

Application for Assessment Certificate - Polymer of Low Concern



Australian Government
Department of Health and Ageing
NICNAS

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

If space is insufficient for any item, an attachment should be completed and signed in accordance with the instructions for this form.

For fees see 'Fee Information below Please make cheque payable to NICNAS.

Where a joint application is made, details of all the applicants and a signed declaration from all the applicants are required.

If a Variation to the Schedule requirements is proposed, Form 2 should accompany this application.

If Exempt Information is proposed, Form 3 should accompany this application.

If data is provided by a third party, either separately or accompanying the notification, Form 5 (signed by the owner of the data) should accompany the third party data.

Please complete forms in BLOCK LETTERS and ensure that all supporting documents and relevant fees are enclosed.

Return to: Director
NICNAS
GPO Box 58, Sydney NSW 2001
Telephone (02) 8577 8800 / 1800 638 528 Fax (02) 8577 8888

FORM PLC-1

Notifier

Business Name

ABN

NICNAS Registration Number

Business Address

Postcode

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

Postcode

Contact Name

Phone ()

Fax ()

Email

Technical Contact

Name

Position

Company

Business Address (if different to above)

Postcode

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

Postcode

Phone ()

Fax ()

Email

Polymer

Chemical Name of Polymer

Other Name(s)

Marketing Name(s)

CAS Number (if known) - -

Has this polymer been notified overseas?

Yes No

If so 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

Are you applying for an Early Introduction Permit (EIP)?

Yes No

(Please note Form EIP-1 is no longer required. An EIP for a PLC is free of charge).

If applying for an EIP, is the major component of the molecule either carbon or silicon atoms?

Yes No

Fee information

Eligible for a reduction in fee/rebate

No

PLC Assessment Fee (full fee)*

Yes

Complete Attachment 1

Justification for application under the Polymer of Low Concern category (Does the polymer meet the criteria for a polymer of low concern in section 5 of the Act and regulations 4A-4I of the regulations to the Act?)

Criterion	Yes	No
Meets Molecular Weight Requirements	<input type="checkbox"/>	<input type="checkbox"/>
Meets Functional Group Equivalent Weight (FGEW) Requirements	<input type="checkbox"/>	<input type="checkbox"/>
Low MW Polyester Manufactured from Allowable Reactants	<input type="checkbox"/>	<input type="checkbox"/>
Low Charge Density	<input type="checkbox"/>	<input type="checkbox"/>
Stable Under Normal Conditions of Use	<input type="checkbox"/>	<input type="checkbox"/>
Approved Elements Only	<input type="checkbox"/>	<input type="checkbox"/>
Not Water Absorbing	<input type="checkbox"/>	<input type="checkbox"/>
Not a Hazardous Substance or Dangerous Good	<input type="checkbox"/>	<input type="checkbox"/>

Molecular formula

Structural formula

Means of identification (list of spectral data available, please attach copies of spectra)

Molecular Weight Information – Please attach analytical test report, e.g. Gel permeation chromatography (GPC) data

Number average molecular weight (NAMW)

Weight average molecular weight (WAMW)

Weight percentage of polymer species with MW < 1000 MW < 500

Functional group equivalent weight (FGEW)

Does the polymer contain any positively or negatively charged groups? Yes No

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

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

Table 1: List of Polymer Constituents (i.e. monomers and other reactants)

Constituent	CAS No.	% Weight

Table 2: Maximum Weight-Percentage of Residual Monomers/Impurities

Monomer or Impurity	CAS No.	% Weight

Does the polymer contain any functional groups which are intended or can reasonably be anticipated to undergo further reaction? If so, give details.

Does the polymer or its breakdown products have PBT characteristics (persistence, bioaccumulation, toxicity)? If so, give details.

Appearance of the polymer (not the solution or formulation)

Melting Point and/or Glass Transition Temperature (for the polymer itself). If data is not available, please provide justification as well as an indication of likely behaviour °C

Density (for the polymer itself) kg/m³ at ...°C

Water solubility (Please provide a quantitative estimate rather than qualitative, for example 'insoluble'. Please attach a copy of the test report. If a test is not able to be conducted, sound scientific reasons should be given as well as an indication of likely solubility based on structural considerations.)

Dissociation Constant (complete if acid or base groups are present)

Particle size distribution (for solids only)

Reactivity (e.g. depolymerisation, hydrolysis, photodegradation, thermal degradation.)

