

**Application for Assessment Certificate
Polymer of Low Concern (PLC)**

FORM PLC-1



Australian Government
Department of Health and Ageing
NICNAS

Application for Assessment Certificate

Use this form to apply for an Assessment Certificate for a Polymer of Low Concern (PLC) under section 24A of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Instructions for Completing form PLC-1

- PART 1** Applicant(s) details and declaration is essential information that must be completed. For joint notifications each applicant must at least complete and sign a separate Part 1.
- PART 2** The PLC template requires the applicant to provide information to NICNAS about the chemical in a standardised format. When third party information is being provided only the holder of the confidential data need complete the sections where this information is required. The third party providing the information should also complete a Third Party Information Lodgement (Form 5).
- PART 3** The notification Checklist is a guide to the information required to support an application for an Assessment Certificate under the Polymer of Low Concern category.

NOTE - INCOMPLETE FORMS WILL LEAD TO DELAYS IN PROCESSING OF APPLICATIONS.

Notification Statement

Applicant(s) to complete. Click in the boxes, or write in the space provided. This notification statement contains:

- A completed electronic copy of Form PLC-1.
- Two** hardcopies of the completed Form PLC-1 with at least one signed and dated by the applicant(s).
- Test reports, chemical structure, spectra and other relevant information in **duplicate**.
- Notification Fee - See the 'Payment advice' section below for further information.

When required the Modular Attachment Form and the Form 5 should also be provided.

Send Notification Statement to:

Director
NICNAS
Level 7, 260 Elizabeth Street
Surry Hills NSW 2010
GPO Box 58, Sydney NSW 2001
Telephone (02) 8577 8800 / 1800 638 528
Fax (02) 8577 8888

PART 1: APPLICANT AND APPLICATION DETAILS

Joint Application YES NO **If yes, number of applicants?:**

(Each applicant must at least complete and sign Part 1. You may reproduce this form, or portions thereof, for this purpose. The fee only needs to be paid once. Only the holder of any confidential data need complete the sections where this information is required.)

Applicant Details (Notifier)

Business Name: _____

ABN: _____

NICNAS Registration Number: _____

Business Address: _____

Postcode: _____

Postal Address (if different to above): _____

Postcode: _____

Contact Name: _____

Position: _____

TEL: _____

FAX: _____

E-mail: _____

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.

Name: _____

Position: _____

Company: _____

Business Address (if different to above) _____

Postcode: _____

Postal Address (if different to above) _____

Postcode: _____

TEL: _____

FAX: _____

E-mail: _____

Authorisation to Act

The NICNAS/technical contact is to act on the behalf of the applicant/notifier(s) in all matters pertaining to this application. YES NO

Correspondence

Please indicate whether correspondence between NICNAS and the NICNAS/technical contact should be electronic wherever possible. YES NO

Modular Application

Are you applying for a reduction in assessment fees due to this application being a modular or foreign scheme notification? YES NO

If yes, please indicate which of the circumstances below applies and complete the Modular Attachment Form, which is available from the NICNAS website. Guidance on the types of modular assessments available and the criteria that must be met when applying for a reduction in fees is provided in the NICNAS *Handbook for Notifiers*.

The notified polymer is similar to a polymer which has been previously assessed by NICNAS.

The notified polymer is being notified at the same time as a polymer which is similar.

An assessment of the notified chemical/polymer by Environment Canada and Health Canada under the New Substances Notification Regulations (Chemicals and Polymers) of the Canadian Environmental Protection Act, 1999 is available.

An assessment of the notified chemical/polymer by a chemicals notification and assessment scheme operating in a member country of the European Union (EU) or the Organisation for Economic Co-operation and Development (OECD) is available.

An assessment of the notified chemical by the Therapeutic Goods Administration (TGA) of the chemical under the Therapeutic Goods Act 1989 is available.

An assessment of the notified chemical by the Australian Pesticides and Veterinary Medicines Authority (APVMA) under the Agricultural and Veterinary Chemicals Code Act 1994 is available.

