b) Acute Dermal Toxicity	<input type="checkbox"/>	<input type="checkbox"/>		
(c) Acute Inhalation Toxicity	<input type="checkbox"/>	<input type="checkbox"/>		
(d) Skin Irritation	<input type="checkbox"/>	<input type="checkbox"/>		
(e) Eye Irritation	<input type="checkbox"/>	<input type="checkbox"/>		
(f) Skin Sensitisation	<input type="checkbox"/>	<input type="checkbox"/>		
Repeated Dose Toxicity	<input type="checkbox"/>	<input type="checkbox"/>		
Genotoxicity				
(g) Induction of Point Mutations	<input type="checkbox"/>	<input type="checkbox"/>		
(h) Genotoxic Damage <i>in vivo</i>	<input type="checkbox"/>	<input type="checkbox"/>		
(i) Chromosome Damage <i>in vitro</i>	<input type="checkbox"/>	<input type="checkbox"/>		
Ecotoxicity				
(j) Fish, Acute Toxicity	<input type="checkbox"/>	<input type="checkbox"/>		
(k) Daphnia sp., Acute Immobilisation/Reproduction	<input type="checkbox"/>	<input type="checkbox"/>		
(l) Alga, Growth Inhibition Test	<input type="checkbox"/>	<input type="checkbox"/>		
Biodegradation				
(m) Ready Biodegradation	<input type="checkbox"/>	<input type="checkbox"/>		
(n) Bioaccumulation	<input type="checkbox"/>	<input type="checkbox"/>		

Schedule D: Polymer Information

	Information Submitted	Proposed Variation	Proposed Exempt Information	Third Party Exempt Information
Identity and Composition				
1. Weight Percentage and Ingredients	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
2. Number-average Molecular Weight	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
3. Residual Monomers/Other Reactants	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
4. Low Molecular Weight Species (<500 and <1000 Da)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
5. Degradation Products	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
6. Loss of Monomers, Additives, Impurities	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>