Degradation products

Intended use(s) (Complete the confidential section only if an application for exempt information for this item has been made, a non-confidential use description should be also be given)

Confidential

Non-confidential

Mode of introduction (import or manufacture). If imported as a formulation, please provide the % of the notified polymer in this formulation.

Port Identity

Estimated manufacture or import volume for each of the first five years. (Complete the confidential section only if an application for exempt information for this item has been made, a non-confidential volume range should be also be given)

Confidential

Non-confidential

Site of manufacture or reformulation

Operation Description (Discuss in turn: manufacturing, processing, (re)formulation, and/or end use, as applicable)

Confidential

Non-confidential

Occupational Health and Safety

What is the likely occupational exposure? Give details of:

- I. the types of workers to be involved in working with the polymer; and
- II. the nature of the work to be done by them; and
- III. the safety procedures to be observed when handling the polymer; and
- IV. a brief description of the training and education in safe working practices to be given to those workers.

What are the likely health effects of the polymer? Give details of:

- I. any toxicological studies available. (Please attach a copy of any study reports); and
- II. any data relating to occupational hazards associated with the polymer; and
- III. information held, or reasonably obtainable, by the notifier about studies and observations of health problems or adverse symptoms occurring in humans exposed to the polymer.

Environmental Impact

What is the likely environmental impact? Provide information about the release of the polymer likely to occur at the manufacture or reformulation site and during normal end-use (rather than from spills, etc.). Take into consideration releases from cleaning of equipment and residues remaining in transport containers. Qualitative or semi-quantitative estimates only are required. Where there is both a high content of low MW species **and** a high release to water, aquatic toxicity data for fish, daphnia and/or algae may be required. If ecotoxicological studies are available, please provide a copy of any study reports).

Public Health

What is the likely public health exposure? Provide a brief description of any way in which a chemical could be harmful or hazardous to the health of the public at large. Where there is both a high content of low MW species **and** the polymer is to be used as an ingredient in a cosmetic product at 1% or more, additional information, eg toxicological data, may be required.

MSDS - Please provide MSDS for the polymer and all commercially available products, or substances used in the workplace, containing the polymer.

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.

Payment Advice

Please indicate method of payment

Electronic Funds Transfer

Payment Date:

Reserve Bank of Australia
London Circuit
Canberra ACT 2600

BSB Number: 092-009
Account Number: 11608-5
Account Name: Dept of Health & Ageing Official Departmental
Receipts and Payments NICNAS Special Account

Please quote your Notification number / Registration number / Invoice number when making the payment. If payment is being made from an overseas bank, all bank charges/fees in getting exact \$AUD to NICNAS is payable by the payee.

Please Fax Remittance Confirmation to NICNAS on (02) 8577 8888.

Cheque

Enclosed Yes

No (Application will be pending until payment received)

Cheques are to be made payable to NICNAS in \$AUD. Payments are to be mailed to:

NICNAS
GPO Box 58
SYDNEY NSW 2001
AUSTRALIA

Credit Card

Mastercard

Visa

Credit Card Number:

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Expiry Date:

Amount:

Authorised Signature

Print Name

Attachment 1 - Application for reduction in assessment fees

Notifiers should complete this attachment to apply for a reduction in assessment fees pursuant to Regulations 15(5), 15 (6), 15 (7) and 15(8) of the *Industrial Chemicals (Notification and Assessment) Act 1989 (the Act)* or when making an application under section 44 of the Act . See Section II of the Handbook for Notifiers for more information regarding the circumstances under which a reduction in fees is applicable.

Please note that this attachment relates solely to the application for a reduction in fees. Completion of this attachment does not fulfil the notification requirements for a PLC notification

Please indicate which of the following circumstances you are applying for a reduction in assessment fees.
Please note only one option can be selected :

		Fee
<input type="checkbox"/>	The chemical is similar to a chemical which has been previously assessed by NICNAS.	Complete part A PLC Assessment Application Entry Fee*
<input type="checkbox"/>	The chemical (secondary chemical) is being notified at the same time as a similar chemical (primary chemical) and for a similar use. (Note this attachment only needs to be completed for secondary chemicals).	Complete part A (except A1 and A4) Modular – Secondary Chemical Fee
<input type="checkbox"/>	Provision of an assessment report compiled by Environment Canada and Health Canada under the <i>New Substances Notification Regulations (Chemicals and Polymers)</i> of the <i>Canadian Environmental Protection Act, 1999</i> .	Complete part B PLC Assessment Application Entry Fee*
<input type="checkbox"/>	Provision of an assessment report by a chemicals notification and assessment scheme operating in a member country of the European Union or the Organisation for Economic Co-operation and Development (other than Canada).	Complete part C PLC Assessment Application Entry Fee*
<input type="checkbox"/>	Provision of an electronic copy of a draft assessment report using the NICNAS electronic template	PLC Assessment Fee (full fee)*

