Application for Controlled Use Permit (Export Only)

Australian Government
Department of Health and Ageing
NICNAS

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

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

Please complete forms 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.				

Attachment 1 – Controlled Use Permit (Export Only) Template

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.

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.

Preferred name

1. APPLICANT AND NOTIFICATION DETAILS

1.1 APPLICANT(S)
[Write here]

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

No details are claimed exempt from publication.

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

1.3 PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

1.4 NOTIFICATION IN OTHER COUNTRIES

2. IDENTITY OF CHEMICAL

2.1 CHEMICAL NAME Confidential/not confidential

2.2 OTHER NAME(S) *Not for publication*

2.3 MARKETING NAME(S)

2.4 CAS NUMBER *Not for publication*

2.5 MOLECULAR FORMULA *Not for publication*

2.6 STRUCTURAL FORMULA *Not for publication*

Comment [N1]: Page: 3
Example of highlighting

Comment [N2]: Page: 2
Please include company name, ACN or ABN, and address for each applicant for the permit.

Comment [N3]: 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; and general use of the chemical.

Comment [N4]: Page: 2
Include here details of any notifications which have previously been submitted by any notifier for this chemical, including current or expired permits, current certificates or certificate notifications which are still in progress.

Comment [N5]: Page: 2
Include country, level at which notified and year of completion (if known).

Comment [N6]: Page: 2
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 *Ch*... [1]

Comment [N7]: Page: 2
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 a... [2]

Comment [N8]: Page: 2
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 ... [3]

Comment [N9]: Page: 2
If a CAS number has been assigned please include it here. The CAS number will not appear in the *Chemical Gazette*.

Comment [N10]: Page: 2
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... [4]

Comment [N11]: Page: 2
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 form... [5]

[Free Space for Structural Formula]

2.7 MOLECULAR WEIGHT *Not for publication*

2.8 SPECTRAL DATA *Not for publication*

ANALYTICAL METHOD

3. INTRODUCTION AND USE INFORMATION

3.1 EXPORT ONLY SCENARIO

- ☐ importation of a new chemical into Australia for export of entire quantity
- ☐ importation of a new chemical into Australia for use in formulation of products for export of entire quantity
- ☐ manufacture of a new chemical in Australia for export of entire quantity: and
- ☐ manufacture of a new chemical in Australia for use in formulation of products for export of entire quantity

3.2 CONCENTRATION DETAILS

3.2 INTRODUCTION VOLUME OF NOTIFIED CHEMICAL

	Year	*1*	*2*	*3*
Confidential	*Kilograms*			
Non-Confidential	*Kilograms*			

3.3 COUNTRY(IES) TO WHICH THE NOTIFIED CHEMICAL IS BEING EXPORTED

3.4a USE **Confidential**

3.4b USE **Non-Confidential** *For publication; this field is compulsory and must contain sufficient information to identify industry category and use scenarios.*

4. PROCESS AND RELEASE INFORMATION

4.1 PRECAUTIONS TAKEN FOR SAFE TRANSPORT

4.2 PRECAUTIONS TAKEN FOR SAFE STORAGE

4.3 OPERATION DESCRIPTION

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

4.4 CONTROL MEASURES EMPLOYED TO PREVENT EXPOSURE TO WORKERS

4.5 CONTROL MEASURES USED TO PREVENT RELEASE TO THE ENVIRONMENT

4.6 CONTROL MEASURES USED TO PREVENT EXPOSURE TO THE PUBLIC

4.7 EMERGENCY PROCEDURES – ENVIRONMENTAL

Comment [N12]: Page: 2 Formula weight for the chemical, or, in the case of reaction products or natural products, molecular weight range. For polymers, please write the Number Average Molecular Weight and attach a copy of the molecular weight characterisation report (paper copy or electronic).

Comment [N13]: Page: 2 In the space below, write the methods used for characterising the notified chemical. Attach copies of the spectra (paper copy or electronic).

Comment [N14]: Tick the relevant scenario box.

Comment [N15]: If the chemical is introduced and/or exported as part of a product or mixture, provide the % concentration details.

Comment [N16]: Page: 2 Provide the volume (of notified chemical, not formulated product) to be introduced per annum for each year of the permit.

Comment [N17]: Provide details of the country, or countries to which the chemical is to be exported.

Comment [N18]: Page: 2 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 ma … [6]

Comment [N19]: Page: 3 The details of the use of the chemical should be provided here, eg anti-oxidant in marine c … [7]

Comment [N20]: Describe how the notified chemical or formulation(s) will be transported to and from the port(s) of … [8]

Comment [N21]: For all intended storage facilities, describe the precautions taken to ensure safe storage. Includ … [9]

Comment [N22]: Concisely describe any manufacturing, processing, reformulation, repackaging and handling … [10]

Comment [N23]: Describe the activities carried out by workers that may result in exposure to the notified c … [11]

Comment [N24]: Describe the methods used to prevent release of the chemical into the environment during … [12]

Comment [N25]: Include all routes by which the public could be exposed (indirect, accidental) and the methods used to p … [13]

Comment [N26]: Describe the procedures required to render the chemical harmless outside the workplace including proc … [14]

4.8 EMERGENCY PROCEDURES – OCCUPATIONAL

5. SUMMARY OF HEALTH AND ENVIRONMENTAL EFFECTS

5.1 HAZARD ASSESSMENT INCLUDING SUMMARY OF HOW THE CHEMICAL MEETS THE DEFINITION OF A HAZARDOUS SUBSTANCE.

Health

Environment

Classification

5.2 LIST OF TOXICOLOGY AND ECOTOXICOLOGY STUDIES AVAILABLE

5.3 PBT CHARACTERISTICS

5.4 OCCUPATIONAL HEALTH AND SAFETY RISK ASSESSMENT

5.5 PUBLIC HEALTH RISK ASSESSMENT

5.6 ENVIRONMENTAL RISK ASSESSMENT

6. MSDS AND LABEL

6.1 LABEL

A copy of the chemical/product label 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*.