An assessment of the notified chemical by Food Standards Australia New Zealand (FSANZ) under the Food Standards Australia New Zealand Act 1991 is available.

Variation of Schedule Requirements

If a test on a scheduled data requirement is not available then a claim for Variation to the Schedule of Data Requirements must be made. Each claim of Variation must be described in full with supporting scientific arguments. There is no fee associated with a Variation to the Scheduled Data Requirements for a PLC application.

Does your submission require a variation? YES NO

Please include full details of the proposed variations and the justification for EACH request here:

Exempt Information

Is there any information you wish to keep confidential? YES **Fee required** NO

If yes, please identify the items to be to be kept exempt from publication below:

<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 (please specify below)
<input type="checkbox"/> Structural formula	<input type="checkbox"/> Polymer constituents	

Please provide justification for requiring the information to be exempt here:

Third Party Information Lodgement

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

If yes, please identify the items to be provided by the third party below. The company providing the information should complete a Third Party Information Lodgement (Form 5) (available from the NICNAS website http://www.nicnas.gov.au/Forms/New_Chemicals/PLC_Notification.asp). No fee is required for a Third Party Information Lodgement (Form 5).

<input type="checkbox"/> Chemical name	<input type="checkbox"/> Molecular weight	<input type="checkbox"/> Residual monomers/impurities
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<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 (please specify below)
<input type="checkbox"/> Structural formula	<input type="checkbox"/> Polymer constituents	

Early Introduction Permit

Are you applying for a free EIP under Section 30A of the Act? YES NO

Industrial Nanomaterials

Is the chemical an industrial nanomaterial under the NICNAS definition? *(Note: for the working definition please consult the document, Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials, http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp)*

YES NO UNSURE#

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

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

Ultraviolet Filter

Is the chemical to be used as an ultraviolet filter in a cosmetic to be applied to the skin? *If yes, please note the application must be submitted in the Standard Notification category.*

YES NO

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 which is false or misleading.

PART 2: THE ASSESSMENT TEMPLATE AND INSTRUCTIONS

Template

The Template has been designed to enable applicants to provide information in a standardised format and also comply with the notification requirements of the Act. The information provided in the Template must contain sufficient information to enable NICNAS to conduct its risk assessment on the notified polymer.

Confidentiality – Claiming Exempt Information

Under the Act applicants may claim confidentiality for certain Schedule data items. In Part 1 (Applicant and Application Details), full details of each item that is claimed as confidential should have been provided to NICNAS along with a justification for requiring confidentiality. These items will be treated as exempt information and will not be published by NICNAS. Please note that there is an additional fee for applications containing 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. The assessment template has been divided into confidential and non-confidential sections for this purpose. Indications have been placed in the non-confidential section where generic or sanitised text is required.

Below is an example of a claim for exempt information for “import volume over the next five years”:

Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Use the table below for the non-confidential introduction volume.

Year	1	2	3	4	5
Tonnes	30-100	100-300	100-300	100-300	100-300

Also use the table below if the introduction volume is confidential.

Year	1	2	3	4	5
Tonnes	50	120	180	240	260

Level of Detail

Sufficient information is required to enable the assessment to be made from an occupational, public health and environmental perspective. This includes details of tests performed, where toxicity data are available and a summary of the data with supporting study reports. Although provision of toxicity data is not a scheduled requirement for PLC applications the Act stipulates that these data be provided if they are available to the applicant (s.23(10)).

Guidance

Detailed guidance for fulfilling prescribed information requirements is provided in the NICNAS *Handbook for Notifiers*, which is available for download from <http://www.nicnas.gov.au>. Guidance for completing the Template is provided in the *Guidance for Completing the New Chemicals Assessment Report Template*, which is available for download from http://www.nicnas.gov.au/Forms/New_Chemicals/PLC_Notification.asp. Should you require further information or assistance or would like to provide feedback on the forms, please contact the NICNAS New Chemicals Program (1800 638 528, info@nicnas.gov.au).