*The application should be accompanied by payment of the appropriate 'fee' (see http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp). The appropriate reduction in fee will be determined based on the information that is included in the original assessment/draft assessment report and the amount of work required by NICNAS. With the exception of provision of an electronic copy of a draft assessment report using the NICNAS electronic template the amount payable will be advised in the screening letter. In the case of the electronic template the fee rebate is decided at the end of the assessment process.

Part A

A1 Previous assessment information

Assessment reference e.g. PLC/XXX for the previously assessed chemical:

Business name and ABN of original notifier:

Business name and ABN of owner of data (if different to above):

Consent on company letterhead included from the original notifier/owner of data to use the original assessment report for the purposes of this NICNAS assessment:

Yes

Same notifier

Is any other information for example, toxicity test data, environmental test data about the previously assessed chemical that was not provided for the original NICNAS assessment available.(provide list below or as a separate attachment):

Yes (provide list below or as a separate attachment)

No

List of available data:

A2 Justification of criteria for similar polymer

The information provided in this section should demonstrate that the notified chemical meets the criteria for similar chemical. These criteria are set out in Section II of the Handbook for Notifiers. Please note that other information is required to be submitted as part of the notification (see Section II of the Handbook for Notifiers for more information).

Chemical Name for originally assessed polymer/primary polymer:

Complete the following (for cases where the primary and secondary chemicals are introduced as an inseparable mixture write 'inseparable mixture':

	Notified polymer/secondary polymer)	Originally assessed polymer/primary polymer
Water Solubility		

Indicate which of the following situations in comparison with the originally assessed polymer/primary polymer applies for notified polymer/secondary polymer:

- Polymer contains one polymer constituent less.
- Polymer contains a polymer constituent which is similar to a polymer constituent in the originally assessed polymer/primary polymer (all other polymer constituents must be the same). Provide a comparison the substituted polymer constituent in section A3
- Polymer is structurally identical. Information to support structural identity should be included as part of the submission

A3 Justification of criteria for similar chemical (for polymers complete A3)

The information provided in this section should demonstrate that the substituted polymer constituent meets the criteria for similar chemical. These criteria are set out in Section II of the Handbook for Notifiers. Please note that other information is also required to be submitted as part of the notification (see Section II of the Handbook for Notifiers for more information).

Chemical Name for original polymer constituent:

Describe the differences in the structure between the substituted polymer constituent and original polymer constituent. Identify the functional groups that play a key role:

Comment on whether the difference in structure/substructure is known to affect the toxicity profile of the chemical:

Complete the following:

	Substituted polymer constituent	Original polymer constituent
Molecular Weight		
Log Pow		
Acute oral toxicity (where available)		
Aquatic toxicity (where available, specify relevant species)		

A4 Similar Use

Are you applying for an additional reduction in fees due to the notified chemical having a similar use to the originally assessed chemical. (The criteria for similar use are set out in the Section II of the Handbook for Notifiers.): Yes No

Part B Canadian Assessment information

Assessment references e.g. NSN XXX for the Canadian assessment

Date of Canadian assessment (if known)

Schedule under which the chemical was assessed in Canada

Business name for Canadian notifier

Trade name for chemical in Canada

Date authorisation request sent to Environment Canada permitting the sharing of assessment reports. (Note the pro-forma letter should be forwarded to Environment Canada at least 60 calendar days before the notification to NICNAS is made and a copy of this letter included as part of the submission).

Is any other information for example, toxicity test data, environmental test data that was not provided for the original Canadian assessment available (provide list below or as a separate attachment)

Yes
(provide list below or as a separate attachment)

No

List of available data:

Part C Overseas Assessment (other than Canada) Information

Overseas authority under which the chemical has been assessed

Date of overseas assessment

Business name for overseas notifier

Trade name for chemical in overseas assessment

Letter of validation from the overseas authority that the report is the full and final report issued for that chemical included as part of submission.

Yes

Is any other information for example, toxicity test data, environmental test data about the chemical that has been previously assessed that was not provided for the original assessment available.

Yes (provide list below or as a separate attachment)

No

List of available data:
