Application for Early Introduction Permit (EIP)

Australian Government
Department of Health and Ageing
NICNAS

FORM EIP-1

Use this form when applying for a permit to allow the early introduction of a chemical under section 30A of the *Industrial Chemicals (Notification and Assessment) Act 1989* in connection with a Standard Notification or Limited Notification. **Do not complete this form if applying for an EIP for a PLC.**

This application must either:

- accompany an application for an assessment certificate, or
- follow a previously submitted application for an assessment certificate.

A fee may be required (see section A6, B4 or C4 and payment advice at the end of this form).

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

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

Notifier

Business Name:

ABN: NICNAS Registration Number:

Business Address:

Postcode:

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

Postcode:

Contact Name: Position:

Phone: Fax: E-mail:

Technical Contact

Name: Position: Company:

Business Address (*if different to above*):

Postcode:

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

Postcode:

Phone: Fax: E-mail:

Application Fee

The application fee is enclosed. ☐ YES ☐ NOT APPLICABLE

Chemical

Chemical name:

Marketing or other name:

CAS number *(if known)*: - -

The notified chemical is a:

Non-hazardous chemical/polymer	☐	Complete Part A
Chemical (including polymers with NAMW <1000) meeting low-hazardous criteria	☐	Complete Part A
Polymer with NAMW ≥1000 meeting low-hazardous criteria	☐	Complete Part B
Low risk highly controlled chemical/polymer	☐	Complete Part C

(Guidance is available to help determine which section of this form should be completed.)

PART A

Complete the following sections if applying for an EIP:

- non–hazardous chemical; or
- non-hazardous polymer; or
- chemical (including polymers with a NAMW < 1000) meeting the low hazard criteria.

Part A is applicable for EIP applications made in connection with a LTD or STD notification. If the chemical does not meet the criteria set out in Part A the chemical may be eligible for other categories of EIP (See Part B or C).

Section A1 Human Health Hazard Criteria
Supporting Information –Chemicals (including polymers with a NAMW < 1000)

To be satisfied that the human health hazard criteria are met certain test data are normally required to be available (see the Handbook for Notifiers for more information). Please indicate:

Data for **all** following endpoints is available:

acute oral toxicity,
acute dermal toxicity,
acute inhalation toxicity (in certain circumstances)
skin irritation,
eye irritation,
sensitisation,
repeat dose toxicity,
genotoxicity – bacterial reverse mutation and
genotoxicity in vitro

☐ ===➔ Meets non-hazardous human health supporting data requirements for chemicals

Comment [N1]: a)The chemical has a vapour pressure ≥ 1.5 kPa; or
b)The chemical as introduced has ≥ 25% of particles having < 10 µm diameter; or
c) The chemical is purposely aerosolised during use (except where this constitutes a "controlled use "

Data for all of the above endpoints **not** available but data available for relevant endpoints for which there is a structural alert.

☐ ===➔ Meets low hazardous human health supporting data requirements for chemicals

Comment [N2]: A list of structural alerts is included in Appendix 15 of the Handbook for Notifiers

Supporting Information –Polymers with a NAMW ≥ 1000)

To be satisfied that the human health hazard criteria are met certain test data are normally required to be available (see the Handbook for Notifiers for more information). Please indicate:

Data for **all** following endpoints is available:

acute oral toxicity,
skin irritation,
sensitisation (in certain circumstances), and
genotoxicity – bacterial reverse mutation

☐ ===➔ Meets non-hazardous human health supporting data requirements for polymers

Comment [N3]: Where the polymer contains one or more High Concern Reactive Functional Groups with FGEW < 5000, as defined in the PLC criteria (except unsubstituted positions ortho and para to phenolic hydroxyl or partially-hydrolysed acrylamides)

Hazard classification

In accordance with the *Approved Criteria for Classifying Hazardous Substances*[1], the chemical/polymer is:

Not classified as hazardous ☐ ===➔ Meets non-hazardous human health hazard criteria for chemicals/polymers

