Application for Controlled Use Permit

Use this form if applying for a Controlled Use Permit pursuant to section 22C of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

Australian Government
Department of Health and Ageing
NICNAS

FORM CUP-1

For fees see http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp .

Where a joint application is made, details of all the applicants and a signed declaration from all the applicants are required. If data are provided by a third party, either separately or accompanying the notification, Form 5 (signed by the owner of the data) should accompany the third party data.

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

Return to: Director
NICNAS
GPO Box 58, Sydney NSW 2001 (postal address) or
Level 7, 260 Elizabeth Street, Sydney NSW 2010 (courier address)
Telephone (02) 8577 8800 / 1800 638 528 Fax (02) 8577 8888

Should you have difficulties completing this form, require further information or to provide feedback on this form, please contact the New Chemicals Program on the above contact details, or visit http://www.nicnas.gov.au.

Notifier Details

Business Name:

ACN / 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 Details

The technical contact is the primary contact for NICNAS and unless indicated otherwise is normally the sole contact for NICNAS with regards to requests for additional information and the giving of the permit if the contact is in Australia.

Business Name:

Business Address:

Postcode:

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

Postcode:

Contact Name: Position:

Phone: Fax: E-mail:

I/We, the Notifier (Applicant), authorise the technical contact to act on my/our behalf in all matters pertaining to my/our application for a permit (Note: this authorisation to act can be amended or cancelled at any time by notifying NICNAS in writing) ☐ Yes ☐ No

Should correspondence between NICNAS and the technical contact be electronic where possible? Note permits will be delivered to the contact via courier. ☐ Yes ☐ No

Chemical Details

Chemical Name:

Marketing or Other Name(s):

CAS Number (*if known*):

Has this chemical been notified overseas? ☐ Yes ☐ No

If so by which competent authority and in what year?

Has this chemical been assessed, or is it currently being assessed by another Australian regulatory agency (e.g. TGA, APVMA)?	☐ Yes	☐ No
If yes, provide details:		
Is the chemical an industrial nanomaterial under the NICNAS definition? *(Note: for the working definition please consult the document, Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials, available from http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp)*	☐ Yes ☐ Unsure[#]	☐ No
If yes or unsure, is the chemical introduced as a solid/powder or as a dispersion? *(Note: if the answer to this question is yes, please consult the above nanomaterial guidance document as additional data requirements may apply).*	☐ Yes	☐ No

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

Exempt Information

Do you wish to claim the chemical name, introduction volume or details of use as being confidential? (fee applies)*	☐ Yes	☐ No
If yes, specify items and provide justification for claims:		

[#]For information regarding fees see http://www.nicnas.gov.au/Industry/New_Chemicals/Fees_and_Charges.asp

Third Party Information Lodgement

Does this submission include third party information to be held confidential from the notifier?	☐ Yes	☐ No
If yes, complete and submit a Form 5 (Third Party Information Lodgement)		

Declaration

I declare that to the best of my knowledge all the information in this application is true, correct and complete. In relation to the notification statement and/or other documentation accompanying this application, I declare that I am entitled to use and give the Director all data in the statement.

Name Position

Signature Date

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

Payment Details				
☐ Electronic Funds Transfer	**Please quote Notification number / Registration number / Invoice number when making the payment**			
	Account Name	Department of Health & Ageing Official Departmental NICNAS Special Account		
	Bank	Reserve Bank of Australia, London Circuit, Canberra ACT 2600		
	BSB Number	092-009	**Account Number**	11608-5
☐ Credit Card	☐ Mastercard ☐ Visa **Credit card no.**			
	Amount:	$	**Expiry Date:**	
	Print Name:			
	Authorised Signature:			
☐ Cheque	Enclosed ☐ Yes ☐ No Cheques are to be made payable to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) in $AUD.			
Please note: If payment is being made from an overseas bank, all bank charges/fees are payable by the payee. Applications will not be processed until correct payment has been received.				

Controlled Use Permit

Notification Template (Electronic Submission)

The template should be filled out completely. Any missing information may result in delays in processing the application.

The completed application should be submitted to NICNAS in both hardcopy and electronic form.

Highlighted headings in the form have associated guidance material inserted as comments, which may be seen by holding the mouse cursor over the highlighted area. The guidance material indicates what information should be included in each section. Please note that this document is protected as a form (this allows completion of check boxes). Once the check boxes have been completed, additional functions (e.g. tracked changes or printing the document without the comments visible) may be enabled by removing the document protection via the forms toolbar.