1. Applicant and Notification Details

1.1. Previous Notification in Australia by Applicant(s)

1.2. Notification in Other Countries

2. Identity of Polymer

2.1. Polymer Name Confidential Non-confidential

2.2. Other Name(s) Confidential Non-confidential

2.3. Marketing Name(s)

2.4. CAS Number Confidential Non-confidential

2.5. Molecular Formula Confidential Non-confidential

2.6. Structural Formula Confidential Non-confidential

Insert structural formula here.

2.7. Molecular Weight (MW) Confidential Non-confidential

Number Average Molecular Weight (NAMW)

Weight Average Molecular Weight (WAMW)

Polydispersity Index (WAMW/NAMW)

% of Low MW Species < 1000 Da

% of Low MW Species < 500 Da

Test report (e.g. GPC) attached.

2.8. Polymer Constituents Confidential Non-confidential

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % starting</i>	<i>Weight % residual</i>
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2.9. Impurities and Adjuvants Confidential Non-confidential

<i>Chemical Name</i>	<i>CAS No.</i>	<i>Weight % residual</i>	<i>Hazardous If yes include risk number (eg R20)</i>
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2.10. Persistence, Bioaccumulation and Toxicity (PBT)

Does the polymer or its breakdown products have PBT characteristics? If so, give details:

2.11. Reactive Functional Groups

Does the polymer contain any high or moderate concern functional groups? YES NO

If yes please list all of the high or moderate concern functional groups below.

Functional Group	Equivalent Weight (FGEW)
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2.12. Cationic polymers

Does the polymer contain any positively or negatively charged groups? YES NO

Is the polymer cationic or reasonably anticipated to become cationic in the pH range (4-9) likely to be encountered in the environment? YES NO

For cationic polymers, please provide a calculation of the charge density (no. of charges per 1000 Da.) or the combined FGEW of charged groups.

2.13. Means of identification Confidential Non-confidential

3. PLC Criteria Justification

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes/No/Not applicable
- Low NAMW Polyester Manufactured from Allowable Reactants	Yes/No/Not applicable
Functional Group Equivalent Weight (FGEW) Requirements	Yes/No/Not applicable
Low Charge Density	Yes/No/Not applicable
Approved Elements Only	Yes/No/Not applicable
Stable Under Normal Conditions of Use	Yes/No/Not applicable
Not Water Absorbing	Yes/No/Not applicable
Not a Hazard Substance or Dangerous Good	Yes/No/Not applicable

4. Physical and Chemical Properties

Appearance at 20 °C and 101.3 kPa
Melting Point/Glass Transition Temp ...°C
Density ... kg/m³ at ...°C
Water Solubility ... g/L at ...°C
Dissociation Constant pKa = ...

Particle Size
Reactivity
Degradation Products

Comments on the physical and chemical properties of the notified polymer

5. Introduction and Use Information

5.1. Maximum Introduction Volume of Notified Chemical (100%) Over Next 5 Years

Use the table below for the **non-confidential** introduction volume.

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

Also use the table below if the introduction volume is **confidential**.

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

5.2. Mode of Introduction

5.3. Reformulation/manufacture processes

5.3.1. **Non-confidential** reformulation/manufacture processes description (required where applicable)

5.3.2. **Confidential** reformulation/manufacture processes description (only include information not mentioned in section 5.3.1)

5.4. Use

5.4.1. **Non-confidential** use description (required)

5.4.2. **Confidential** use description (only include information not mentioned in section 5.4.1.)