Classified as hazardous with only the Risk phrase R36 and/or R38 and irritation is reversible. ☐ ===➔ Meets low hazardous human health hazard criteria for chemicals (including polymers with a NAMW < 1000)

[1] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Section A2 Dangerous Goods Criteria

In accordance with the Australian Dangerous Goods Code[2], the chemical is:

Not a Dangerous good	☐	===➔	Meets non-hazardous dangerous goods criteria for chemicals/polymers
A dangerous good that is only a class 3 flammable liquid	☐	===➔	Meets low hazardous dangerous goods criteria for chemicals (including polymers with a NAMW < 1000)

Section A3 Environmental hazard criteria

To be satisfied that the environmental hazard criteria are met, data should normally be available for all three trophic levels. Where data are not available i.e. for Limited notifications, the chemical/polymer may be eligible for EIP if certain release criteria are met (see section A5ii).

The chemical's toxicity:

	≥ 100 mg/L	Not determined
to fish (i.e. LC_{50}), as determined using the Fish Acute Toxicity Test, is	☐	☐
to aquatic invertebrates (i.e. EC_{50}), as determined using the *Daphnia* sp, Acute Immobilisation Test and Reproduction Test, is	☐	☐
to algae (i.e. EC_{50}), as determined using the Algal Growth Inhibition Test, is	☐	☐
	⇓	⇓
	Meets non/low-hazardous environmental hazard criteria*	May be eligible for EIP if certain release criteria are met (see section A5ii)*

* **Note:** *A chemical only meets the non/low hazardous environmental hazard criteria where the toxicity to **all** species is ≥100 mg/L or if toxicity has not been determined and certain release criteria are met (see Section A5ii).*

Section A4 Environmental fate

To be eligible for an EIP the chemical/polymer must not be persistent and/or bioaccumulative, or have persistent and/or bioaccumulative breakdown products. National environmental persistence and bioaccumulation criteria are set out in Appendix 16 of the Handbook for Notifiers and are not specifically addressed in this form. Environmental fate criteria are only prescribed for non-hazardous chemicals/polymers.

Complete the following only if applying for an Early Introduction Permit for a non-hazardous chemical/polymer

***A4i** To be satisfied that the chemical meets the environmental fate criteria for non-hazardous chemicals/polymers, ready biodegradability data should normally be available. Where data is not available i.e. for Limited notifications, the chemical/polymer may be eligible for EIP if certain release criteria are met (see section A5ii).*

In accordance with a Ready Biodegradability Test, the chemical/polymer is:

Ready biodegradable	☐	===➔	May meet non-hazardous environmental fate criteria where criteria in **A4ii** are met.
Not determined	☐	===➔	May be eligible for EIP for a non-hazardous chemical/polymer if criteria in **A4ii** are met **and** certain release criteria are met (Section A5ii)

[2] Australian Code for the Transport of Dangerous Goods by Road and Rail, National Transport Commission (Australia)

A4ii

To be considered a non-hazardous chemical/polymer, the chemical must also satisfy at least **ONE** of the following. Please indicate:

• If the chemical dissolves in water without dissociation or association and it is not surface active, its (n-octanol/water) partition coefficient at 20ºC (log P_{ow}) is not greater than 3	☐ YES	☐ NO
• The solubility of the chemical in water is greater than 1 mg/L	☐ YES	☐ NO
• The number-average molecular weight (for polymers) or the molecular weight (for non-polymers) is greater than 1,000	☐ YES	☐ NO

Section A5 Environmental Release criteria

In deciding whether to grant the EIP, the Director will take into account the likelihood of release of the chemical to the aquatic environment. For Standard and Limited Notifications, direct release into a natural waterway must be considered. For Limited notifications where there is no ecotoxicity or ready biodegradability data to support the application, the Director must also take into account release into a water treatment works. Based on this release information, NICNAS will advise whether a permit can be granted.