Comment [N1]: Page: 3
Example of highlighting

The NICNAS *Handbook for Notifiers* is available from the NICNAS website (via the following link http://www.nicnas.gov.au/Publications/NICNAS_Handbook.asp), and should be consulted for additional information.

Requirements for toxicological/ecotoxicological data: All available toxicological/ecotoxicological data should be summarised in this application. Where a structural alert exists for a certain human health endpoint e.g. sensitisation, then data (test data, literature data, read across data, modelled data) are required to demonstrate that the chemical or polymer is eligible for the Controlled Use Permit. Data (test data, literature data, read across data, modelled data) are required for each environmental hazard criterion to demonstrate that the chemical or polymer is eligible for the Controlled Use Permit. Other studies may be required where they are deemed necessary to determine no unreasonable risk.

Provision of original studies to NICNAS: For introduction volumes exceeding 10 tonnes per year, copies of all available toxicological and ecotoxicological data must be provided with the application. Otherwise, original data should only be provided to NICNAS where a structural alert exists for this endpoint. However, NICNAS may request copies of original data where deemed necessary to determine no unreasonable risk.

Down-stream users A chemical introduced under a CUP can be supplied to down-stream users. However, the down-stream user and their practices must be known. The application should provide a description of the operations at the proposed users site. The notifier is responsible for ensuring that this description is accurate. Only those users whose details have been provided to NICNAS can 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.

CONTROLLED USE PERMIT ELIGIBILITY CHECKLIST

Complete the following checklist to determine eligibility for a **Controlled Use Permit.** Each of the following criteria must be met. See the Handbook for Notifiers for more information on these criteria.
Supporting information to demonstrate criteria should be included in this template.

	Criterion	*Criterion met?*
1. Occupational exposure	Any worker exposure that is likely to occur will be highly controlled through use of engineering controls, work practices and personal protective equipment	Yes ☐ No ☐
2. Public exposure	There are no exposures to consumers or the general public inherent in the proposed manufacturing, processing or uses of the substance	Yes ☐ No ☐
3. Human health hazard classification	Not classified* 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 ☐
4. Aquatic toxicity	Toxicity to fish, aquatic invertebrate and algae > 10 mg/litre	Yes ☐ No ☐
5. Environmental release to water	Ambient release to surface water results in concentrations < 1ppb	Yes ☐ No ☐
6. Environmental release to air	Ambient release to air < 1mg/m^3 average annual concentration	Yes ☐ No ☐
7a. Environmental release to land/landfill	There is ***no*** release to land or landfill	Yes ☐ No ☐ If no, please address Question 7b.
7b. Environmental release to land/landfill	The chemical has ***negligible*** potential for migration to groundwater	Yes ☐ No ☐

* In accordance with the Approved Criteria for Classifying Hazardous Substances 3rd edition [NOHSC:1008(2004)])

Preferred name

1. APPLICANT AND NOTIFICATION DETAILS

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
[*Delete as appropriate*]

No details that are to be published are claimed exempt from publication.

Data items and details claimed exempt from publication:
Chemical Name
Introduction Volume
Details of Use

Has this chemical been notified overseas?	Yes ☐ No ☐
Has this chemical been assessed previously by NICNAS?	Yes ☐ No ☐
Has this chemical been assessed, or is it currently being assessed by another Australian Regulatory Agency? (e.g. TGA, APVMA)	Yes ☐ No ☐
If yes, provide details:	

2. IDENTITY OF CHEMICAL

CHEMICAL NAME — **Confidential/non-confidential** *Delete as appropriate*

OTHER NAME(S) — *Not for publication*

Comment [N2]: Page: 4
If present in products used by the public, the chemical must be completely reacted, encapsulated in a polymer matrix, or otherwise not bioavailable in the final product

Comment [N3]: Page: 4
The name under which the permit will be issued. This is the chemical name unless an application for exemption of the chemical name has been made; otherwise the tradename by which the chemical will be known in Australia.

Comment [N4]: Page: 4
Only certain information is published in the chemical gazette. A request for exempt information is not required for data items not published. Details published are as follows: name of the chemical or trade name; whether the chemical is a hazardous substance; name and postcode of the company to which the permit is issued; volume of chemical which may be introduced; duration of the permit (maximum three years); and general use of the chemical.

