Guidance Document

PLC Self-Assessment

The purpose of this guidance document is to assist applicants using the self-assessment system to complete Form 1-PLC self-assessment.

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Brief instructions for the completion of a Self-Assessment

NOTIFICATION PROCEDURE

The self-assessment application must consist only of a hard copy and an electronic copy of Form PLC-1 Self-assessment with the attached self-assessment report (Attachment 1), the relevant fee, and a copy of the material safety data sheet for the notified polymer. If supporting data (e.g. physiochemical and toxicological studies) are submitted then this application would not be considered a self-assessed application. In addition, the applicant(s) may claim certain information to be exempt from publication, in which case Form 3 - Exempt Information and the relevant fee should also be submitted with the application.

The attached self-assessment report consists of two Parts:

- Part 1- should contain information for which an exemption is claimed. Do not complete Part 1 if no information is being claimed as exempt.
- Part 2- should contain information suitable for publication.

Note that PLC self-assessment applications may not be Joint Notifications, or make use of a Variation of Schedule Requirements or Third Party Information Lodgement. If these options are required, then a non self-assessment PLC notification must be used. A rebate of up to 15% of the assessment fee may be paid to the notifier if a completed PLC self-assessment template is attached to a non-self-assessed PLC application form.

COMPLIANCE

The following obligations apply to certificate holders under the self-assessment system:

- Supporting documentation must be retained for at least five years from the date of the certificate; and
- The introduction volume (import and/or manufacture) of the notified polymer and any adverse health or environmental effects must be reported to NICNAS before the end of the NICNAS registration year (i.e. before 28 Sept the following year); and
- Inform the director within 28 days of becoming aware of changes in circumstances under Section 64.

NICNAS may audit/inspect the certificate holders to monitor compliance with the obligations associated with the self-assessment category.

GUIDANCE

To assist in filling out the attached self-assessment report, there is guidance material within this template in the form of highlighted headings (hover the mouse pointer over the highlighted text to see the comments). If you cannot see yellow highlighting in the previous sentence, please ensure that Tools → Options → Screen Tips is selected.

There is also additional guidance and an example notification available from NICNAS, which can be accessed on: http://www.nicnas.gov.au/Forms/New_Chemicals/Self_Assessment.asp

Other useful references are previous PLC Full Public Reports, which can be downloaded from: http://www.nicnas.gov.au/Publications/CAR/New.asp

Please contact NICNAS on phone 1800 638 528 or email info@nicnas.gov.au if you have any questions.

SCREENING

On receipt of a self-assessment application, NICNAS will screen the notification for three issues:
1. correct application of the PLC criteria, including confirmation of the identity of the polymer; and
2. that the risk assessment section addresses all issues and concerns in a scientific manner; and
3. completeness of the self-assessment.

During screening if it is determined that the PLC criteria have been incorrectly applied to the polymer, or if there is a possibility of unreasonable risk, the application will be refused and the notifier advised to re-notify in the correct category.

Note that a polymer will not be accepted for self-assessment if it can be predicted to be persistent and/or bioaccumulative or to have breakdown products that can be predicted to be persistent and/or bioaccumulative, under the Stockholm Convention on Persistent Organic Pollutants (further guidance on this can be found in the January 2004 gazette). Currently fluorinated and brominated chemicals are of particular concern with respect to persistence and bioaccumulation.

The self-assessment application is required to be a complete record of the risk assessment for the notified polymer. If NICNAS is not satisfied with the assessment, the notifier may be requested to revise the document and re-submit it. The assessment clock will not be started until NICNAS has accepted that the report is complete. Upon receiving a complete application, NICNAS will prepare an Assessment Report, Full Public Report, Summary Report and certificate within 28 days.

Attachment 1 - PLC Self Assessment Report

File No: (NICNAS use only)

Day Month Year
Please fill in

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

ASSESSMENT REPORT
(Exempt Information and Full Public Report)

Preferred name for the notified polymer (please fill in)

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and Ageing and the Department of the Environment and Heritage has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

Under subsection 38(5) of the Act the Director NICNAS publishes this assessment report by giving a copy of it to the:

- Secretary of the Department of Environment and Heritage; and
- Secretary of the Department of Health and Ageing.

This assessment report will not be available for inspection by the public.

Director
NICNAS

Part 1 –PLC Self Assessment Exempt Information

Note regarding the use of Part 1 - Exempt Information:

This self-assessment template is divided into two parts:

Part 1 should contain the claimed exempt information that will not be published in the Full Public Report or Summary Report. In this case, Form 3 - Exempt Information should be submitted with the application (Download this from http://www.nicnas.gov.au/Forms.asp). Do not complete Part 1 if no information is being claimed as exempt.

Part 2 should contain information that will appear in the public reports. This part must contain sufficient information to support the risk assessment. For example, the marketing name must be provided, along with a non-confidential percentage quantity of the notified polymer within the marketed product. Also, sufficient Introduction and Use information must be provided to identify all potential exposure. Upper limits must be given for Introduction Volume.

To avoid delays in processing the application, attention should be paid formatting as well as content. Delete any unused fields. For example, if Chemical Name is claimed as exempt, then the Chemical Name field in Part 2 should be deleted. Or if no information regarding the Use and Mode of Introduction and Disposal is claimed as confidential information, then this field can be deleted from Part 1.

DISTRIBUTION

Where exempt information is requested, please include the name of the person who will correspond with NICNAS with respect to the exempt information. This will generally be the person completing the self-assessment template.

Technical contact (please complete)
NICNAS
Department of Environment and Heritage

Preferred name

Enter a preferred name for publication purposes. This name will be published in Chemical Gazette notices, in the Full Public Report and in the Summary Report. It is particularly important to enter the preferred name if you are claiming the chemical name as confidential. The name must uniquely identify the chemical; generic names such as "Acrylic Copolymer" are not acceptable, while "Acrylic Copolymer in ABC123" would be. If the chemical name is not confidential, the Chemical Abstracts (CA) Preferred Index name should be used as the preferred name.

1. APPLICANT AND NOTIFICATION DETAILS

1.1 APPLICANT

Company Name, I/ABN (specify which) & Street Address of each applicant.

Eg
ABC Chemical Company (ABN 12 345 678 999)
123 Forth St
Five Dock NSW 6789

2. IDENTITY OF CHEMICAL

2.1 CHEMICAL NAME

Fill in this box only if you are claiming 'CHEMICAL NAME' of the notified polymer as confidential information. In this case, the corresponding field in Part 2 should be deleted.

The chemical name(s) to be provided is that which will be used in the AICS, that is, the Chemical Abstracts (CA) Preferred Index name(s). If this is not available, then use the International Union for Pure and Applied Chemistry (IUPAC) name(s). For substances that are not pure chemicals, that is, chemicals of unknown or variable composition, a complex product of a chemical reaction, or a biological material (UVCB), the chemical name must describe the substance as completely as possible. For biopolymers, the biological source must be indicated.

The name is normally in the form "A, polymer with B, C and D". Use the name that corresponds to the CAS number if available.

2.2 OTHER NAME(S)

Fill in this box only if you are claiming some or all of the 'OTHER NAME(S)' of the notified polymer as confidential information. Enter only those names that you are claiming as confidential. If there are also names that you are not claiming as confidential, enter them in the non-confidential part of the template.

Other names may include:

- names by which the polymer is known or identified in the scientific or technical literature,
- name(s) used to notify the polymer in other countries, if different to the 'Chemical Name' entered in 2.1,
- company code numbers, internal names or report names.

If the notified polymer is used in cosmetics, enter its International Nomenclature Cosmetic Ingredient (INCI) name.

2.4 CAS NUMBER

Fill in this box only if you are claiming 'CAS NUMBER' of the notified polymer as confidential information.