***A5i** Complete the following:*

The Director must consider the following when deciding to grant the permit. Please indicate:

Is the chemical likely to be released into a natural waterway?	☐ YES	☐ NO

***A5ii** Complete the following only where environmental hazard or fate data are not available i.e. for LTD notifications:*

The Director must consider the following when deciding to grant the permit. Please indicate:

Is the chemical likely to be released into a water treatment works?	☐YES	☐ NO
If the answer to the last question is "yes", please address the following		
Is the quantity of the chemical to be released into the water treatment works from a single site likely to exceed 10 kilograms/year?	☐ YES	☐ NO
Is the total quantity of the chemical to be released into the water treatment works from all sites likely to exceed 50 kilograms/year?	☐ YES	☐ NO

Section A6 Fees

The associated fee for an Early Introduction permit is as follows:

Non-hazardous chemical/polymer (non-hazardous criteria for human health supporting data requirements, human health hazard, dangerous goods, environmental hazard* and fate* (**all** met) * or environmental release	☐ ===➔	Free of charge
Chemical meeting low-hazardous criteria (low-hazardous criteria met for **any** of human health supporting data requirements, human health hazard, dangerous goods and fate **and** non-hazardous or low-hazardous criteria met for **all**)	☐ ===➔	Fee applies

DECLARATION

***Note:** It is an offence under the Act to supply a statement which is false or misleading*

I declare that to the best of my knowledge all the information supplied in this form is true, correct and complete.

Name:	Position:
Signature:	Date:

PART B

Complete the following sections if applying for an EIP for a polymer with a NAMW ≥ 1000 meeting the low hazardous criteria.

Part B is applicable for EIP applications made in connection with a LTD notification. If the chemical does not meet the criteria set out in Part B the chemical may be eligible for other categories of EIP (See Part A or C).

Section B1 Low Molecular weight species criteria

To be considered a low-hazardous polymer, the polymer must satisfy **EACH** of the following. Please indicate:

Less than 10% (by mass) of molecules have molecular weight < 500	☐ YES	☐ NO
Less than 25% (by mass) of molecules have molecular weight < 1000	☐ YES	☐ NO

Section B2 Human health hazard criteria Supporting Information

To be satisfied that the human health hazard criteria are met certain test data may be required (see the Handbook for Notifiers for more information). Please indicate:

Polymer contains a structural alert	☐ YES	☐ NO
Data available for relevant endpoints for which there is a structural alert	☐ YES	☐ NO
Data not available for an endpoint where there is a structural alert but the % by mass of molecules with molecular weight that is less than 1000 is less than the concentration cut-offs (used to determine whether or not a mixture is hazardous on the basis of its ingredients)	☐ YES	☐ NO

Comment [N4]: A list of structural alerts is included in Appendix 15 of the Handbook for Notifiers.

Hazard classification

To be considered a low-hazardous polymer, the polymer must satisfy the following. Please indicate:

Not classified in accordance with the *Approved Criteria for Classifying Hazardous Substances* [3] as hazardous with **any** of the following Risk phrases:

R23, R24, R25, R26, R27, R28, R34, R35, R39, R40, R42, R43, R45, R46, R48, R49, R60, R61, R62, R63, R64 or R68.	☐ YES	☐ NO

B3 Environmental criteria

To be considered a low-hazardous polymer, the polymer must satisfy at least ONE of the following. Please indicate:

The polymer is not cationic or not likely to become cationic in an aquatic environment that has a pH value greater than 4 and less than 9	☐ YES	☐ NO
The polymer is a solid that is not soluble or dispersible in water and is to be used only in its solid phase	☐ YES	☐ NO
For a polymer that includes one or more cationic groups, the total combined functional group equivalent weight of any cationic group is ≥ 5000	☐ YES	☐ NO

To be eligible for an EIP the chemical/polymer must not be persistent and/or bioaccumulative, or have persistent and/or bioaccumulative breakdown products. National environmental persistence and bioaccumulation criteria are set out in Appendix 16 of the Handbook for Notifiers and are not specifically addressed in this form

Section B4 Fees

There is an associated fee for an Early Introduction permit for a polymer meeting the low-hazardous criteria (see payment advice at the end of this form)

[3] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

DECLARATION

Note: *It is an offence under the Act to supply a statement which is false or misleading*

I declare that to the best of my knowledge all the information supplied in this form is true, correct and complete.