6. Human Health Implications

6.1. Occupational Exposure and Health

6.2. Public Exposure and Health

6.3. Toxicological Hazard Characterisation

Is toxicological data available for the notified polymer or an analogue? **YES** **NO**

If toxicological data is available for the notified polymer please complete the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Classified?</i>	<i>Effects Observed?</i>	<i>Test Guideline (Choose one or add new method)</i>
1. Rat, acute oral	LD50 ... mg/kg bw	yes/no	yes/no	OECD TG 401 OECD TG 423
2. Rat, acute dermal	LD50 ... mg/kg bw	yes/no	yes/no	OECD TG 402
3. Rat, acute inhalation	LC50 ... mg/L/4 hour	yes/no	yes/no	OECD TG 403
4. Rabbit, skin irritation	irritating/non-irritating	yes/no	yes/no	OECD TG 404
5. Rabbit, eye irritation	irritating/non-irritating	yes/no	yes/no	OECD TG 405
6. Skin sensitisation - adjuvant test/non-adjuvant test/LLNA. [<i>Delete as appropriate</i>]	evidence/ no evidence of sensitisation.	yes/no	yes/no	OECD TG 406 (Buehler and Maximisation tests) OECD TG 429 (LLNA)
7. Rat, <route of exposure> repeat dose toxicity - ... days.	NOEL/NOAEL/ LOAEL	yes/no	yes/no	OECD TG 407 – 409, 422, 410 – 411, 412 – 413
8. Genotoxicity - bacterial reverse mutation	mutagenic/non mutagenic	yes/no	yes/no	OECD TG 471 – 472
9. Genotoxicity – in vitro <test type>	genotoxic/non genotoxic	yes/no	yes/no	OECD TG 473, 476, 479 – 482
10. Genotoxicity – in vivo <test type>	genotoxic/non genotoxic	yes/no	yes/no	OECD TG 474, 475, 486
11. Developmental and reproductive effects	NOEL/NOAEL/ LOAEL	yes/no	yes/no	
12. Carcinogenicity		yes/no	yes/no	
12. Other		yes/no	yes/no	

Briefly discuss any effects observed in the above studies in a few sentences here.

Discuss any other hazardous properties the notified polymer may possess here:

7. Environmental Implications

7.1. Environmental Release

7.2. Disposal

7.3. Environmental Hazard Characterisation

Is ecotoxicological data available for the notified polymer or an analogue? **YES** **NO**

If ecotoxicological data is available for the notified polymer please complete the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Effects Observed?</i>	<i>Test Guideline (Choose one or add new method)</i>

Fish Toxicity		EC50 ... mg/L	yes/no	OECD TG 203
Daphnia Toxicity		EC50 ... mg/L	yes/no	OECD TG 202
Algal Toxicity		EC50 ... mg/L	yes/no	OECD TG 201
Inhibition of	Bacterial	EC50 ... mg/L	yes/no	OECD TG 209
Respiration				
Other			yes/no	

Briefly discuss any observed effects in a few sentences here.

PART 3: POLYMER OF LOW CONCERN NOTIFICATION CHECKLIST

This checklist is a guide to the information required to support an application for an Assessment Certificate for a Polymer of Low Concern pursuant to section 24A of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Click or tick each box when information has been supplied for items in the notification statement.

	Information Submitted	Proposed Variation	Proposed Exempt Information	Third Party Exempt Information	NICNAS USE ONLY	
					Met	Remarks
1. Details of any notification made in another country	<input type="checkbox"/>				<input type="checkbox"/>	
2. Chemical Name(s)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3. Other Name(s)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4. Marketing Name(s)	<input type="checkbox"/>				<input type="checkbox"/>	
5. CAS Number	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6. Justification for Variations to Schedule Data Requirements	<input type="checkbox"/>				<input type="checkbox"/>	
7. Molecular Formula	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8. Structural Formula	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9. Means of Identification	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10. Number Average Molecular Weight (with test report)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
11. Weight-average Molecular Weight (with test report)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
12. Weight Percentage of polymer species with MW < 1000 and MW < 500 (with test report)	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
13. Reactive Functional Groups – include FGEW	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
14. Charge Density	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15. Polymer Constituents	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16. Residual Monomers and Impurities	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
17. PBT Characteristics	<input type="checkbox"/>				<input type="checkbox"/>	
18. Appearance	<input type="checkbox"/>				<input type="checkbox"/>	