Comment [N5]: Page: 5
The chemical name should be provided in CA Preferred Index Name format (eg as obtained from a CAS Registry search). The chemical name may be claimed as confidential and in this case will not be published in the Chemical Gazette.

Comment [N6]: Page: 5
Other names include any other names by which the chemical is known apart from the CA Index name and trade names which will be used in Australia, such as chemical synonyms, internal codes or trade names not used in Australia. These names will not appear in the Chemical Gazette.

MARKETING NAME(S)

CAS NUMBER *Not for publication*

MOLECULAR FORMULA *Not for publication*

STRUCTURAL FORMULA *Not for publication*

[Free Space for Structural Formula]

MOLECULAR WEIGHT *Not for publication*
..Da

MOLECULAR WEIGHT (COMPLETE FOR POLYMERS ONLY) *Not for publication*

Number Average Molecular Weight (Mn)	..Da
Weight Average Molecular Weight (Mw)	..Da
% of MW Species < 1000 Da	%
% of MW Species < 500 Da	%

SPECTRAL DATA *Not for publication*

ANALYTICAL METHOD AND REMARKS
TEST FACILITY

3. COMPOSITION

DEGREE OF PURITY *Not for publication*
…%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
[If none write 'None' *here. Otherwise complete boxes below.]*

[Copy and paste this box as needed.]
Chemical Name
CAS No. *Weight %*
Hazardous Properties

POLYMER CONSTITUENTS

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

4. PHYSICAL/CHEMICAL PROPERTIES

Complete all sections **for which information is available** for the notified chemical. Particular endpoints may be necessary to demonstrate that the Controlled Use Permit criteria have been met.
Where a physico-chemical property is required to demonstrate that the Controlled Use criteria are met then this test report should be supplied, otherwise, test reports need not be supplied. NICNAS may request copies of original data for endpoints where classification as a dangerous good may be appropriate.

Comment [N7]: Page: 5
All trade names used in Australia for the chemical or products incorporating the chemical should be included here. The preferred name will be published in the Chemical Gazette if exemption has been claimed for the chemical name.

Comment [N8]: Page: 5
If a CAS number has been assigned please include it here. The CAS number will not appear in the Chemical Gazette.

Comment [N9]: Page: 5
Include a molecular formula for the notified chemical if it is possible to assign one; for polymers or reaction products write the formulae of all of the ingredients; it may not be possible to provide a formula for complex natural products.

Comment [N10]: Page: 5
A structural formula must be included unless it is impossible to assign one, eg for complex natural products. For polymers or reaction products, a structural formula showing the essential details of the types of bonds present should be drawn. The formula may be embedded in the document, or separately submitted electronically. A structure in ChemDraw .cdx format is preferred. Alternatively, a structure may be drawn on … [1]

Comment [N11]: Page: 5
Enter the gram-molecular weight of the notified chemical. For UVCB substances, enter an estimate or range if known.

Comment [N12]: Page: 5
This can be taken from molecular weight characterisation report. If taken from a method such as light scattering which does not give all parameters, leave cells blank. Note: use of such methods … [2]

Comment [N13]: Page: 5
In the space below, write the methods used for characterising the notified chemical.

Comment [N14]: Page: 5
Please enter details of the typical weight percentage purity of the notified chemical (and not the formulation) here.

Comment [N15]: Page: 5
Give the identity and percentage of starting monomers and other reactants (chain transfer & cross linking agents, modifying groups, and other end groups incorporated into the polymer), which w … [3]

Comment [N16]: Page: 6
If no data is available, an indication of expected properties can be provided or write 'no data available'.

Appearance at 20°C and 101.3 kPa	
Melting Point/Glass Transition Temp	…°C
Boiling Point	
Density	… kg/m^3 at …°C *(Note: units are kg/m^3; density in kg/m^3 is 1000 x density in g/cm^3)*
Vapour pressure	… kPa at 25°C (or 20°C)
Water Solubility	… g/L at 20°C *(Include a brief description of the test, including the method used)*
Hydrolysis as a Function of pH	$t_{½}$ = … at pH … (shortest $t_{½}$)
Partition Coefficient (n-octanol/water)	Log Pow = … at 20°C
Absorption/Desorption	Log Koc = … at 20°C
Dissociation Constant *(delete if no acid or base groups are present)*	pKa = …
Particle Size *(delete if liquid or solution)*	
Flash Point	…°C at … kPa (open cup/closed cup)
Autoignition Temperature	…°C
Flammability	Yes/No
Explosive Properties	Yes/No
Reactivity	e.g. Stable under normal conditions of use.
Degradation Products	e.g. None under normal conditions of use.