Name: Position:

Signature: Date:

PART C

Complete the following sections if applying for an EIP for a low risk highly controlled chemical/polymer.

Part C is applicable for EIP applications made in connection with a LTD notification. If the chemical does not meet the criteria set out in Part C the chemical may be eligible for other categories of EIP (See Part A or B).

Section C1 Human health hazard criteria
Supporting Information

To be satisfied that the human health hazard criteria are met certain test data may be required (see the Handbook for Notifiers for more information). Please indicate:

Chemical/polymer contains a structural alert	☐ YES	☐ NO
Data available for endpoints for which there is a structural alert	☐ YES	☐ NO
Data not available for an endpoint where there is a structural alert but the % by mass of molecules with molecular weight that is less than 1000 is less than the concentration cut-offs (used to determine whether or not a mixture is hazardous on the basis of its ingredients)	☐ YES	☐ NO

Comment [N5]: A list of structural alerts is included in Appendix 15 of the Handbook for Notifiers.

Hazard classification

To be considered a low risk highly controlled chemical/polymer, the chemical/polymer must satisfy the following. Please indicate:

Not classified in accordance with the *Approved Criteria for Classifying Hazardous Substances* [4] as hazardous with **any** of the following Risk phrases: R23, R24, R25, R26, R27, R28, R34, R35, R39, R40, R42, R43, R45, R46, R48, R49, R60, R61, R62, R63, R64 or R68.	☐ YES	☐ NO

Section C2 Human Exposure

To be considered a low risk highly controlled chemical/polymer, the chemical must satisfy **EACH** of the following (see Appendix 14 of the *Handbook for Notifiers* for guidance on acceptable exposure scenarios and work practices). Please indicate:

There are no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the chemical	☐ YES ===➔	Provide details below
	☐ NO ===➔	Not eligible for EIP
Any worker exposure that is likely to occur will be highly controlled through use of engineering controls, work practices and personal protective equipment	☐ YES ===➔	Provide details below
	☐ NO ===➔	Not eligible for EIP

Comment [N6]: Page: 7
Only those down-stream users whose details have been provided to NICNAS will be able to use the chemical (these users will be listed on the permit). NICNAS must be satisfied that the user of the chemical is aware of the conditions of the permit i.e. that the use is highly controlled.

Comment [N7]: Page: 7
Include all routes by which the public could be exposed (indirect, accidental) and the methods used to prevent exposure. Please note for an Controlled Use permit, direct public exposure is not expected.

Comment [N8]: Page: 7
Describe the activities carried out by each category of workers that may result in exposure to the notified chemical. Describe how exposure may occur (eg drips and spills, splashes, vapours, aerosols or dusts – give particle size) and the route of exposure (eg inhalation, ocular, dermal). Include the concentration of notified chemical in the formulation at each step. Give these details even if protective equipment which will minimise exposure is used. Describe the control measures in place such as automated enclosed systems, codes of practice, local exhaust ventilation, and personal protective equipment to prevent this exposure. Refer to Appendix 14 for further information

If yes, please complete the following:

Identity of down-stream users

Control measures used to prevent exposure to the public

Exposure details and control measures employed to prevent exposure to workers

[4] Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Section C3 Environmental hazard and fate criteria

To be satisfied that the environmental hazard criteria are met, data should normally be available for all three trophic levels.

To be considered a low risk highly controlled chemical/polymer, the chemical/polymer must satisfy **EACH** of the following. Please indicate:

The chemical has toxicity to fish (ie LC_{50}), that is greater than 10 mg/L, as determined using the Fish Acute Toxicity Test	☐ YES	☐ NO
The chemical has toxicity to aquatic invertebrates (ie EC_{50}), that is greater than 10 mg/L, as determined using the *Daphnia* sp, Acute Immobilisation Test and Reproduction Test	☐ YES	☐ NO
The chemical has toxicity to algae (ie EC_{50}), that is greater than 10 mg/L, as determined using the Algal Growth Inhibition Test	☐ YES	☐ NO

To be eligible for an EIP the chemical/polymer must not be persistent and/or bioaccumulative, or have persistent and bioaccumulative breakdown products. National environmental persistence and bioaccumulation criteria are set out in Appendix 16 of the Handbook for Notifiers and are not specifically addressed in this form.