Enter the CAS (Chemical Abstracts Service) number for the notified polymer. If a CAS number has not yet been assigned, state this, and state when an application for a number was or will be made.

2.5 MOLECULAR FORMULA

Fill in this box only if you are claiming 'MOLECULAR FORMULA' of the notified polymer as confidential information.

Enter a molecular formula for the notified polymer. The molecular formula should give the identity and number of atoms of each element in the molecule; it should be given according to the CAS system, as shown below for polymers.

Eg $(C_8H_8)_m.(C_3H_4O_2)_n$ for ethenylbenzene, polymer with 2-propenoic acid

2.6 STRUCTURAL FORMULA

Fill in this box only if you are claiming 'STRUCTURAL FORMULA' of the notified polymer as confidential information.

Include the key structural features (the types of linkages, functional groups and the range and typical values for the number of repeating units) and the type of polymerisation (graft, block or random). Provide approximate relative mole ratios of precursors.

Normally, a structural formula showing the essential features of the notified polymer can be drawn, however, if no structural formula can be given (for example, where the polymer is a product of complex reactions of natural products such as oxidised linseed oil or rosin), comment on this here.

Where possible insert the structure in the free space indicated in the self-assessment template. It is recommended that the structural formula be provided as an embedded object in ChemDraw (.cdx) format; alternately a structure can be provided as an embedded picture, eg from scanning a diagram of the structure.

2.7a MOLECULAR WEIGHT (MW)

Fill in this box only if you are claiming 'MOLECULAR WEIGHT' of the notified polymer as confidential information.

The below items can be taken from the molecular weight characterisation report. If the molecular weight characterisation is performed by a method such as light scattering that does not give all of the parameters, leave the cells blank. Note that the use of such methods will only normally be acceptable for very high molecular weight polymers (> 100000).

2.7.1 Number Average Molecular Weight (NAMW)
2.7.2 Weight Average Molecular Weight (WAMW)
2.7.3 Polydispersity Index (WAMW/NAMW)
2.7.4 % of Low MW Species < 1000
2.7.5 % of Low MW Species < 500

2.8 POLYMER CONSTITUENTS

Fill in this box only if you are claiming 'POLYMER CONSTITUENTS' of the notified polymer as confidential information.

Give the identity (using CAS preferred names) and percentage of starting monomers and other reactants (initiators, chain transfer and cross linking agents, modifying groups, and other end groups incorporated into the polymer, but excluding solvents), which will be used in the manufacture of the polymer in the table below, including those that are used or incorporated at 2% or less. Also include post-reacting agents used in the manufacture of post-reacted polymers. Calculate percentages based on dry weight of polymer so that the total of all ingredients is 100%. Percentage of residual monomers and other non-reacted chemicals are listed in the right hand column of the table.

Polymers that do not fulfil the criteria for a new synthetic polymer (and thus do not require notification) include:

- an existing synthetic polymer where only a change in monomer ratios has occurred, for example, if the ethylene-vinyl acetate ratio in an ethylene-vinyl acetate copolymer has change from 70-30% to 40-60%; and
- an existing synthetic polymer containing one or more new monomer(s) or reactant(s), each at less than 2% weight.

The Handbook for Notifiers and the Act contain more information regarding these criteria.

Additional rows can be obtained by placing the cursor in the lower right hand cell of the table and pressing TAB.

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*

4. PHYSICAL AND CHEMICAL PROPERTIES

4.9 **Comments**

Please include here any confidential information that is essential for understanding the physical and chemical properties of the notified polymer. For example, formulation details if the polymer is never isolated.

5. INTRODUCTION AND USE INFORMATION

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

Fill in this box only if you are claiming 'INTRODUCTION VOLUME' of the notified polymer as confidential information. The box in the non-confidential part (Part 2) must also be filled in and should contain non-confidential ranges or upper limits.

Estimate the maximum manufacture or import volume (in tonnes) for each consecutive 12-month period during the first five years of introduction. Report only the amount of neat (100%) notified polymer manufactured or imported, not including solvents or other components if the polymer is in a

mixture.

Year	*1*	*2*	*3*	*4*	*5*
Tonnes					

5.3a USE AND MODE OF INTRODUCTION AND DISPOSAL

Fill in this box only if you are claiming aspects of 'USE AND MODE OF INTRODUCTION AND DISPOSAL' of the notified polymer as confidential information.

Include here any commercially sensitive information regarding the processes that occur. This may include proportions imported vs. manufactured, exact percentage composition of the notified polymer in products, or the precise function of the polymer.

Eg 'The notified polymer is an anti-oxidant used at 7% in GenericLube, used in marine diesel engine oils'.

Include the location of manufacture or reformulation here if this is exempt information. The box in the non-confidential part (Part 2) must also be filled in and should contain sufficient information to carry out a full risk assessment.

EXEMPT INFORMATION

File No: (NICNAS use only)

Day Month Year
Please fill in

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Preferred Name (please fill in)

This Self Assessment has been compiled by the applicant and adopted by NICNAS in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS), administered by the Department of Health and Ageing and the Department of the Environment and Heritage has screened this assessment report. The data supporting this assessment will be subject to audit by NICNAS.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at:

Library
Australian Safety and Compensation Council
25 Constitution Avenue
CANBERRA ACT 2600
AUSTRALIA

To arrange an appointment contact the Librarian on TEL + 61 2 6279 1162 or email ascc.library@dewr.gov.au

This Full Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

Street Address: 334 – 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800
FAX: + 61 2 8577 8888
Website: www.nicnas.gov.au

Director
NICNAS

Part 2 –PLC Self Assessment

Preferred name

Part 2 of this template will form the Full Public Report. Part 2 should contain information that is suitable to appear in the public reports. There must be sufficient information to support the risk assessment. For example, the marketing name must be provided, along with a non-confidential percentage quantity of the notified polymer within the marketed product. Also, sufficient Introduction and Use information must be provided to identify all potential exposure. Upper limits must be given for Introduction Volume.

Where there has been a claim for Exempt Information, please place the confidential information in Part 1 and use generic values here. Do not complete Part 1 if no information is being claimed as exempt.

1. APPLICANT AND NOTIFICATION DETAILS

1.1 APPLICANT
Company Name, I/ABN (specify which) & Street Address of each applicant.

Eg
ABC Chemical Company (ABN 12 345 678 999)
123 Forth St
Five Dock NSW 6789

1.2 NOTIFICATION CATEGORY
Self-Assessment: Polymer of Low Concern

1.3 EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are claimed exempt from publication. (In this case, do not complete Part 1)

Or

Data items and details claimed exempt from publication:
List the data items here, and on Form 3 – Exempt information.

In some cases, for example, "INTRODUCTION VOLUME", the exact details can be claimed confidential, and the specific details included in Part 1. Generic or sanitised text/values must be included in Part 2 in order to provide sufficient information to conduct the risk assessment.

1.4 PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
If there has been no previous notification in Australia by the applicant(s), write "None".
If there has been previous notification in Australia by the applicant(s), state the notification category and the year(s) the notified chemical was notified to NICNAS:

Eg 1, Commercial evaluation permit: 1998.
Eg 2, Low volume chemical permit: 1997.
Eg 3, Less than 10kg per annum (cosmetic): 2000.

Where the notified chemical has also been notified to another Australian government agency, for example, the Therapeutic Goods Administration, the Australian Pesticide and Veterinary Medicine Authority or the Food Standards Australia and New Zealand, state the agency and the year of registration.

1.5 NOTIFICATION IN OTHER COUNTRIES
Provide details of any notification made to other national agencies.

Eg 1, US EPA: PMN P-999-999, 29 February 2020.
Eg 2, Environment Canada: NSN9999, 29 February 2020.
Eg 3, EC, Italy: 20-00-0001-01, 29 February 2020.