Comments on the physical and chemical properties *Discuss particularly physico-chemical hazards such as flammability, explosive properties and reactivity.*

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL FOR THE DURATION OF THE PERMIT (INCLUDING TRANSPORTATION AND PACKAGING)

CONCENTRATION DETAILS

INTRODUCTION VOLUME OF NOTIFIED CHEMICAL

	Year	*1*	*2*	*3*
Confidential	*Tonnes*			
Non-confidential	*Tonnes*			

USE **Confidential**

USE **Non-Confidential** *For publication; this field is compulsory and must contain sufficient information to identify industry category and use scenarios.*

CONTROLLED USE SCENARIO

Please tick one of the below boxes if the proposed use of the chemical fits into either of the low exposure scenarios:

☐ Containment and controlled reformulation
☐ Site limited and closed system
☐ Other (NOTE: other use scenarios may meet the criteria set out in the checklist above. However, for such other uses it is preferred that Industry work with NICNAS to develop additional exposure scenarios.)

For more information on the human and environmental exposure criteria and two controlled use scenarios which have been developed see the NICNAS *Handbook for Notifiers.*
NOTE: The information detailed below should demonstrate that the Controlled Use Permit criteria are met.

IDENTITY OF DOWN-STREAM USERS *If claimed confidential provide generic text*

Comment [N17]: Page: 6
Vapour pressure information may be necessary to demonstrate that the Controlled Use criteria for release to air is met.

Comment [N18]: Page: 6
If no data is available, an indication of likely solubility based on structural considerations can be provided.

Comment [N19]: Page: 6
Absorption/desorption information may be necessary to demonstrate that the Controlled Use criteria for release to land is met, namely that the notified chemical has negligible potential for migration to groundwater from releases to land/landfill.

Comment [N20]: Page: 6
If no data is available, an estimate based on structural considerations can be provided.

Comment [N21]: Page: 6
Please also include here any essential comments for understanding the physical and chemical properties, eg formulation details if the polymer is never isolated or comments on water solubility testing if any.

Comment [N22]: Page: 6
Indicate if the notified chemical is introduced by import or local manufacture.

Comment [N23]: Page: 6
Give the concentration of the chemical in all products to be used under this permit.

Comment [N24]: Page: 6
Volume (of notified chemical, not formulated product) to be introduced per annum for each year of the permit. If claimed confidential enter introduction volume as a range. Note: if a range is specified here, the upper limit of the range is used for release calculations.

Comment [N25]: Page: 6
If an application for exempt information has been made for this item, the details of the use of the chemical should be provided here, eg anti-oxidant in marine diesel engine oils. The non confidential box must also be filled in and should contain a use defined in enough detail as … [4]

Comment [N26]: Page: 7
The details of the use of the chemical should be provided here, eg anti-oxidant in marine diesel engine oils. Less detail should be provided here if an applica … [5]

Comment [N27]: 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). NICN … [6]

OPERATION DESCRIPTION

[Free space for process flow diagram (where available)]

PRECAUTIONS TAKEN FOR SAFE TRANSPORT

PRECAUTIONS TAKEN FOR SAFE STORAGE

6. OCCUPATIONAL EXPOSURE *Not for publication*

OCCUPATIONAL EXPOSURE
Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration (hours per day)*	*Exposure Frequency (days per year)*

EXPOSURE DETAILS AND CONTROL MEASURES EMPLOYED TO PREVENT EXPOSURE TO WORKERS

EMERGENCY PROCEDURES – OCCUPATIONAL

7. PUBLIC EXPOSURE *Not for publication*

CONTROL MEASURES USED TO PREVENT EXPOSURE TO THE PUBLIC

8. HUMAN HEALTH EFFECTS INFORMATION *Not for publication*

LIST OF TOXICOLOGY DATA AVAILABLE

SUMMARY OF THE CHEMICAL'S HEALTH EFFECTS
Acute toxicity.