Section C4 Environmental Release

To be considered a low risk highly controlled chemical/polymer, the chemical must satisfy **EACH** of the following (see Appendix 14 of the *Handbook for Notifiers* for guidance). Please indicate:

Ambient release to surface water results in concentrations < 1ppb	☐ YES	===➔	Provide details below
	☐ NO		
Ambient release to air < 1mg/m^3 average annual concentration	☐ YES	===➔	Provide details below
	☐ NO		
No release to land or landfill unless the chemical has negligible potential for migration to groundwater.	☐ YES	===➔	Provide details below
	☐ NO		

If yes, please complete the following:

Release of chemical at site and control measures used to prevent release to the environment

Release of chemical from use and control measures used to prevent release to the environment

Release of chemical from disposal

Release of chemical to surface water

Release of chemical to air

Comment [N9]: Page: 8
Discuss the releases during activities described under "**Operation Description e.g.** manufacturing or reformulation processes and describe the methods used to prevent release of the chemical into the environment during manufacturing or reformulation processes. For each situation give quantity (kg/day) and media of release in which environmental release of the notified chemical may occur. All potential releases such as cleaning wastes, spills, residues in containers should be considered.

Comment [N10]: Page: 8
Give information on releases and methods used to prevent release of the chemical into the environment not covered above.
For each situation give quantity (kg/day) and media of release in which environmental release of the notified chemical may occur.

Comment [N11]: Page: 8
Describe disposal procedures, include procedures for contaminated packaging. Include: route of disposal (eg landfill), quantity (kg/year) to be disposed by each route, include residues in contaminated packaging (eg empty drums), identify hazards of degradation products resulting from disposal.

Comment [N12]: Page: 8
Please provide details of the calculation to determine PEC in water after secondary or tertiary wastewater treatment arising from any controlled point-source release of the notified chemical described above. See Appendix 14 of the Handbook for notifiers for guidance in performing this calculation.

Comment [N13]: Page: 8
Please provide details of the calculation to determine the maximum Annual Average Concentration in air from all releases to air described above. See Appendix 14 of the Handbook for notifiers for guidance in performing this calculation.

Comment [N14]: Page: 8
Please demonstrate that the chemical has negligible potential for migration to groundwater from releases to land or landfill. . See Appendix 14 of the Handbook for notifiers for guidance

Section C4 Fees

There is an associated fee for an Early Introduction permit for a low risk highly controlled polymer (see payment advice at the end of this form)

DECLARATION

Note: *It is an offence under the Act to supply a statement which is false or misleading*

I declare that to the best of my knowledge all the information supplied in this form is true, correct and complete.

Name: Position:

Signature: Date:

Payment Advice

Please indicate whether a fee applies and method of payment

Non-hazardous chemical/polymer	☐	Free of charge
Chemical (including polymers with NAMW < 1000) meeting low-hazardous criteria	☐	Fee*
Polymer with NAMW ≥ 1000 meeting low-hazardous criteria	☐	Fee*
Low risk highly controlled chemical/polymer	☐	Fee*

* A list of fees and charges is located on the NICNAS website
http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_And_Charges.asp

☐ **Electronic Funds Transfer** Payment Date:

Reserve Bank of Australia
London Circuit
Canberra ACT 2600

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

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

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

☐ **Cheque** Enclosed ☐ Yes

☐ No (Application will be pending until payment received)

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

NICNAS
GPO Box 58
SYDNEY NSW 2001
AUSTRALIA

☐ **Credit Card**

☐ Bankcard ☐ Mastercard ☐ Visa

Credit Card Number:

Expiry Date: Amount:

Authorised Signature Print Name