

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



Australian Government
Department of Health and Ageing
NICNAS

FORM PLC-1

Guidance for Completing Form PLC-1

This guidance document contains additional information that can be used to aid in the completion of an application for an assessment certificate for a PLC using Form PLC-1. Additional guidance has been provided for all of Part 2 of Form PLC-1 and some sections of Part 1 where it was considered useful. The guidance information in this document is shown in **blue text**.

PART 1: APPLICANT AND APPLICATION DETAILS

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**

Where a valid 'Authorisation to Act' is conveyed the authorised person/company will receive all correspondence and requests for further information from NICNAS and is able to sign the "Applicant Reply to Final Reports". The 'Authorisation to Act' is effective from the date of signature for the duration of the application and approval process. The 'Authorisation to Act' is only valid for a single application. This Authorisation to Act can be amended or cancelled at any time by notifying NICNAS in writing.

Correspondence

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

This would include the screening letter and any further requests for information, as well as the draft final reports (Day 90). Any permits or certificates would continue to be couriered to the NICNAS/technical contact.

Exempt Information

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

For current fees and charges please see the following NICNAS website:
http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_And_Charges.asp

Is any information to be withheld from the notifier? **YES** **NO**

Information can be held confidential from the notifier with the third party sending the information directly to NICNAS. The third party should complete Form 5 and include it with any information submitted to NICNAS.

Please list all of the information that is being claimed as exempt from publication with justification for requiring the information to be exempt here:

Information will only be exempt from publication if the notifier can justify how its commercial interests in withholding information from the public would outweigh providing the public with that information.

PART 2: THE ASSESSMENT TEMPLATE AND INSTRUCTIONS

1. Applicant and Notification Details

The information provided must be sufficient quantity and quality to allow NICNAS to conduct an adequate risk assessment.

1.1. Previous Notification in Australia by Applicant(s)

Write the category and year of any previous notification for this polymer in Australia, through any Australian regulatory agency (eg. TGA, FSANZ or APVMA).

1.2. Notification in Other Countries

Write the year, country and category (if known) of any overseas notifications for this polymer of which you are aware.

2. Identity of Polymer

2.1. Polymer Name Confidential Non-confidential

Preferably using CAS nomenclature, although IUPAC nomenclature is also acceptable.

2.2. Other Name(s) Confidential Non-confidential

This item should include all other names, eg synonyms, INCI names, names used in study reports. Please indicate which names, if any, are considered confidential.

2.3. Marketing Name(s)

Required non-confidential information. Please include here all names under which the notified polymer (either alone or as a component of a formulation) will be marketed in Australia, including trade names. Also include the concentration of the notified polymer within each product. Where the concentration of notified polymer within products has been claimed as exempt information, also include a non-confidential concentration range. The upper limit of this range will be used by NICNAS in the risk assessment. For example: confidential Acryloplash 31 (47.3% notified polymer in xylene); non-confidential Acryloplash 31 (40-50% notified polymer in xylene).

2.4. CAS Number Confidential Non-confidential

If no CAS number is available, please write "None allocated".

2.5. Molecular Formula Confidential Non-confidential

Order the monomers from highest to lowest carbon numbers, for example (C₆H₁₄O₂.C₆H₁₀O₄.C₅H₁₂O₂)_x

2.6. Structural Formula Confidential Non-confidential

Please insert a depiction of the structural formula below. It should show all of the relevant structural features and should indicate the bonds formed when the (different) monomers combine.

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

Please include the test report for the molecular weight determination in the application to NICNAS.

2.8. Polymer Constituents

Confidential

Non-confidential

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

Please include all monomers and other reactants (chain transfer and cross linking agents, modifying groups, and other end groups incorporated into the polymer, but excluding solvents) which will be tied in the polymer material, including those that are incorporated at 2% or less. Also include post-reacting agents used in the manufacture of post-reacted polymers.

2.9. Impurities and Adjuvants

Confidential

Non-confidential

| <i>Chemical Name</i> | <i>CAS No.</i> | <i>Weight % residual</i> | <i>Hazardous (yes/no) If yes include risk number (eg R20)</i> |
|----------------------|----------------|------------------------------|-----------------------------------------------------------------------|
|----------------------|----------------|------------------------------|-----------------------------------------------------------------------|

Please list any impurities and/or adjuvants present in the notified polymer if it is not known whether the impurities and/or adjuvants are hazardous then write 'unknown'.

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

Only fill out this table for moderate and high concern reactive functional groups (RFGs). For more information on polymer RFGs and how to calculate the functional group equivalent weight (FGEW) see the appendices of the Handbook for Notifiers <http://www.nicnas.gov.au/publications/handbook/>

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.

| <i>Functional Group</i> | <i>Equivalent Weight (FGEW)</i> |
|-------------------------|---------------------------------|
|-------------------------|---------------------------------|

The FGEW cut-off for moderate and high concern functional groups is 1000 and 5000 respectively. If the calculated FGEW is less than these values then the notified polymer will not meet the PLC criteria unless sufficient additional information is provided in order to negate any concern caused by the RFGs present. Please see the Handbook for Notifiers for further information.

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 identificationConfidential Non-confidential

Provide a list of spectral data available for the notified polymer and attach copies of all the spectra.