Irritation and Sensitisation.

Repeated Dose Toxicity (sub acute, sub chronic, chronic).

Genotoxicity.

SUMMARY OF HOW THE CHEMICAL MEETS THE DEFINITION OF A HAZARDOUS SUBSTANCE.

JUSTIFICATION FOR READ ACROSS DATA

9. ENVIRONMENTAL RELEASE *Not for publication*

Comment [N28]: Page: 7
Concisely describe the manufacturing, processing, reformulation, repackaging, handling and end use operations involved with the notified chemical; a process flow diagram may be inserted if available. Include a description of the ... [7]

Comment [N29]: Page: 7
Describe how the notified chemical or formulation(s) will be transported to and from the port(s) of entry, the manufacturing/reformulati ... [8]

Comment [N30]: Page: 7
For all intended storage facilities, describe the precautions taken to ensure safe storage. Include details on the size, type and capacity of containers used ... [9]

Comment [N31]: Page: 7
In the following table, please write all categories of workers who will handle the notified chemical, including transport and storage, along with the nu ... [10]

Comment [N32]: 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 d ... [11]

Comment [N33]: Page: 7
Describe the procedures required to render the chemical harmless in the workplace, including: (1) workplace emergencies affecting the public at large, for ex ... [12]

Comment [N34]: Page: 7
Include all routes by which the public could be exposed (indirect, accidental) and the methods used to prevent exposure. Please note for a Controlled Use perm ... [13]

Comment [N35]: Page: 7
List all relevant available toxicological studies, published literature and read across data. Copies of all available toxicological and ecotoxi ... [14]

Comment [N36]: Page: 7
All available information should be summarised below (an optional template for providing information is available in attachment 1). Even wher ... [15]

Comment [N37]: Page: 8
State whether or not the notified chemical is classified as a hazardous substance. A hazardous substance is defined as (a) a chemical that is clas ... [16]

Comment [N38]: Page: 8
If read across data has been provided, include sound scientific argument as to why the read across chemical(s) should be considered acceptable, in ... [17]

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

RELEASE OF CHEMICAL TO LAND

EMERGENCY PROCEDURES – ENVIRONMENTAL

10. ENVIRONMENTAL FATE/EFFECTS INFORMATION

Not for publication

LIST OF ECOTOXICOLOGY DATA AVAILABLE

Summary of the chemicals environmental effects

	Fish toxicity	Daphnia toxicity	Algal toxicity	Other (describe):	Other (describe):
Result	EC50 … mg/L	EC50 … mg/L	EC50 … mg/L		
Effects Observed?[1]	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Data Source (e.g. study, read across, journal, model)					

[1] *briefly discuss any observed effects in a few sentences below.*

Discussion of any effects observed:

JUSTIFICATION FOR READ ACROSS DATA

PBT CHARACTERISTICS

11. MSDS AND LABEL

Label

A copy of the proposed label(s) for the chemical in the form(s) that is intended to be introduced should be attached to this application. The label should be compiled in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances*.

Comment [N39]: 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 … [18]

Comment [N40]: Page: 8 Give information on releases and methods used to prevent release of the chemical into the env … [19]

Comment [N41]: Page: 8 Describe disposal procedures, include procedures for contaminated packaging. … [20]

Comment [N42]: Page: 8 Please provide details of the calculation to determine PEC in water after secondary or t … [21]

Comment [N43]: Page: 8 Please provide details of the calculation to determine the maximum Annual Averag … [22]

Comment [N44]: Page: 8 Please demonstrate that the chemical has negligible potential for migration to groundw … [23]

Comment [N45]: Page: 8 Describe the procedures required to render the chemical harmless outside the workplace inc … [24]

Comment [N46]: Page: 8 List all relevant available toxicological studies, published literature and read across … [25]

Comment [N47]: Page: 8 Evidence to demonstrate that each environmental hazard criterion are satisfied should be provid … [26]

Comment [N48]: Page: 10 Indicate Test guideline used e.g. OECD TG 405, similar to OECD TG 405, in-house, etc

Comment [N49]: Page: 8 The types of effects to report are any observations worthy of remark during the toxicol … [27]

Comment [N50]: Page: 9 If read across data has been provided, include sound scientific argument as to why the re … [28]