Eg 4, Not known.

2. IDENTITY OF CHEMICAL

Delete fields that will not be used i.e. where the information is presented in Part 1.

Note that the following sections are required information, and should not be deleted:

2.3 MARKETING NAMES
2.7 MOLECULAR WEIGHT (One of either 2.7a or 2.7b must be included for all polymers)

2.1 CHEMICAL NAME

The chemical name(s) to be provided is that which will be used in the AICS, that is, the Chemical Abstracts (CA) Preferred Index name(s). If this is not available, then use the International Union for Pure and Applied Chemistry (IUPAC) name(s). For substances that are not pure chemicals, that is, chemicals of unknown or variable composition, a complex product of a chemical reaction, or a biological material (UVCB), the chemical name must describe the substance as completely as possible. For biopolymers, the biological source must be indicated.

The name is normally in the form "A, polymer with B, C and D". Use the name that corresponds to the CAS number if available.

Delete if claimed as exempt information.

2.2 OTHER NAME(S)

In this box, enter 'OTHER NAMES (S)' by which the notified polymer is known. Note that names that are entered here will be able to be published in Chemical Gazette notices, in the Full Public Report and in the Summary Report. If there are any names that you wish to claim as confidential information, enter them in Part 1.

Other names include:

- names by which the polymer is known or identified in the scientific or technical literature
- name(s) used to notify the polymer in other countries, if different to the 'CHEMICAL NAME' entered in 2.1
- company code numbers, internal names or report names

If the notified polymer is used in cosmetics, enter its International Nomenclature Cosmetic Ingredient (INCI) name.

Delete if all other names are claimed as exempt information.

2.3 MARKETING NAME(S)

Marketing names cannot be confidential information.

Marketing names are all names under which the notified polymer (either alone or as a component of a formulation) has been, or will be, marketed in Australia, including trade names.

This section should include the concentration of the notified polymer within each product. Where the concentration of notified polymer within products has been claimed as exempt information, include a generic concentration range within imported or reformulated products. The upper limit of this range would be used when discussing exposure. In this case the precise concentration should be given in the confidential Part 1 "USE AND MODE OF INTRODUCTION AND DISPOSAL".

e.g.
Acrylosplash 31 (47.3 % notified polymer in xylene)
Acrylosplash 31 (40-50 % notified polymer in xylene) (with Marketing Name claimed as exempt on Form 3.)

2.4 CAS NUMBER

Enter the CAS (Chemical Abstracts Service) number for the notified polymer, if one has been assigned. If a CAS number has not yet been assigned, state this, and state when an application for a number was or will be made.

Delete if claimed as exempt information.

2.5 MOLECULAR FORMULA

Enter a molecular formula for the notified polymer. The molecular formula should give the identity and number of atoms of each element in the molecule; it should be given according to the CAS system, as shown below for polymers.

Delete if claimed as exempt information.

Eg $(C_8H_8)_m.(C_3H_4O_2)_n$ for ethenylbenzene, polymer with 2-propenoic acid

2.6 STRUCTURAL FORMULA

Include the key structural features (the types of linkages, functional groups and the range and typical values for the number of repeating units) and the type of polymerisation (graft, block or random). Provide approximate relative mole ratios of precursors.

Normally, a structural formula showing the essential features of the notified polymer can be drawn, however, if no structural formula can be given (for example, where the polymer is a product of complex reactions of natural products such as oxidised linseed oil or rosin), comment on this here.

Where possible insert the structure in the free space indicated in the self-assessment template. It is recommended that the structural formula be provided as an embedded object in ChemDraw (.cdx) format; alternately a structure can be provided as an embedded picture, eg from scanning a diagram of the structure.

Delete if claimed as exempt information.

2.7a MOLECULAR WEIGHT (MW)

The following items can be taken from the molecular weight characterisation report. If the molecular weight characterisation is performed by a method such as light scattering that does not give all of the parameters, leave the cells blank. Note that the use of such methods will only normally be acceptable for very high molecular weight polymers (> 100000).

2.7.1 Number Average Molecular Weight (NAMW)
2.7.2 Weight Average Molecular Weight (WAMW)
2.7.3 Polydispersity Index (WAMW/NAMW)
2.7.4 % of Low MW Species < 1000
2.7.5 % of Low MW Species < 500

Where the above information is claimed as exempt, delete the above table and use the table below to indicate whether the polymer is between 1000 and 10000 NAMW, or ≥ 10000 NAMW.

2.7b MOLECULAR WEIGHT (MW)

Number Average Molecular Weight (NAMW)	>1000 or ≥10000

2.8 POLYMER CONSTITUENTS

Delete if claimed as exempt information.

Give the identity (using CAS preferred names) and percentage of starting monomers and other reactants (initiators, chain transfer and cross linking agents, modifying groups, and other end groups incorporated into the polymer, but excluding solvents), which will be used in the manufacture of the polymer in the table below, including those that are used or incorporated at 2% or less. Also include post-reacting agents used in the manufacture of post-reacted polymers. Calculate percentages based on dry weight of polymer so that the total of all ingredients is 100%. Percentage of residual monomers and other non-reacted chemicals are listed in the right hand column of the table.

Polymers that do not fulfil the criteria for a new synthetic polymer (and thus do not require notification) include:

- an existing synthetic polymer where only a change in monomer ratios has occurred, for example, if the ethylene-vinyl acetate ratio in an ethylene-vinyl acetate copolymer has change from 70-30% to 40-60%; and
- an existing synthetic polymer containing one or more new monomer(s) or reactant(s), each at less than 2% weight.

The Handbook for Notifiers and the Act contain more information regarding these criteria.

Additional rows can be obtained by placing the cursor in the lower right hand cell of the table and pressing TAB.

Chemical Name	*CAS No.*	*Weight % starting*	*Weight % residual*

2.9 REACTIVE FUNCTIONAL GROUPS
Insert more rows for FGs if required

Only moderate and high concern functional groups need be listed. These are defined in the NICNAS Handbook for Notifiers (http://www.nicnas.gov.au/publications/handbook/ in Appendix 10). Information on how to calculate FGEW is also given in this document. Use the table below to list the moderate/high concern functional groups. Note that this information cannot generally be claimed as exempt.

Functional Group	Category	Equivalent Weight (FGEW)
	Moderate/High Concern	

If the polymer contains no moderate/high concern RFGs, delete the above table and state:

The notified polymer contains only low concern functional groups.

3. PLC CRITERIA JUSTIFICATION

Indicate if each criterion has been met. This table should not be used if the notified polymer is a low MW polyester composed only of allowable reactants – in this case the second table should be used to indicate that the PLC criteria have been met. Note that the FGEW requirements do not apply if the NAMW of the polymer is 10000 or greater; however the charge density requirements still apply in this case. In addition, the water absorbing criteria is only applicable for polymers with a NAMW of 10000 or greater.

See Appendix 10 in the Handbook for Notifiers for extensive guidance on the PLC criteria, including the requirements for low-MW polyesters.

Criterion	*Criterion met*
Molecular Weight Requirements	Yes/No
Functional Group Equivalent Weight (FGEW) Requirements	Yes/No
Low Charge Density	Yes/No
Approved Elements Only	Yes/No
Stable Under Normal Conditions of Use	Yes/No
Not Water Absorbing	Yes/No
Not a Hazard Substance or Dangerous Good	Yes/No

OR

Criterion	*Criterion met*
Low MW Polyester Manufactured from Allowable Reactants	Yes/No

The notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

If endpoints are not available for the relevant item, adequate scientific justification based on the structure of the polymer must be provided.

