

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 and sign the declaration. Where a joint application is made, details of all the applicants and signed declarations 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. Ensure that all supporting documents and relevant fees are enclosed.

This notification statement contains:

- A completed electronic copy of the New Chemical Notification Form (if possible).
- Two hardcopies 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 8, 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:
Is a joint application being made?		<input type="checkbox"/> Yes <input type="checkbox"/> No
If yes, please provide the names of the additional applicants (note that completed forms, up to and including the signed declaration, are required from all applicants):		

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 Yes
in all matters pertaining to my/our application for an assessment certificate (Note: this No
authorisation to act can be amended or cancelled at any time by notifying NICNAS in writing)

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

Type of NotificationStandard 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)

Are you utilising one of the Modular (reduced fee) categories? Yes No

If yes, please indicate which of the circumstances below applies and complete the Modular attachment form (http://www.nicnas.gov.au/Forms/New_Chemicals/STD_LTD_Notification.asp).

- Similar to Chemical Previously Assessed by NICNAS
- Group Assessment
- Assessed by Comparable Agency
- Approved Foreign Scheme

Chemical Details

Chemical Name (<i>if not confidential from the notifier</i>):		
Marketing or Other Name(s):		
CAS Number (<i>if known and not confidential from the notifier</i>):		
Has this chemical been notified overseas?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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)?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, provide details:		
Is the chemical to be used as an ultraviolet filter in a cosmetic to be applied to the skin?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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? (<i>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</i>)	<input type="checkbox"/> Yes <input type="checkbox"/> Unsure [#]	<input type="checkbox"/> No
If yes or unsure, is the chemical introduced as a solid/powder or as a dispersion? (<i>Note: if the answer to this question is yes, please consult the above nanomaterial guidance document as additional data requirements may apply</i>).	<input type="checkbox"/> Yes	<input type="checkbox"/> No

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

Exempt Information		
<i>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.</i>		
Do you wish to claim any information as confidential? (fee applies)*	<input type="checkbox"/> Yes	<input type="checkbox"/> 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 (outline below)
<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?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please identify the items to be provided below and complete a Third Party Information		

Lodgement Form (http://www.nicnas.gov.au/Forms/New_Chemicals/STD_LTD_Notification.asp).

- | | | |
|---|---|--|
| <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 | |

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, you do need to provide calculated data/data on a similar chemical/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 and provide full details of the proposed variations and justification for each claim (including for the use of modelled and/or analogue data):

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
Please note: If payment is being made from an overseas bank, all bank charges/fees are payable by the remitter (payer). The NICNAS SWIFT code is RSBKAU2S.			
<input type="checkbox"/> Credit Card	Card Type	<input type="checkbox"/> Mastercard <input type="checkbox"/> Visa	
	Credit card no.	<input type="text"/>	<input type="text"/>
	Amount:	\$ <input type="text"/>	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.		
Applications will not be processed until correct payment has been received.			

Instructions for Completing the Remainder of this Form

The form should be filled out completely. Any missing information may result in delays in processing the application and/or return of the application.

The completed application should be submitted to NICNAS in both hardcopy (in duplicate) and electronic form (if possible). With the exception of Schedule E items and certain Schedule C items, hardcopies of all test reports and other relevant information should be submitted to NICNAS in duplicate. The Schedule C items for which only one hardcopy of the test report is required include the human health endpoints (the test reports for the environmental endpoints are required in duplicate).

The NICNAS *Handbook for Notifiers* is available from the NICNAS website (*via* the following link http://www.nicnas.gov.au/Publications/NICNAS_Handbook.asp), and should be consulted for information on data requirements.

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.

A guidance document is available on-line. This document indicates the information that should be included in each section.

The remainder of the form consists of 2 parts:

1. Exempt Information: this section should only be completed if exempt information is being applied for and the associated fee paid. Information in this section should not be duplicated in Part 2 (and *vice-versa*).
2. This section should contain information that is suitable for publication.

Note: some sections that may be claimed as Exempt Information require generic text for publication in the *Chemical Gazette* and Public Report. In these instances, the generic information should be entered in Part 2 of the form. For example:

1. Use details: while the specific use of a chemical may be claimed as Exempt Information, the chemicals general uses are considered to be basic information.
2. Where numerical information is being claimed as Exempt Information (e.g. Purity, Introduction Volume) a range (e.g. <x%, 10-20 tonnes) is required for publication in the *Chemical Gazette* and Public Report.