Comment [N51]: Page: 9 Provide comment on whether the chemical is likely to be persistent or bioaccumulative, or ha … [29]

Comment [N52]: Page: 9 Please check the proposed label for the notified chemical against the checkbox. All of the i … [30]

Label Checklist

- ☐ Signal word eg ‘hazardous’ or ‘warning’ (where appropriate)
- ☐ Ingredient disclosure for Type I hazardous ingredient
- ☐ Risk and Safety phrases, if hazardous
- ☐ Australian contact details
- ☐ Information on label consistent with information detailed in MSDS
- ☐ If hazardous, does label refer to MSDS

Material Safety Data Sheet

A copy of the MSDS for the chemical and the chemical in the form(s) that is intended to be introduced should be attached to this application. Where reformulation of the chemical occurs in Australia by the notifier (or known other parties) and the chemical is required to be disclosed on the MSDS (either by its full chemical name or generic name), then MSDS for those products should also be attached. The MSDS should be compiled in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets.*

Comment [N53]: Page: 9
Please check the proposed MSDS for the notified chemical against the checkbox. All of the items are required to be present if applicable for the chemical. All ingredients of a product should be listed (totalling 100 %) although generic names may be used where allowed by the Code of Practice.

MSDS Checklist

- ☐ Permit statement (i.e. permit granted under 21U of the Act)
- ☐ Australian contact details
- ☐ Hazardous statement on MSDS
- ☐ Risk and Safety phrases, if hazardous
- ☐ Ingredient disclosure for Type I hazardous ingredient
- ☐ Information on MSDS consistent with information detailed on label

Attachment 1 – Optional Template for toxicological information

	Acute oral toxicity	Acute dermal toxicity	Acute inhalation toxicity	Skin irritation/ corrosion	Eye irritation	Skin sensitisation
Structural alert?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Data available?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Data Source (e.g. study, read across, journal, model)						
Effects observed?	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA
Result (if study conducted)	LD50 … mg/kg bw	LD50 … mg/kg bw	LC50 … mg/L/4 hour	irritating/slightly irritating/non-irritating	irritating/slightly irritating/non-irritating	evidence/no evidence of sensitisation

Comment [N54]: Page: 10 Indicate Test guideline used e.g. OECD TG 405, similar to OECD TG 405, in-house, etc

NA = not applicable, i.e. study not conducted

	Bacterial mutagenicity	*In vitro* genotoxicity	*In vivo* genotoxicity	Repeat Dose toxicity	Developmental/ Reproductive toxicity	Carcinogenicity
Structural alert?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Data available?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Data Source (study, read across, journal, model)						
Effects observed?	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA	☐ Yes ☐ No ☐ NA
Result (if study conducted)	positive/negative/ equivocal	positive/negative/ equivocal	positive/negative/ equivocal	NOEL/NOAEL/ LOAEL =	NOEL/NOAEL / LOAEL =	

Comment [N55]: Indicate Test guideline used e.g. OECD TG 405, similar to OECD TG 405, in-house, etc

NA = not applicable, i.e. study not conducted

Acute Oral Toxicity

Dose mg/kg bw	*Number of Animals*	*Mortality*	*Signs of toxicity*

Acute Dermal Toxicity

Dose mg/kg bw	*Number of Animals*	*Mortality*	*Signs of local toxicity*	*Signs of systemic toxicity*

Acute Inhalation Toxicity

Concentration <units>		*Number and Sex of Animals*	*Mortality*	*Signs of toxicity*
Nominal	*Actual*			

Eye Irritation Scores

Lesion	*Mean score* Animal no.*			*Maximum Score*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: *redness*						
Conjunctiva: chemosis						
Conjunctiva:discharge						
Corneal opacity						
Iridial inflammation						

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Skin Irritation Scores

Lesion	*Mean Score* Animal no.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Erythema/Eschar						
Oedema						

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Skin Sensitisation Scores

Guinea Pig Test (GPMT or Buehler)

Group	*Challenge Concentration*	*Number of Animals Showing Any Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group					
Control Group					

OR

Local Lymph Node Assay (LLNA)

Concentration (% w/w)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance 0 (vehicle control)		
Positive Control		

Repeat Dose Toxicity

Comment [N56]: Page: 11
Describe critical effects used to establish the NO(A)EL.