3. PLC criteria Justification

Use the second table for polyesters with a NAMW of < 1000 Da and the first table for all other polymers.

| <i>Criterion</i> | <i>Criterion met</i> |
|----------------------------------------------------------|-----------------------|
| Molecular Weight Requirements | 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 |
| Or | |
| <i>Criterion</i> | <i>Criterion met</i> |
| Low NAMW Polyester Manufactured from Allowable Reactants | Yes/No/Not applicable |

If the notified polymer does not meet the criteria in one of the two tables then it may not be suitable for notification as a PLC. The list of 'Allowable Reactants' for low NAMW polyesters is given in the appendices of the Handbook for Notifiers.

4. Physical and Chemical Properties

| | |
|--------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Appearance at 20°C and 101.3 kPa | Eg Opaque yellow liquid, the description should apply to the notified polymer rather than a solution or product unless no other information is available. |
| Melting Point/Glass Transition Temp | Not required for polymers that are not isolated from solution. If data is not available, please provide justification as well as an indication of likely behaviour. |
| Density | Not required for polymers that are not isolated from solution. Note: density should be provided in kg/m ³ which is 1000 × density in g/cm ³ . |
| Water Solubility | If no data is available, please provide an estimate based on structural considerations. Include a brief description of the test, including the method used. |
| Dissociation Constant | If no data is available, please provide an estimate based on structural considerations. If no acid or base groups are present the dissociation constant is not required, but state that this is the case. |
| Particle Size | Not required if the notified polymer is a liquid or is not isolated from solution. |
| Reactivity | eg Stable under normal environmental conditions |
| Degradation Products | eg None under normal conditions of use |

Comments on the physical and chemical properties of the notified polymer

Please include here any essential comments for understanding the physical and chemical properties of the notified polymer. For example, formulation details if the polymer is never isolated or comments on water solubility testing (if any).

5. Introduction and Use Information

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

This is required non-confidential information, however the most accurate estimate of the introduction volume can be kept confidential. If the most accurate estimate introduction volume is to be kept confidential then fill in both tables below but if it is non-confidential then fill in only the upper table.

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

In what form, and in what size containers will the polymer be imported/manufactured? What is the concentration of the notified polymer in imported/manufactured products? How is the imported/manufactured product transported? Through what ports will the notified polymer be imported? If certain information, such as the concentration of the notified polymer in the imported product, is confidential please clearly state this, sufficient non-confidential information must also be provided to allow NICNAS to conduct an adequate risk assessment. For example For example: confidential Acryloplash 31 (47.3% notified polymer in xylene); non-confidential Acryloplash 31 (40-50% notified polymer in xylene).

5.3. Reformulation/manufacture processes

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

Does reformulation/manufacture occur in Australia, and if so, what procedures are involved?

Following reformulation, in what form is the polymer, and in what containers? If certain information is confidential it can be placed in section 5.3.2 below, however sufficient non-confidential information must be provided to allow NICNAS to conduct an adequate risk assessment.

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)

What is the function of the notified polymer?

What are the applications of the finished product, and which sectors of industry will use the polymer or formulations? Will the notified polymer or products containing it be used by the public? Where there are multiple uses, give an approximate percentage of the total introduction volume of the notified polymer for each application, and describe which sector(s) the use applies to (site limited/ industry/ commercial/ consumer).

If the notified polymer is to be used in cosmetics, please indicate the types of products it will be present in and the concentration.

If certain information is confidential it can be placed in section 5.3.2 below, however sufficient non-confidential information must be provided to allow NICNAS to conduct an adequate risk assessment.

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

Please describe any expected exposure of workers to the notified polymer based on the proposed processes and uses. Please provide information on any PPE or engineering controls that will be used to limit exposure. Where appropriate provide a brief description of any way in which the polymer could be harmful or hazardous to the health of workers.

6.2. Public Exposure and Health

Please describe any expected exposure of the public to the notified polymer based on the proposed processes and uses. Please provide information on any controls that will limit exposure of the notified polymer to the public. Where appropriate provide a brief description of any way in which the polymer could be harmful or hazardous to the health of the public.

6.3. Toxicological Hazard Characterisation

Is toxicological data available for the notified polymer or an analogue? Yes No

Please include copies of all toxicological tests conducted on the notified polymer or suitable analogues with the application.

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. [Delete as appropriate] | 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.

If any effects were observed in the toxicological tests briefly discuss them here. Appropriate effects to

comment on include clinical observations or mortalities in acute toxicity tests, non-zero Draize scores in irritation or sensitisation tests or elevated mutation frequencies in genotoxicity tests.

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

These may be based on the physical and chemical properties of the notified polymer. For example: 'The powdered notified polymer may cause temporary lung overloading if inhaled'. If there are no other known hazardous properties state this.

7. Environmental Implications

7.1. Environmental Release

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.

7.2. Disposal

How will the notified polymer and any waste, products, articles or residues containing the notified polymer be disposed of. If there is more than one possible route of disposal estimate the proportion going to each. If certain information is confidential please clearly state this, sufficient non-confidential information must be provided to allow an adequate risk assessment.

7.3. Environmental Hazard Characterisation

Is ecotoxicological data available for the notified polymer or an analogue? Yes No

Please include copies of all ecotoxicological tests conducted on the notified polymer or suitable analogues with the application.

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</i> (Choose one or add new method) |
|-------------------------------------|---------------|--------------------------|---------------------------------------------------------|
| 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 Respiration | EC50 ... mg/L | yes/no | OECD TG 209 |
| Other | | yes/no | |

Briefly discuss any observed effects in a few sentences here.

The types of effects to report are any observations worthy of remark during the toxicological studies. These include mortalities or sublethal effects in fish or daphnia tests, insolubility or adhesion of test material, and reductions of cell counts or biomass in algal studies.