All headings/sub-headings within the form should not be altered, unless instructed to do so. Text should be entered into the relevant sections within the form in Times New Roman, 10 point font. Please note that this document is protected as a form (this allows completion of check boxes). Once the check boxes have been completed, additional functions (e.g. tracked changes) may be enabled by removing the document protection *via* the forms toolbar. Sufficient information should be entered into each section to enable the conduct of an adequate assessment.

Where a joint application is made, details of all the applicants and a signed declaration from all the applicants are required, i.e. the preceding form pages should be completed by all applicants, whereas, the remainder of the form (Part 1: Exempt Information and Part 2: Public Report) need only be submitted by one of the applicants.

PART 1: EXEMPT INFORMATION

Only complete the sections for which an Application for Exempt Information is being made. Delete sections which are not required. Information in this section should not be duplicated in Part 2 (and vice-versa). However, some sections that may be claimed as Exempt Information require generic text for publication in the Chemical Gazette and Public Report (see Part 2 for details). In these instances, the generic information should be entered in Part: 2 Public Report. Note: numbering below refers to the corresponding section in Part 2: Public Report.

1. IDENTITY OF CHEMICAL

1.2. CAS NUMBER *[If a CAS number has not been assigned, write 'not assigned' in the below cell]*

1.3. CHEMICAL NAME

If a CAS number has not been assigned, indicate which of the following applies:

- 1) The chemical name was assigned by CAS (*a copy of the documentation from CAS should be submitted to NICNAS with the application*) OR
- 2) The chemical name has not been assigned by CAS

1.4. OTHER NAME(S)

1.5. MOLECULAR FORMULA

1.6. STRUCTURAL FORMULA

[Free Space for Structural Formula]

1.7. MOLECULAR WEIGHT *[Use this box for non-polymers, otherwise delete]*

1.8. MOLECULAR WEIGHT (MW) *[Use this box for polymers, otherwise delete]*

Number Average Molecular Weight (Mn)	... Da
Weight Average Molecular Weight (Mw)	... Da
Polydispersity Index (Mw/Mn)	
% of Low MW Species <1000 Da	...%

% of Low MW Species <500 Da	...%
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1.9. ANALYTICAL DATA *[Remove or copy/paste additional boxes below as necessary]*

METHOD	
Remarks	
TEST FACILITY	

METHOD	
Remarks	
TEST FACILITY	

2. COMPOSITION
2.1. DEGREE OF PURITY

...%

2.2. HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
[If none write 'None' here. Otherwise delete this row and complete box below. Copy/paste additional boxes below as necessary]

<i>Chemical Name</i>			
<i>CAS No.</i>		<i>Weight %</i>	
<i>Hazardous Properties</i>			

2.3. NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight)
[If none write 'None' here. Otherwise delete this row and complete box below. Copy/paste additional boxes below as necessary]

<i>Chemical Name</i>			
<i>CAS No.</i>		<i>Weight %</i>	

2.4. ADDITIVES/ADJUVANTS
[If none write 'None' here. Otherwise delete this row and complete box below. Copy/paste additional boxes below as necessary]

<i>Chemical Name</i>			
<i>CAS No.</i>		<i>Weight %</i>	

2.5. POLYMER CONSTITUENTS *[Complete for polymers only]*

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>

4. INTRODUCTION AND USE INFORMATION

4.2. MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>					

4.4. IDENTITY OF MANUFACTURER/RECIPIENTS

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4.6. USE *[Include exempt details of all proposed uses of the notified chemical]*

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[Include details of any other items for which Exempt Information is being claimed here]

--

EXEMPT INFORMATION

PART 2: PUBLIC REPORT

If an Application for Exempt Information is being made for certain sections (that were completed in Part 1 and the appropriate fee paid), then the corresponding sections in Part 2 should be deleted or generic information supplied where indicated ().*

Preferred Name for the Notified Chemical/Polymer**1. IDENTITY OF CHEMICAL**

1.1. MARKETING NAME(S)

1.2. CAS NUMBER *[If a CAS number has not been assigned, write 'not assigned' in the below cell]*

1.3. CHEMICAL NAME

If a CAS number has not been assigned, indicate which of the following applies:

- 1) The above chemical name was assigned by CAS (*a copy of the documentation from CAS should be submitted to NICNAS with the application*) OR
- 2) The above chemical name has not been assigned by CAS

1.4. OTHER NAME(S)

1.5. MOLECULAR FORMULA

1.6. STRUCTURAL FORMULA

[Free Space for Structural Formula]

1.7. MOLECULAR WEIGHT * *[Use this box for non-polymers, and for polymers for which molecular weight is being claimed as confidential, otherwise delete]*

1.8. MOLECULAR WEIGHT <i>[Use this box for polymers if not claimed as confidential, otherwise delete]</i>	
Number Average Molecular Weight (Mn)	... Da
Weight Average Molecular Weight (Mw)	... Da
Polydispersity Index (Mw/Mn)	
% of Low MW Species <1000 Da	...%
% of Low MW Species <500 Da	...%

1.9. ANALYTICAL DATA * <i>[Delete as appropriate and/or copy/paste tables as necessary]</i>
Reference NMR, IR, HPLC, GC, GPC and UV spectra are provided.