Bacterial Mutagenicity

Comment [N57]: Page: 11
For equivocal or positive results give details of the response observed for each strain, for example, the dose response relationship, the magnitude of the increase in revertants, the degree of statistical significance. State whether the results were confirmed in an independent experiment. State whether the positive controls and the vehicle gave satisfactory responses. State the concentrations at which cytoxicity or precipitation were observed.

In Vitro Genotoxicity

Comment [N58]: Page: 12
For equivocal or positive results give details of the response observed, for example, the type of structural damage, the degree of statistical significance, and any dose-response. Similar information is required if significant ploidy effects (such as polyploidy) were observed. State the concentrations at which cytoxicity or precipitation were observed.

In Vivo Genotoxicity

Comment [N59]: Page: 12
Comment on the adequacy of the test, justification of the doses used and indications of systemic absorption or target organ exposure, for example target organ toxicity, discoloured urine or staining of tissues. For equivocal or positive results, give details of the response observed, for example the type of structural damage or the degree of statistical significance, and any dose response relationship. Similar information is required if significant ploidy effects (such as polyploidy) were observed.

Page 6: [1] Comment [N10] **NICNAS**

Page: 5

A structural formula must be included unless it is impossible to assign one, eg for complex natural products. For polymers or reaction products, a structural formula showing the essential details of the types of bonds present should be drawn. The formula may be embedded in the document, or separately submitted electronically. A structure in ChemDraw .cdx format is preferred. Alternatively, a structure may be drawn on a sheet of paper and provided as a hard copy attachment.

Page 6: [2] Comment [N12] **NICNAS**

Page: 5

This can be taken from molecular weight characterisation report. If taken from a method such as light scattering which does not give all parameters, leave cells blank. Note: use of such methods will only normally be acceptable for very high molecular weight polymers (> 100 000).

Page 6: [3] Comment [N15] **NICNAS**

Page: 5

Give the identity and percentage of starting monomers and other reactants (chain transfer & cross linking agents, modifying groups, and other end groups incorporated into the polymer), which will be chemically incorporated in the polymer material, including those that are used or incorporated at 2% or less. Also include post-reacting agents used in the manufacture of post-reacted polymers. List percentage of residual monomers and other non-reacted substances in the right hand column of the table.

Page 7: [4] Comment [N25] **NICNAS**

Page: 6

If an application for exempt information has been made for this item, the details of the use of the chemical should be provided here, eg anti-oxidant in marine diesel engine oils. The non confidential box must also be filled in and should contain a use defined in enough detail as to indicate the industry sector and type of application for the notified chemical, eg in this case “oil additive”.

Page 7: [5] Comment [N26] **NICNAS**

Page: 7

The details of the use of the chemical should be provided here, eg anti-oxidant in marine diesel engine oils. Less detail should be provided here if an application for confidentiality for the use has been made; in which case the detailed use will be recorded in the confidential box above.

Page 7: [6] Comment [N27] **NICNAS**

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.

Page 8: [7] Comment [N28] **NICNAS**

Page: 7

Concisely describe the manufacturing, processing, reformulation, repackaging, handling and end use operations involved with the notified chemical; a process flow diagram may be inserted if available. Include a description of the operations at the proposed down-stream users site. The notifier is responsible for ensuring that this description is accurate.

Page 8: [8] Comment [N29] **NICNAS**

Page: 7

Describe how the notified chemical or formulation(s) will be transported to and from the port(s) of entry, the manufacturing/reformulation sites and storage facilities and the precautions taken to ensure safe transportation. Indicate the quantity transported, the mode of transport, and how the chemical or formulation(s) will be packaged. Include details of UN Number, Dangerous Goods Class(es) and the Hazchem Code if relevant.

Page 8: [9] Comment [N30] **NICNAS**

Page: 7

For all intended storage facilities, describe the precautions taken to ensure safe storage. Include details on the size, type and capacity of containers used to store the notified chemical or formulation(s) and any other storage requirements.

Page 8: [10] Comment [N31] **NICNAS**

Page: 7
In the following table, please write all categories of workers who will handle the notified chemical, including transport and storage, along with the number of workers in each category, the predicted length of time each will handle the chemical, and the frequency of handling the chemical; to insert additional rows place the cursor in the last box and press Tab.