4.1	**Appearance at 20°C and 101.3 kPa**	Give the state of the notified polymer itself (rather than a formulation) under these conditions, and any identifying features such as colour.
4.2	**Melting Point/Glass Transition Temp**	…°C (for the polymer itself) Not required for polymers that are not extracted from solution.
4.3	**Density**	… kg/m^3 at …°C (for the polymer itself, or for the product) Not required for polymers that are not extracted from solution. Please provide the specific gravity of the polymer solution if available, and indicate that this value is obtained for the product rather than the notified polymer itself. *(Note: units are kg/m^3; density in kg/m^3 is 1000 x density in g/cm^3)*
4.4	**Water Solubility**	… g/L at 20°C A brief description of the test, including the method used, should be included. Examples: Water solubility was determined via the flask method, using HPLC to determine the concentration of the notified polymer in the filtrate, as described in OECD TG 105. The preliminary test indicated a low solubility. Thus, the column elution method was used in the main test. This test conformed to OECD TG 105. Study data is not required if polymer is not extracted from solution. In this case, provide an indication of likely solubility based on structural considerations. If the structure has been claimed as exempt information, be sure not to include any confidential information here. Examples: The polymer is a salt and contains acid functionalities, therefore would be expected to be water soluble up to X g/L. The notified polymer is expected to have low water solubility due to the predominantly hydrophobic character of its monomers.
4.5	**Dissociation Constant** *(delete if no acid or base groups are present)*	pKa = … The dissociation constant may be estimated based on the known properties of acidic or basic functional groups present, and should be given for any polymers containing groups such as carboxylic acid, carboxylate anions, amines, phenols, or any other known acidic or basic groups.
4.6	**Particle Size** *(delete if liquid or solution)*	For a powdered polymer, give the Mass Median Aerodynamic Diameter (MMAD) and percentage by weight below 10 microns and below 100 microns diameter. Please indicate whether the value was obtained for the polymer itself or for a product containing the polymer.
4.7	**Reactivity**	Indicate whether the polymer is intended to be stable,

or has specific reactivity, such as in a polymer intended as a pre-polymer for a specific further reaction. Where applicable, include oxidising properties, incompatibility with other substances, or conditions contributing to instability. Please note that a PLC should not readily break down under the conditions in which it is used.

4.8 **Degradation Products**

Give details of known degradation products on storage, thermal decomposition or reaction with water.

4.9 **Comments**

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, comments on water solubility testing (if any). As water solubility is one of the few required endpoints, it is particularly important that it is clear and can be used for estimation of environmental fate (Section 7.1.2). In particular this is needed for those polymers that contain some degree of polar functionality, which will increase water solubility. Whether the polymer is truly soluble or miscible or dispersible due to its physical form or presence of other ingredients in the formulation should be made clear.

Do not include information that has been claimed as confidential information in this section. Where a claim for confidentiality has been made, provide sanitised text here and place the detailed information in Part 1 – Exempt Information.

5. INTRODUCTION AND USE INFORMATION

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

Estimate the maximum manufacture or import volume (in tonnes) for each consecutive 12-month period during the first five years of introduction. Report only the amount of neat (100%) notified polymer manufactured or imported, not including solvents or other components if the polymer is in a mixture.

If claiming the 'INTRODUCTION VOLUME' as confidential information, enter the introduction volume as a range. Suggested ranges are, <1, 1-3, 3-10, 10-30, 30-100, or so on. Note that if a range is specified below, the upper limit of the range should be used for all subsequent calculations dealing with the imported volume.

Year	*1*	*2*	*3*	*4*	*5*
Tonnes					

5.2 MODE OF INTRODUCTION, USE AND DISPOSAL

If no claim for exempt information is made for this section, delete the Mode of Introduction, Use and Disposal box in Part 1 and fully complete this section.

If the specific use is confidential, provide a general description here. For example, a chemical that is used as an antioxidant in a lubricant could be described generically as a lubricant additive, as this adequately describes the potential for exposure. The extra information should be provided in part 1. If the maximum content of the notified polymer in formulations is confidential, a generic non-confidential concentration range should be used. Where Introduction Volume has been claimed as exempt information, use the upper limit for the non-confidential import volume in your calculations. The generic text that is entered here should be suitable for publication in Chemical Gazette notices, in the Full Public Report and in the Summary Report.

Items that may be claimed as exempt information include:

- The location/identity of warehouses/factories/customers
- Precise percentages of the notified polymer in products (a generic range must be supplied)
- The precise function of the notified polymer within the product (e.g. surfactant, crosslinker)
- Percentages of the imported volume used in each applications (a generic range must be supplied)

Concisely describe the importation, manufacturing, processing, reformulation, repackaging and/or end use operations involving the notified polymer or formulation. Identify the major unit operation steps and chemical conversions, including secondary operations involving the notified polymer, such as loading/unloading transport

containers (give size and type). Note that "unit operation" means a functional step in a manufacturing, processing or end-use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics.

This section should not contain information on exposure or release of the notified chemical arising from these operations. Such information is to be given in the Human Health Implications and Environmental Implications sections.

Briefly answer the following questions (point form is acceptable):

5.2.1 Mode of Introduction

In what form, and in what containers will the polymer be imported/manufactured?
How is the imported/manufactured product transported?

- If the concentration of the notified polymer in the product is confidential, then please supply a non-confidential range.
- State whether the notified polymer will be manufactured locally or imported.
- If imported, what is the port of entry?
- Describe the physical state of the notified polymer, or products containing the polymer.
- Describe the containers used when importing the polymer.

Also describe any foreseeable circumstances that may impact on either the scale of manufacture or the volume of the notified polymer imported. For example, the polymer may initially be imported, but manufacture may be anticipated at a later date.

Examples of the mode of introduction for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style:

NASpol1, containing 70% notified polymer as a solution in xylene, is imported via Sydney or Melbourne harbour in 200 L steel barrels. It is transported by road to a warehouse for storage before being onsold to customers without repackaging.

OR
The notified polymer is imported as a 7% component of the powdered ink product InkPowder in 20 kg polyethylene lined cardboard boxes. After arriving by ship at Sydney, it is transported by truck to a warehouse for distribution.

OR
The notified polymer is manufactured from raw materials as a 30% emulsion in water. This is stored in a holding tank at the manufacturing site before being pumped into tank trucks and taken to the customers' sites.

5.2.2 Reformulation/Manufacture Process

Does reformulation/manufacture occur in Australia, and if so, what procedures occur?
Following reformulation, in what form is the polymer, and in what containers?

Briefly describe any reformulation, manufacturing or repackaging operations. Inclusion of process flow diagrams can be useful to assist the description.

Examples of the type of procedures carried out for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style.

The notified polymer will not be manufactured or reformulated in Australia.

OR (repackaging)
After arriving at the manufacturers warehouse, the product is repackaged into 10 kg containers before being on sold to customers.

AND/OR (reformulation of powders)
Reformulation involves manual weighing out of the product containing the notified polymer into 400 L mixing tanks, followed by automated mixing and filling of 1-3 L containers. After reformulation, the notified polymer will be present at <10% concentration in the products P101, P102 and P103.

AND/OR (reformulation of liquids)
The notified polymer is poured from 200 L drums into 1000 L capacity stainless steel vats. Other batch ingredients are added, and mixing occurs at room temperature. The final product Poly35 (containing 35% notified polymer) is then piped to 20 L steel cans.

AND/OR (polymer additives)
The notified polymer will be compounded with other resins and additives in a melt processing operation to form molten plastic. The molten plastic will be injected into appropriate moulds to form plastic articles.

5.2.3 Use

What is the function of the notified polymer?
What are the applications of the finished product, and which sectors will use the polymer or formulations?
Where there are multiple uses, what proportion of the total imported volume goes towards each use?

For each intended use of the notified polymer:

- describe its function and application. Function refers to the inherent physical and chemical properties of the chemical, for example, paint component, surfactant, dyestuff, adhesive, plasticiser, stabiliser. Application refers to the use of the substance in particular processes or products. For example, a paint may be used in architectural applications (water or oil based), automotive refinish, industrial coatings by a variety of methods, and many others.
- The function can be applied for as exempt information and placed in Part 1 (confidential information). However, the application is required information, necessary for conducting the risk assessment.
- give the approximate percentage of total manufacture or import volume for each use
- give information on which sector(s) will use the polymer or formulation(s), and in what proportion. That is, state the proportion of the notified polymer or formulation(s) that will be used for site limited use(s), that will be used industrially, that will be used commercially or that will be used by the consumer, where:
  - "site-limited" use means use that is confined to the site of manufacture of the notified polymer solely for the purpose of further manufacture, for example, intermediates
  - "industrial use" means use at other sites of manufacture or processing, for example, paint formulation or use of a curable resin to manufacture an article
  - "commercial use" means use as professional products in public areas or in providing a consumer service, for example, office machinery products such as printing toners, professional use cosmetics and spray paints
  - "consumer use" means personal or domestic use, for example, cosmetics, automotive polish and do-it-yourself products
- indicate the industry group, for example, automotive industry, textile industry, building industry or hairdressing industry
- give details on:
  - the form in which the notified polymer will be made available (eg powder, pellets, solution)
  - the maximum content and/or range in percentages of the notified polymer in the formulation(s)
  - the marketing name(s) of the formulation(s), where known

Where the notified polymer or formulation is destined for commercial or consumer use, describe how it is used, including estimates on the frequency and mode of application and the amount used at each application.

Examples of the Use appropriate for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style:

(construction)
Product1 (containing 12% notified polymer) will be used as a plasticiser additive for concrete; formulated into concrete admixtures containing 0.3-0.4% notified polymer. Around 30% of the additive will be used for pouring concrete slabs, and 70% will be used as mortar for bricklaying.

OR (printer ink)
The ink cartridges contain liquid ink (20% notified chemical) will be available to both consumers (15% of import volume) and commercial users (85% of import volume). The notified chemical will improve the durability, chemical resistance, appearance, adhesion and speed of drying of the ink vehicle.

OR (photocopying)
The notified chemical will coat carrier particles in toners, and will be present at 1.5%. The toner cartridges will be used exclusively in office photocopiers.

OR (spraypainting)
The notified polymer is a crosslinking agent for use in automotive spraypaint. The spraypaint (containing 37% notified polymer) will be used for vehicle repairs, and will not be available to the general public.

OR (printing industry)
The notified chemical acts as a binder, and will be used at 24% in the liquid ink product BlueGreen. This ink will be used by commercial magazine publishing houses only.

OR (surface coatings)
The paint/lacquer/varnish (containing 20% notified chemical) will be applied to decking/walls/a variety of surfaces, primarily using brushes/rollers/aerosol. It is estimated that 85% of the product will be used by professional painters, while the remaining 15% will be sold by hardware outlets to the public.

OR (cosmetic)
The notified polymer will be used as a hair fixative agent at 3.3% in consumer hairsprays. This product will be used daily by hairdressers, cosmeticians, and beauticians (30% of import volume) and will also be used weekly by members of the public (70% of import volume).

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

Include a brief assessment of exposure here. Where there is wide dispersive use (e.g. cosmetics, automotive oil, paints) please provide a more detailed assessment, including the estimated exposure limits. Examples of the exposure scenarios appropriate for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style.

6.1.1 OCCUPATIONAL EXPOSURE *Please use point form if possible.*
(where all reformulation and use processes are automated)
Dermal and ocular exposure may potentially occur during certain processes involving the notified polymer. However, exposure to significant amounts of the notified polymer is limited because of the fully automated processes, and the engineering controls and personal protective equipment worn by workers.

AND/OR (repackaging)
During repackaging of the product containing 10% notified chemical, exposure to workers is limited due to the use of a down-draft weighing station and PPE such as full-length overalls, gloves and protective footwear.

AND/OR (manual weighing out)
Dermal and ocular exposure can occur during weighing out prior to reformulation, however exposure to significant amounts of the notified polymer is limited because personal protective equipment, including a full face

respirator, overalls, gloves and protective footwear, is worn while weighing is performed.

AND/OR (polymer additives)
Workers may be exposed to dust particles generated from the compounding of the resin. Dermal exposure to the pellets may also occur. However, exposure to significant amounts of the notified polymer is limited due to the personal protective equipment worn by workers, including overalls and face mask. The notified polymer will be bound within the finished articles and thus exposure is unlikely.

AND/OR (when contact with solid polymer will occur)
Workers will make dermal contact with pellets/powder/dried ink/dried paint containing the notified polymer. However, the notified polymer is cured into an inert matrix and is hence unavailable to exposure.

AND/OR (cartridges)
Dermal and inhalation exposure to the notified polymer may occur when refilling/replacing spent cartridges. However, the concentration of the notified polymer in the ink is low, and the design of the cartridges is such that exposure to the notified polymer should be low. Once the ink dries, the chemical would be trapped in the printed paper, and therefore dermal exposure to the notified chemical from contact with the dried ink is not expected.

AND/OR (construction)
Construction workers may have inhalation and dermal exposure to the dry mortar containing the notified polymer at 1%, however exposure to the notified polymer would likely be limited due to the low concentration and the use of face masks and gloves.

AND/OR (photocopying)
Dermal and inhalation exposure of office workers and maintenance engineers to the notified chemical could potentially occur when replacing spent cartridges and clearing paper jams from the printer or photocopier. Once the ink dries, the chemical would be trapped in the printed paper, and therefore dermal exposure to the notified chemical from contact with the dried ink is not expected.

AND/OR (spray painting)
Spray painters may come into contact with the notified polymer through dermal, inhalation and ocular routes. The risk of exposure, however, will be minimal as the spray paint is applied in a ventilated spray booth by workers using protective equipment. After application and once dried, the paint containing the notified polymer is cured into an inert matrix and the polymer is hence unavailable to exposure.

AND/OR (printing industry)
Dermal, and ocular exposure may occur during certain printing processes. However, exposure to significant amounts of the notified polymer is limited given the use of engineering controls and personal protective equipment by workers. The notified polymer will not be available to the public. Members of the public may come into contact with products containing the notified polymer. Once the ink dries, the chemical would be trapped in the printed paper, and therefore dermal exposure to the notified chemical from contact with the dried ink is not expected.

AND/OR (surface coatings)
Dermal, and to a lesser extent oral and ocular exposure may occur while applying the paint to walls and ceilings. Exposure will be limited by personal protective equipment, likely to be overalls and protective footwear. According to EASE (1997) modelling of this work environment, dermal exposure in the range of XX mg/cm2.day of products containing YY% of the notified polymer could result.

AND/OR (cosmetics)
Intermittent, wide-dispersive use with direct handling is expected to occur among hairdressers, cosmeticians, and beauticians. According to EASE (1997) modelling of this work environment, dermal exposure in the range of XX mg/cm2.day of products containing YY% of the notified polymer could result.

6.1.2 PUBLIC EXPOSURE

Where the notified polymer or formulation is destined for commercial or consumer use, describe how it is used, including estimates on the frequency and mode of application and the amount used at each application. Examples

of the exposure scenarios appropriate for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style.

(industry use only)
The notified polymer is intended only for use in industry and as such public exposure to the notified chemical is not expected.

AND/OR (only available to the public in articles)
The notified polymer will not be sold to the public except in the form of finished articles. There is potential for extensive public exposure to articles such as plastic chairs/automotive interiors/electronic items comprised wholly or partly of the notified polymer. (Blooming/leeching of the notified polymer from the articles is not expected and hence exposure will be low.)

AND/OR (cartridges)
The scenarios by which the public may be exposed to the notified chemical would involve home use of printers, and are similar to those for office workers. However, it is expected that the public will be using the printer less often than workers.

AND/OR (photocopying)
The scenarios by which the public may be exposed to the notified chemical would involve home use of photocopiers, and are similar to those for office workers. However, it is expected that the public will be using the photocopier less often than workers.

AND/OR (surface coatings)
Since the notified polymer will be in products sold to the general public, there is the potential for dermal, and to a lesser extent oral and ocular exposure. Exposure is likely to be limited by personal protective equipment, for example overalls and protective footwear. According to EASE (1997) modelling of this work environment, dermal exposure in the range of XX mg/cm^2/day of products containing YY% of the notified polymer could result where personal protective equipment was not present.

AND/OR (cosmetics)
Since the notified polymer will be in products sold to the general public, widespread public exposure is expected. Exposure to the notified chemical will vary depending on individual use patterns. Typically, x g of product containing y% notified polymer is applied to the hair/hands/face once/twice a day/week. The hair/skin is rinsed after application.

6.2. Toxicological Hazard Characterisation

The following text is appropriate in the absence of toxicity data or suspicion of toxicity from other sources, and the rest of the section can be deleted:

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Include here any other information regarding Hazard. For example:

The powder may cause mechanical irritation to the eyes, and to the respiratory tract if inhaled. Repeated or prolonged skin contact may result in mild irritation.

If data are available, the results should be reported, as shown in the second example:

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by toxicological endpoints observed in testing conducted on the notified polymer or analogue chemical.

Please use the table below to provide results from any toxicological tests available to you. Delete the rows that do not apply (ie those endpoints for which no data are available). For any endpoints for which there are data, fill in the result and indicate whether the result would lead to classification of the notified polymer as a hazardous

substance according to the NOHSC criteria (which should not be the case under any circumstances for a PLC). If effects are observed (short of classification of the polymer as a hazardous substance), they should be indicated in the Effects Observed column.

Please indicate the Test Guideline used to determine the toxicological endpoint. Toxicology reports that followed an OECD test guideline are preferred. Where another test guideline was used, please indicate in the last column (for example EC Directive 92/69/EEC B.1 Acute Toxicity (Oral) – Limit Test). It is not necessary to provide full references for these study reports.

Where data has been obtained on an analogous chemical, include as much information here as possible. Where this information has been claimed as exempt, include a brief description of the analogue in Part 1 (Exempt information) under the heading '6.2. Hazard Characterisation', including scientific justification as to why it is a good analogue of the notified polymer.

Endpoint	*Result*	*Classified?*	*Effects Observed?*	*Test Guideline (Choose one)* or enter the test guideline if non-OECD
Rat, acute oral	LD50 … mg/kg bw	yes/no	yes/no	OECD TG 401 OECD TG 423
Rat, acute dermal	LD50 … mg/kg bw	yes/no	yes/no	OECD TG 402
Rat, acute inhalation	LC50 … mg/L/4 hour	yes/no	yes/no	OECD TG 403
Rabbit, skin irritation	irritating/non-irritating	yes/no	yes/no	OECD TG 404
Rabbit, eye irritation	irritating/non-irritating	yes/no	yes/no	OECD TG 405
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)
Rat, <route of exposure> repeat dose toxicity - … days.	NOEL/NOAEL/ LOAEL	yes/no	yes/no	OECD TG 407 – 409, 422, 410 – 411, 412 – 413
Genotoxicity – bacterial reverse mutation	mutagenic/non mutagenic	yes/no	yes/no	OECD TG 471 – 472
Genotoxicity – in vitro <test type>	genotoxic/non genotoxic	yes/no	yes/no	OECD TG 473, 476, 479 – 482
Genotoxicity – in vivo <test type>	genotoxic/non genotoxic	yes/no	yes/no	OECD TG 474, 475, 486
Developmental and reproductive effects	NOEL/NOAEL/ LOAEL	yes/no	yes/no	
Carcinogenicity		yes/no	yes/no	
Other		yes/no	yes/no	

All results were indicative of low hazard.

OR briefly discuss any observed effects in a few sentences.

The types of effects to report are any observations worthy of remark during the toxicological studies. These include mortalities or sublethal effects such as clinical observations in acute toxicity tests; any non-zero scores in any animals at any time point during irritation or sensitisation tests, or significant increases in responses in genotoxicity testing. Please provide a brief comment about these effects in the space provided after the table.

Some examples of the type of effects which could be reported:

Two out of ten rats treated with 2000 mg/kg bw in the acute oral toxicity test showed diarrhoea that resolved within 24 hours of dosing.

Five out of ten test animals and one out of five control animals showed erythema (Grade 1) at 24 hours after challenge in a Buehler sensitisation test in guinea pigs. After 48 hours, erythema (Grade 1) was observed in two test animals only.

6.3. Human Health Risk Assessment

The health risk is characterised by integrating the hazard and exposure assessments. Due to the inherently low hazard of PLCs, this section only requires a brief summary of exposure, and a statement regarding the low hazard.

6.3.1 Occupational Health and Safety

Examples of the type of risk assessment appropriate for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style.

The OHS risk presented by the notified polymer is expected to be low, based on the minimal exposure to workers and the low intrinsic hazard of the polymer.

OR
Although exposure to the notified polymer could occur during <insert text>, the risk to workers is considered to be low due to the intrinsic low hazard of the notified polymer.

AND (if appropriate)
The level of atmospheric nuisance dust should be maintained as low as possible. The NOHSC exposure standard for atmospheric dust is 10 mg/m^3.

6.3.2 Public Health

Examples of the type of risk assessment appropriate for many PLCs are given below. If none of these are appropriate for the current circumstances, adapt one of these or write an assessment in a similar style.

As there will be no exposure of the public to the notified polymer (or products containing the notified polymer) the risk to the public from exposure to the notified polymer is considered to be negligible. Where exposure occurs, the low hazard of the polymer translates to low risk.

OR
The notified polymer will not be available to the public. Members of the public may make dermal contact with products containing the notified polymer. However, the risk to public health will be negligible because the notified polymer is of low hazard, and is (present at low concentrations/bound within a matrix/chemically stable/resistant to degradation.

OR
The notified polymer is intended for use by professional spray painters in (auto repair workshops/automotive manufacturing plants) only, and will not be sold to the public. Following application, the notified polymer will become trapped within a film and will not be bioavailable. Therefore, the risk to public from exposure to the notified polymer is considered low.

OR (toner cartridge)
The risk to public health presented by the notified polymer is expected to be low due to its intrinsic low toxicity, low concentration in toner and low potential for exposure. Nevertheless, due to the particulate nature of the toner, skin, eye and respiratory exposure should be avoided. Photocopiers and printers should be located in well-ventilated areas

OR (consumer products/cosmetics)
Although the public will be exposed to the notified polymer during use of <insert consumer product>, the risk to public health is considered to be low due to the predicted low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Exposure Assessment

7.1.1 Environmental Release

Examples of the type of environmental release information appropriate for many PLCs are given below. If none of these are appropriate for current circumstances, please adapt one of these or write an assessment in a similar style.

Paints – All

Use the following paragraph in conjunction with either of the specific cases, as appropriate.

There is the potential for release during manufacture and application. Any spills that occur during reformulation will be contained by bunding. Approximately [Up to] X kg per annum of waste is expected to be generated due to spills and cleaning equipment during paint manufacture. A licensed waste disposal contractor will collect the aqueous waste from the manufacturing process for treatment with flocculants prior to burying the solids in a secure landfill.