METHOD	
Remarks	
TEST FACILITY	

METHOD	
Remarks	
TEST FACILITY	

2. COMPOSITION

2.1. DEGREE OF PURITY *	...%
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2.2. HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
<i>[If none write 'None' here. Otherwise delete this row and complete box below. Copy/paste additional boxes below as necessary]</i>

<i>Chemical Name</i>	
<i>CAS No.</i>	<i>Weight %</i>
<i>Hazardous Properties</i>	

2.3. NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
<i>[If none write 'None' here. Otherwise delete this row and complete box below. Copy/paste additional boxes below as necessary]</i>

<i>Chemical Name</i>	
<i>CAS No.</i>	<i>Weight %</i>

2.4. ADDITIVES/ADJUVANTS
<i>[If none write 'None' here. Otherwise delete this row and complete box below. Copy/paste additional boxes below as necessary]</i>

<i>Chemical Name</i>	
<i>CAS No.</i>	<i>Weight %</i>

2.5. POLYMER CONSTITUENTS *[Complete for polymers only]*

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>

2.6. LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES *[Complete for polymers only]*

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2.7. DEGRADATION PRODUCTS *[Complete for polymers only]*

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3. PHYSICAL AND CHEMICAL PROPERTIES

[Include the relevant value and data source in the table below. Copies of the full study reports and other relevant documentation should accompany this notification form when submitted to NICNAS.

Indicate below by marking the relevant endpoints if a Variation of Schedule Requirements has been applied for and appropriate fee paid, i.e. the boxes for which a variation is being applied for (if applicable) should be checked. Full justification for all variations (including use of modelled and analogue data) should be included under Variation of Schedule Data Requirements in the front section of this form].

The endpoints for which a variation of the schedule data requirements is being claimed include:

<input type="checkbox"/> Melting point/Boiling Point	<input type="checkbox"/> Partition Co-efficient	<input type="checkbox"/> Flammability Limits
<input type="checkbox"/> Specific Gravity/Density	<input type="checkbox"/> Absorption/Desorption	<input type="checkbox"/> Autoignition Temperature
<input type="checkbox"/> Vapour Pressure	<input type="checkbox"/> Dissociation Constant	<input type="checkbox"/> Explosive Properties
<input type="checkbox"/> Water Solubility	<input type="checkbox"/> Particle Size	<input type="checkbox"/> Oxidising Properties
<input type="checkbox"/> Hydrolysis as a Function of pH	<input type="checkbox"/> Flash Point	<input type="checkbox"/> Reactivity

3.1. PHYSICAL STATE AND APPEARANCE AT 20 °C AND 101.3 kPa

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Property	Value [or 'not determined']	Data Source/Justification
Melting Point/Freezing Point	... °C	Measured/Estimated/Calculated/Analogue data/(M)SDS
Boiling Point	... °C at 101.3 kPa	Measured/Estimated/Calculated/Analogue data/(M)SDS
Density	... kg/m ³ at ... °C	Measured/Estimated/Calculated/Analogue data/(M)SDS
Vapour Pressure	... kPa at 25 °C (or 20 °C)	Measured/Estimated/Calculated/Analogue

Year	1	2	3	4	5
Tonnes					

4.3. PORT OF ENTRY

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4.4. IDENTITY OF MANUFACTURER/RECIPIENTS *

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4.5. TRANSPORTATION AND PACKAGING

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4.6. USE *

[Include details of all proposed uses of the notified chemical, including concentrations of the notified chemical in the specific product types.]

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4.7. STORAGE

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4.8. EMERGENCY PROCEDURES – OCCUPATIONAL

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4.9. EMERGENCY PROCEDURES – ENVIRONMENTAL

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4.10. OPERATION DESCRIPTION

[Describe the manufacturing, processing, reformulation, repackaging and/or end use operations involving the notified chemical in the sections below. A process flow diagram may be useful to assist the description – see free space below, or include with the submission as an attachment.]

4.10.1 MANUFACTURE

[If the notified chemical is manufactured in Australia, describe the manufacturing processes. If imported into Australia, delete this section or write 'not applicable']

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4.10.2 REFORMULATION/REPACKAGING

Will the notified chemical be repackaged and/or reformulated in Australia? Yes No

[If the notified chemical will be repackaged or reformulated in Australia, describe the processes (including details of the concentration of the notified chemical at the relevant stages). If it will not be repackaged or reformulated, write 'not applicable']

4.10.3 END-USE

[Describe the end-use operations involving the notified chemical (including the concentration of the notified chemical at the relevant stages/different product types).]

[Free Space for Process Flow Diagram (if available)]

5. HUMAN HEALTH IMPLICATIONS

5.1. Exposure assessment

5.1.1. Occupational exposure

5.1.1.1. CATEGORY OF WORKERS

[Include all categories of workers who will handle the notified chemical or products containing the notified chemical, including transportation and storage]

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>

5.1.1.2. NATURE OF WORK DONE AND PREVENTION OF WORKER EXPOSURE

[Information given here should cover all workers involved from the manufacturing or import processes onwards, including those where the actual exposure is expected to be minimal]

5.1.1.3. EDUCATION & TRAINING

5.1.1.4. PREVALENCE OF WORK-RELATED INJURIES & DISEASES

5.1.1.5. OTHER OCCUPATIONAL HAZARDS

5.1.1.6. OCCUPATIONAL HEALTH MONITORING

5.1.2. Public exposure

5.2. Human health effects assessment
<p><i>The following table contains Schedule Data Requirements for a Standard (STD) notification. If data is available for chemicals/polymers that will be assessed in the Limited (LTD) notification category, then the table should be completed to the extent possible. Include the study result and the data source in the table below.</i></p> <p><i>Indicate below by marking the relevant endpoints if a Variation of Schedule Requirements has been applied for and appropriate fee paid, i.e. the boxes for which a variation is being applied for (if applicable) should be checked. Full justification for all variations (including use of analogue data) should be included under Variation of Schedule Data Requirements in the front section of this form.</i></p> <p><i>Copies of the full study reports and other relevant documentation should accompany this notification form when submitted to NICNAS. Please also note that only <u>one</u> hardcopy of the test report is required to be submitted for these items (all other test reports, such as physicochemical or ecotoxicity, should be submitted as hardcopies to NICNAS in duplicate).</i></p>

The endpoints for which a variation of the schedule data requirements is being claimed include:		
<input type="checkbox"/> Acute Oral Toxicity	<input type="checkbox"/> Eye Irritation	<input type="checkbox"/> Induction of Point Mutations
<input type="checkbox"/> Acute Dermal Toxicity	<input type="checkbox"/> Skin Sensitisation	<input type="checkbox"/> Genotoxic Damage <i>in vivo</i>
<input type="checkbox"/> Acute Inhalation Toxicity	<input type="checkbox"/> Repeated Dose Toxicity	<input type="checkbox"/> Chromosome Damage <i>in vitro</i>
<input type="checkbox"/> Skin Irritation		

<i>Endpoint [delete as appropriate]</i>	<i>Result</i>	<i>Data Source/Justification</i>
Acute oral toxicity	LD50 ... mg/kg bw	Measured/Analogue Data
Acute dermal toxicity	LD50 ... mg/kg bw	Measured/Analogue Data
Acute inhalation toxicity	LC50 ... mg/L/4 hour	Measured/Analogue Data
Skin Irritation	corrosive/severely	Measured/Analogue Data

	irritating/moderately irritating/slightly irritating/non-irritating	
Eye Irritation	corrosive/severely irritating/irritating/slightly irritating/non-irritating	Measured/Analogue Data
Skin Sensitisation	evidence/limited evidence/no evidence/inadequate evidence of sensitisation	Measured/Analogue Data
Repeated Dose Toxicity	NOEL/NOAEL/LOAEL	Measured/Analogue Data
Induction of Point Mutations	mutagenic/non mutagenic	Measured/Analogue Data
Genotoxic Damage <i>in vivo</i>	genotoxic/non genotoxic	Measured/Analogue Data
Genotoxic Damage <i>in vivo</i>	genotoxic/non genotoxic	Measured/Analogue Data
Other		Measured/Analogue Data

5.2.1. OBSERVATIONS ON HUMAN EXPOSURE

5.3. Human health risk assessment

5.3.1. Occupational health and safety

5.3.2. Public health

6. ENVIRONMENTAL IMPLICATIONS

6.1. Environmental exposure Assessment

6.1.1. RELEASE OF CHEMICAL AT SITE

6.1.2. RELEASE OF CHEMICAL FROM USE

6.1.3. RELEASE OF CHEMICAL FROM DISPOSAL

6.2. Environmental effects assessment

The following table contains Schedule Data Requirements for a Standard (STD) notification. If data is available for chemicals/polymers that will be assessed in the Limited (LTD) notification category, then the table should be completed to the extent possible. Include the study result and the data source in the table below.

Indicate below by marking the relevant endpoints if a Variation of Schedule Requirements has been applied for and appropriate fee paid, i.e. the boxes for which a variation is being applied for (if applicable) should be checked. Full justification for all variations (including use of modelled and analogue data) should be included under Variation of Schedule Data Requirements in the front section of this form..

Copies of the full study reports and other relevant documentation should accompany this notification form when submitted to NICNAS.

The endpoints for which a variation of the schedule data requirements is being claimed include:

<input type="checkbox"/> Ready Biodegradation	<input type="checkbox"/> Fish, Acute Toxicity	<input type="checkbox"/> Alga, Growth Inhibition Test
<input type="checkbox"/> Bioaccumulation	<input type="checkbox"/> Daphnia sp., Acute Immobilisation/Reproduction	

<i>Endpoint</i>	<i>Result</i>	<i>Data Source/Justification</i>
Ready Biodegradability		Measured/Analogue Data/Modelled
Bioaccumulation		Measured/Analogue Data/Modelled
Fish Toxicity	EC50 (96 h) ... mg/L	Measured/Analogue Data/Modelled
Daphnia Toxicity	EC50 (48 h) ... mg/L	Measured/Analogue Data/Modelled
Algal Toxicity	E _r C50 (72 h) ... mg/L	Measured/Analogue Data/Modelled
Inhibition of Bacterial Respiration	EC50 ... mg/L	Measured/Analogue Data/Modelled
Other		Measured/Analogue Data/Modelled

6.3. Environmental risk assessment**7. SUMMARY OF HOW THE CHEMICAL MEETS THE DEFINITION OF A HAZARDOUS SUBSTANCE (CLASSIFICATION)****8. (M)SDS AND LABEL****8.1. Label**

A copy of the proposed label(s) for the chemical in the form(s) that is intended to be introduced should be attached to this application. The label should be compiled in accordance with the Safe Work Australia Code of Practice for the *Labelling of Workplace Hazardous Chemicals* or the NOHSC *National Code of Practice for the*

Labelling of Workplace Substances. [Check the proposed label for the notified chemical against the check boxes. All of the items should be present if applicable for the chemical.]

Label Checklist

- Signal word e.g. ‘hazardous’ or ‘warning’ (where appropriate)
- Ingredient disclosure, if appropriate (e.g. for Type I hazardous ingredients)
- Risk and safety phrases/hazard class and category, if hazardous
- Australian contact details
- Information on label consistent with information detailed on (M)SDS
- If hazardous, label refers to (M)SDS

8.2. (Material) Safety Data Sheet

A copy of the (M)SDS for the chemical and the chemical in the form(s) that is intended to be introduced should be attached to this application. Where reformulation of the chemical occurs in Australia by the notifier (or known other parties) and the chemical is required to be disclosed on the (M)SDS (either by its full chemical name or generic name), then (M)SDS for those products should also be attached. The (M)SDS should be compiled in accordance with the Safe Work Australia Code of Practice for the *Preparation of Safety Data Sheets for Hazardous Chemicals* or the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets*. [Check the proposed (M)SDS for the notified chemical against the check boxes. All of the items should be present if applicable for the chemical.]

(M)SDS Checklist

- Australian contact details
- Hazardous statement on (M)SDS
- Risk and safety phrases/hazard class and category, if hazardous
- Ingredient disclosure, if appropriate (e.g. for Type I hazardous ingredients)
- Information on (M)SDS consistent with information detailed on label

9. BIBLIOGRAPHY/LIST OF ATTACHMENTS

[In the table below, include a list of all the attachments that will accompany the notification statement (e.g. study reports). The list should also identify any publications referred to in the statement. Note that any publications (e.g. literature sources) referred to in the statement should be provided as attachments, unless they are standard test methods, codes of practice etc.]

<i>Attachment</i>	<i>Full Reference [Add or delete rows, as appropriate]</i>
1	
2	
3	
4	
5	
6	
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