Page 8: [11] Comment [N32] **NICNAS**

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

Page 8: [12] Comment [N33] **NICNAS**

Page: 7
Describe the procedures required to render the chemical harmless in the workplace, including: (1) workplace emergencies affecting the public at large, for example, a gas release affecting nearby residents, and (2) personnel emergencies, for example, inhalation of leaking vapours by workers

Page 8: [13] Comment [N34] **NICNAS**

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

Page 8: [14] Comment [N35] **NICNAS**

Page: 7
List all relevant available toxicological studies, published literature and read across data. Copies of all available toxicological and ecotoxicological data must be provided with the notification for volumes exceeding 10 tonnes per year. Otherwise, original data should only be provided to NICNAS where a structural alert exists for this endpoint. Toxicological and ecotoxicological information may be requested in other cases.

Page 8: [15] Comment [N36] **NICNAS**

Page: 7
All available information should be summarised below (an optional template for providing information is available in attachment 1). Even where data is not available, consider the potential for the chemical to cause adverse local (irritation and sensitisation) and systemic (acute and chronic) effects when providing a summary of the chemicals health effects. Where the chemical contains a structural alert for a certain endpoint e.g. sensitisation then data would need to be available for this endpoint to support applications. A list of structural alerts is included in Appendix 15 of the Handbook for notifiers.

Page 8: [16] Comment [N37] **NICNAS**

Page: 8
State whether or not the notified chemical is classified as a hazardous substance. A hazardous substance is defined as (a) a chemical that is classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances 3rd edition* [NOHSC: 1008 (2004)] published in October 2004 by the National Occupational Health and Safety Commission; or (b) a chemical that is included in the Hazardous Substances
Information System (HSIS) published on the website of the Australian Safety and Compensation Council.

If the notified chemical is a hazardous substance, list the appropriate risk and safety phrases for the notified chemical and products containing the notified chemical.

Page 8: [17] Comment [N38] **NICNAS**

Page: 8
If read across data has been provided, include sound scientific argument as to why the read across chemical(s) should be considered acceptable, including discussion of comparability of the physico-chemical properties of the chemical and proposed read across chemical(s).

Page 9: [18] Comment [N39] **NICNAS**

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.

Page 9: [19] Comment [N40] **NICNAS**

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.

Page 9: [20] Comment [N41] **NICNAS**

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.

Page 9: [21] Comment [N42] **NICNAS**

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.

Page 9: [22] Comment [N43] **NICNAS**

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.

Page 9: [23] Comment [N44] **NICNAS**

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

Page 9: [24] Comment [N45] **NICNAS**

Page: 8

Describe the procedures required to render the chemical harmless outside the workplace including procedures for managing: (1) transport emergencies, (2) environmental emergencies, for example, spillage or release of the chemical to outside of the workplace, (3) emergencies at storage facilities outside the workplace.

This information should include the possibility of recovery, containment, neutralisation and destruction, for example, incineration.

Page 9: [25] Comment [N46] **NICNAS**

Page: 8

List all relevant available toxicological studies, published literature and read across data. Copies of all available toxicological and ecotoxicological data must be provided with the notification for volumes exceeding 10 tonnes per year. Toxicological and ecotoxicological information may be requested in other cases.

Page 9: [26] Comment [N47] **NICNAS**

Page: 8

Evidence to demonstrate that each environmental hazard criterion are satisfied should be provided. This may be based on ecotoxicological data, published literature, read across data or modelled data. Evidence is not required for polymers meeting the PLC criteria or low-hazardous polymer criteria.

Page 9: [27] Comment [N49] **NICNAS** **12/22/2010 4:50:00 PM**

Page: 8

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.

Page 9: [28] Comment [N50] **NICNAS**

Page: 9

If read across data has been provided, include sound scientific argument as to why the read across chemical(s) should be considered acceptable, including discussion of comparability of the physico-chemical properties of the chemical and proposed read across chemical(s).

Page 9: [29] Comment [N51] **NICNAS**

Page: 9

Provide comment on whether the chemical is likely to be persistent or bioaccumulative, or have breakdown products with these characteristics. Persistence and bioaccumulation criteria are set out in Appendix 16 of the Handbook for Notifiers.

Page 9: [30] Comment [N52] **NICNAS**

Page: 9

Please check the proposed label for the notified chemical against the checkbox. All of the items are required to be present if applicable for the chemical.