Paints – Architectural

Empty polymer import containers and cans and pails containing dry paint residue (containing up to Y kg of the notified polymer per annum) will be consigned to landfills. Up to Z kg of the notified polymer could be disposed of the sewer system during the cleaning of application equipment, especially from the washing of the brushes or rollers used by do-it-yourself home painters.

Paints – Automotive

Professional spray painters will use the paint to refinish motor vehicles. It will be applied in combination spray/oven booths that comply with Australian Standards. Spray booths are fitted with environmental control measures. Water curtains or a dry filter medium will collect excess spray. The coating is either air-dried or oven-baked at 60 ^{0}C to form a stable inert film.

There is potential for release of the notified polymer during mixing, spray-gun loading, spraying, equipment cleaning, from container residues and in the event of an accidental spill. Up to 70% of the notified polymer could be released through overspray within spray booths. This will be captured by standard engineering controls, treated and the solid waste disposed to landfill. An estimated 2.5% of the polymer will remain as residues in containers, which will cure and harden before disposal to landfill. Less than 1% of waste polymer will be generated from cleaning the application. Therefore the total waste polymer could amount to up to 74% of the import volume at market maturity. It is expected that no waste notified polymer would enter the sewerage system or natural waterways.

Personal Care Products

During formulation a small amount of the notified polymer could be washed from machinery during cleaning. This is normally treated as site industrial waste and dealt with by licensed disposal contractors. Some will ultimately be released into the sewer. Empty import containers with any remaining residual material will be disposed of to landfill.

The formulated product will be applied to hair or skin. Therefore, the majority of the notified polymer is expected to be washed off and enter the sewer, with the remainder disposed of in landfill as residues in product containers. Sludge containing the polymer will be disposed of in landfill.

Photocopying toner

Environmental release of the toner is not expected during importation, storage and transportation. Spillage during a transport accident is the most likely reason for environmental release. In such an event, individual container capacity and container specifications would limit the extent of release since each toner cartridge, containing XX grams of toner, is designed to prevent leakage. If leakage does occur, the toner will be collected and sent to landfill for disposal.

Used cartridges containing up to 10% of toner (estimated to be up to YY kg per annum) will be sent to landfill for disposal. Residues contained in the empty bottles/cartridges are expected to remain within these containers, although release could occur from deterioration of the cartridge while in the landfill waste.

Toner containing the notified polymer will be applied to paper products. Some waste paper could be disposed of directly to landfill with the notified polymer strongly bound to the paper. In addition to landfill, some printed paper will enter the paper recycling process.

Inks

The notified polymer will be imported in formulated inks. A small amount (<1%) of the notified polymer could be washed off from printing machinery during the normal cleaning process using an organic solvent mix. A licensed disposal contractor for off-site solvent regeneration will deal with this, with the notified polymer being disposed of to landfill.

Residues remaining in the import containers (1-2%) will be disposed of either through metal recycling companies or the controlled waste system (plastic cans) and be disposed of by incineration or washed and sent to landfill.

The majority of the notified polymer will be bound within the cured coating matrix adhering to printing inks, varnishes and self-adhesive labels. Once the chemical is within a cured coating it is likely to share the fate of the substrate, which might involve recycling or landfill.

7.1.2 ENVIRONMENTAL FATE

Generic examples of the type of environment fate assessment appropriate for many PLCs are given below. If inappropriate for the current circumstances, please adapt or write an assessment in a similar style.

The notified polymer contains groups in the [backbone/side chains] that might hydrolyse under severe conditions, but is expected to be stable under normal environmental conditions. Due to its low water solubility, the notified polymer in solid wastes is expected to remain bound within the soils and sediments of landfills and eventually degrade through biotic and abiotic processes. If spilt on land, the notified polymer is expected to bind to soil and become immobilised in the soil layer. If spilt to water, it is not expected to dissolve but rather disperse or settle to sediment. It is not expected to be readily biodegradable but due to its high molecular weight, it is not expected to bioaccumulate. Incineration of the notified polymer will result in the formation of water vapour and oxides of carbon and nitrogen.

The notified polymer is water soluble, expected to be hydrolytically stable and not expected to be readily biodegradable. On the basis of water solubility, the notified polymer is likely to be mobile in soils, and should work its way into the grass root zone and below. The notified polymer should not hydrolyse (due to the lack of suitable functionality) but is expected to slowly degrade into oxides of carbon and water. Incineration of the notified polymer will result in the generation of water vapour and carbon dioxide. The notified polymer's high molecular weight will preclude absorption across biological membranes and thus it is unlikely to bioaccumulate.

If, however, a ready biodegradability test is available, complete the following table:

Endpoint	*Results and Conclusion*	*Test Guideline (Choose or replace)*
Ready Biodegradability	Not readily biodegradable	OECD TG 301 D

Briefly discuss any observed effects in a few sentences.

Comment on any protocol deviations, or effects (such as toxicity) arising from the notified chemical.

e.g.
The temperature ranged between 19.7-22.3°C. This variation was not considered to have affected the result of the biodegradation test.

7.2. Environmental Hazard Characterisation

The following text is appropriate in the absence of toxicity data or suspicion of toxicity from other sources, and the rest of the section can be deleted:

No ecotoxicological data were submitted.
PLCs without significant ionic functionality are of low concern to the aquatic environment.
OR
Anionic polymers are known to be moderately toxic to algae. The mode of toxic action is over-chelation of nutrient elements needed by algae for growth. The highest toxicity is when the acid is on alternating carbons of the polymer backbone. [Whether this applies to the notified polymer is unclear. OR This is unlikely to apply to the notified polymer.] However, the toxicity to algae is likely to be further reduced due to the presence of calcium ions, which will bind to the functional groups.

If data are available, the results should be reported, as shown in the second example:

The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard. This is supported by environmental endpoints observed in testing conducted on the notified or analogue polymer.

Please use the table below to provide results from any ecotoxicological tests available to you. Delete the rows that do not apply. If effects are observed, they should be discussed in the space provided after the table. If no ecotoxicological tests are available, please delete the rest of this section.

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.

Please indicate the Test Guideline used to determine the environmental endpoint. Reports that followed an OECD test guideline are preferred. Where another test guideline was used, please indicate in the last column (for example US EPA Series 850. Ecological Effects Test Guidelines OPPTS Number 850.1075). It is not necessary to provide full references for these study reports.

Where endpoints have been obtained on an analogous chemical, include as much information here as possible. Where this information has been claimed as exempt, include a brief description of the analogue in Part 1 (Exempt information) under the heading '7.2. Hazard Characterisation', including scientific justification as to why it is a good analogue of the notified polymer.

It may be necessary to add additional rows to the following table, for example where two levels of water hardness are used in an algal toxicity test.

Endpoint	*Result*	*Effects Observed?*	*Test Guideline (Choose or replace)*
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	

All results were indicative of low hazard.

OR briefly discuss any observed effects in a few sentences.

Fish toxicity
The test solutions contained a surface film and were hazy throughout, indicating that the polymer was not completely solubilised. After [value] h duration, five fish were discoloured and lethargic and two lost coordination when swimming, however no mortality was observed. The NOEC was [value] mg/L and the LOEC [value] mg/L.

Aquatic invertebrate toxicity
After [value] h duration, four daphnia were observed floating at the surface and covered with slick. The NOEC was [value] mg/L and LOEC [value] mg/L.

7.3. Environmental Risk Assessment

The environmental risk is characterised by integrating the hazard and exposure assessments. Some examples of the type of environmental risk assessment appropriate for many PLCs are given below. If this is appropriate for the current circumstances, adapt this or write an assessment in a similar style.

Paints – Architectural

The products containing the notified substance are likely to be used throughout Australia. The major environmental exposure is expected to be due to the disposal of waste from the coatings manufacture and particularly from overspray during application to landfill. If spilt on land, the notified polymer is expected to become immobilised in the soil layer. Due to its low water solubility, the polymer will remain bound within the soils and sediments of the landfill and to be slowly degraded by the abiotic processes.

The waste polymer is discharged in domestic wash waters to waste water treatment systems through washing of brushes etc. (In this case a worst case PEC can be estimated using a similar calculation to that described for personal care products below, assuming that 5% of the total import volume is washed to the sewer.)

Based on the proposed use pattern, the release of the notified polymer to the aquatic environment is expected to be low and dispersed. Adsorption to sludge, soil and sediment as well as dilution in receiving waters should reduce environmental concentrations to acceptable levels. Abiotic or slow biotic processes are expected to eventually degrade the notified polymer.

Given the above, environmental exposure and the overall environmental risk are expected to be low.

Paints – Automotive

Up to ZZ tonnes per annum of waste notified polymer might be generated during coatings manufacturing and use each year as a result of incidental spills, equipment cleaning (brushes, rollers, spray equipment), and residues in containers. The majority of this waste will be sent to landfill for disposal. In landfill, the notified polymer in solid wastes is expected to be immobile, and eventually will degrade through biotic and abiotic processes, and consequently, should not pose a significant risk to the environment.

Spills of notified polymer to land are expected to bind to soil and should not be mobile or affect groundwater due to very low water solubility. Spills of notified polymer to waters are not expected to dissolve due to the lack of water solubility, and the product is expected to disperse or to settle to sediment.

Most of the notified polymer used in automotive finishes will eventually be incorporated in metal recycling programs or sent to landfill for disposal following its lifecycle. During reclamation, the notified polymer would be destroyed in furnaces and converted to water vapour and oxides of nitrogen and carbon (etc).

Personal care

Since most of the polymer will be washed into the sewer, under a worst-case scenario with no removal of the notified polymer in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis is estimated to be AA μg/L.

Amount entering sewer annually	BB kg
Population of Australia	20 million
Amount of water used per person per day	200 L
Number of days in a year	365

Based on dilution factors of 1 and 10 for inland and ocean discharges of STP-treated effluents, the PECs of the notified chemical in freshwater and marine water may approximate AA or DD μg/L, respectively.

As the PEC/PNEC ratio [AA/HH] is considerably less than 1, there should be a low risk to aquatic organisms. (If a PNEC is used, HH is the lowest toxicity value determined in toxicity testing).

Photocopying toners

While environmental exposure is limited during toner use, the total import volume of the notified polymer will

ultimately be disposed of in either landfill or be incinerated. The widespread use pattern indicates that landfills throughout Australia would receive the notified polymer bound into the toner matrix within cartridges and on paper products. The used toner would be expected to remain within the container unless breached. On paper the notified polymer will interact with other components to form a stable polymer matrix and, once dry, is expected to be immobile and pose little risk to the environment.

During recycling processes, waste paper is repulped using a variety of alkaline, dispersing and wetting agents, water emulsifiable organic solvents and bleaches. These agents enhance fibre separation, toner detachment from the fibres, pulp brightness and the whiteness of paper. These aqueous wastes are expected to go to sewer. Very little of the notified polymer is expected to partition to the supernatant water which is released to the sewer. Sludge generated during the washing process is dried and incinerated or sent to landfill for disposal.

The notified polymer is not likely to present a risk to the environment when it is stored, transported, used, recycled and disposed of in the proposed manner.

Inks

The notified chemical will be used as a component of UV curable inks. Once these inks have been cured the notified chemical is expected to remain within the product matrices. Hence, the majority of the notified chemical will share the fate of the articles into which it is incorporated. It is anticipated that these will be disposed of to landfill or incinerated at the end of their useful lifetime. In landfill it is expected that the notified chemical will remain immobile within the soil. Incineration of the notified chemical will result in the formation of water vapour and oxides of carbon and nitrogen. (The words on recycling as for photocopying toners may also be relevant.)

Very little if any will be released to water and it is not possible to calculate a reasonable predicted environmental concentration (PEC).

The above considerations indicate minimal risk to the environment when the notified chemical is used in the manner and levels indicated by the notifier.

8. CONCLUSIONS

In all the risk assessment conclusions, consider only the notified polymer. If a risk arises due to the presence of other ingredients, such as solvents and surfactants that are on AICS, these are separately subject to controls, and the controls have the effect of reducing exposure to the notified polymer. A risk arising from the other ingredients is subject to the controls arising from State and Territory legislation, eg hazardous substances and environmental regulation, and is not the subject of the self-assessment report.

8.1. Level of Concern for Occupational Health and Safety

There is No Concern/Low Concern to occupational health and safety under the conditions of the occupational settings described.

Normally these are the only two options applicable for a PLC – no concern in the case of effectively no occupational exposure, low otherwise. It is possible that both scenarios can arise if there are multiple uses and the circumstances should be defined under which concern is non-existent and those under which it is low.

8.2. Level of Concern for Public Health

There is Negligible Concern/No Significant Concern to public health when used….

Normally these are the only two options applicable for a PLC – negligible in the case of effectively no public exposure, low otherwise. Complete the "when used…." to specify the circumstances under which concern is low; it is possible that both scenarios can arise if there are multiple uses and the circumstances should be defined under which concern is negligible and those under which it is low.

8.3. Level of Concern for the Environment

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

For a PLC, the above statement should satisfactorily describe the environmental risk; if this is not the case, explain why. Additional assessment may be needed in this case.

9. MATERIAL SAFETY DATA SHEET

9.1. Material Safety Data Sheet

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

The notifier must provide an MSDS for the notified polymer, in the form in which it is introduced to Australia, and for any products containing the notified polymer. The MSDS must conform with the NOHSC requirements - see http://www.nohsc.gov.au/pdf/standards/MSDSCodeNOHSC20112003.pdf

10. RECOMMENDATIONS

Some examples of recommendations are listed here. If alternative recommendations are required, amend or replace these recommendations. Recommendations for the safe use of the notified polymer must be completed as part of the self-assessment template, and should be aligned with requirements identified in the risk assessment.

NICNAS will amend this section as necessary in cases where the recommendations do not align with the risk assessment. This may include cases where either insufficient, or overly severe, recommendations have been made.

CONTROL MEASURES

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- Service personnel should wear cotton or disposable gloves and ensure adequate ventilation is present when removing spent printer cartridges containing the notified polymer and during routine maintenance and repairs.

- Atmospheric monitoring should be conducted [by ……] to measure workplace concentrations of nuisance dust/decomposition products during (manufacture, formulation, use) of the notified polymer.

- A copy of the MSDS should be easily accessible to employees.

- The notified polymer may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

- The following concentration limits should be implemented [by ……] for release of the notified polymer to the environment:
  - *[List limits]*

- The following control measures should be implemented by [by ……] to minimise environmental exposure during (manufacture, formulation, use) of the notified polymer:
  - *[List control measures]*

- The following monitoring should be conducted [by ……] to measure environmental release during (manufacture, formulation, use) of the notified polymer:
  - *[List methods of monitoring]*

Disposal

- The notified polymer should be disposed of by [insert method of disposal].

Storage

- The following precautions should be taken [by ……] regarding storage of the notified polymer:
  – *[List]*

Emergency procedures

- Spills/release of the notified polymer should be handled by [insert method of treatment].

Transport and Packaging

(if necessary)

10.1. Secondary Notification

NICNAS will complete this section and include any non-standard secondary notification conditions.