Label Checklist

- ☐ Signal word e.g. 'hazardous' or 'warning' (where appropriate)
- ☐ Ingredient disclosure for NOHSC 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

6.2 MATERIAL SAFETY DATA SHEET

A Copy of the chemical/product MSDS should be attached to this application. The MSDS should be compiled in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets*.

MSDS Checklist

- ☐ Permit statement (i.e. permit granted under 22F of the Act)
- ☐ Australian contact details
- ☐ Hazardous statement on MSDS
- ☐ Risk and Safety phrases, if hazardous
- ☐ Ingredient disclosure for NOHSC Type I hazardous ingredient
- ☐ Information on MSDS consistent with information detailed on label

Comment [N27]: Describe the procedures required to render the chemical harmless in the workplace, including: (1) environmental emergencies, for example, spillage or release of the chemical in the workplace and (2) personnel emergencies, for example, inhalation of leaking vapours by workers

Comment [N28]: Describe any toxic effects and/or hazardous properties (e.g. flammability) of the chemical. Any available toxicity data should be briefly summarised.

Comment [N29]: Describe any ecotoxic effects of the chemical. Any available ecotoxicity data should be briefly summarised here.

Comment [N30]: State whether or not the notified chemical is classified as a hazardous substance. Under the NOHSC Standard Control of Workplace Hazardous Substances: National Model Regulations and National Code of Practice, a hazardous substance is defined as: (1) a substance which is listed on the NOHSC L ... [15]

Comment [N31]: Copies of all available toxicological and ecotoxicological data must be provided with the notification for volumes exceeding 10 ton ... [16]

Comment [N32]: Provide comment on whether the chemical is likely to be persistent or bioaccumulative, or have breakdown products with ... [17]

Comment [N33]: Taking into account the hazards related to human health and occupational health and safety (eg toxicity, reactivity), the likely rout ... [18]

Comment [N34]: Taking into account the public exposure (indirect and accidental) and the hazards to human health posed by the notified chemical, dis ... [19]

Comment [N35]: Taking into account the environmental hazards posed by the notified chemical; the likely environmental release and the environm ... [20]

Comment [N36]: Please check the proposed label for the notified chemical against the checkbox. All of the items are required to be present if ... [21]

Comment [N37]: Please check the proposed MSDS for the notified chemical against the checkbox. All of the items are required to be present if ... [22]

Comment [N38]: The Material Safety Data Sheet (MSDS) for the chemical and products containing it should carry advice that the chen ... [23]

Page 4: [1] Comment [N6] **NICNAS**

Page: 2

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*.

Page 4: [2] Comment [N7] **NICNAS**

Page: 2

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*.

Page 4: [3] Comment [N8] **NICNAS**

Page: 2

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.

Page 4: [4] Comment [N10] **NICNAS**

Page: 2

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. The molecular formula will not appear in the *Chemical Gazette*.

Page 4: [5] Comment [N11] **NICNAS**

Page: 2

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, and preferably also 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. The structural formula will not appear in the *Chemical Gazette*.

Page 5: [6] Comment [N18] **NICNAS**

Page: 2

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 5: [7] Comment [N19] **NICNAS**

Page: 3

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 5: [8] Comment [N20] **NICNAS**

Describe how the notified chemical or formulation(s) will be transported to and from the port(s) of entry/export, 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 5: [9] Comment [N21] **NICNAS**

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 5: [10] Comment [N22] **NICNAS**

Concisely describe any manufacturing, processing, reformulation, repackaging and handling operations involving the notified chemical; a process flow diagram may be inserted if available.

Page 5: [11] Comment [N23] **NICNAS**

Describe the activities carried out by workers that may result in exposure to the notified chemical and the control measures in place such as automated enclosed systems, codes of practice, local exhaust

ventilation, and personal protective equipment to prevent this exposure. Consider how exposure may occur (eg drips and spills, splashes, vapours, aerosols or dusts) and the route of exposure (eg inhalation, ocular, dermal).

Page 5: [12] Comment [N24] **NICNAS**

Describe the methods used to prevent release of the chemical into the environment during manufacturing or reformulation processes. All potential releases such as cleaning wastes, spills, residues in containers should be considered.

Page 5: [13] Comment [N25] **NICNAS**

Include all routes by which the public could be exposed (indirect, accidental) and the methods used to prevent exposure. Please note for an export only permit, direct public exposure is not expected.

Page 5: [14] Comment [N26] **NICNAS**

Describe the procedures required to render the chemical harmless outside the workplace including procedures for managing: (1) workplace emergencies affecting the public at large, for example, a gas release affecting nearby residents, (2) transport emergencies, (3) environmental emergencies, for example, spillage or release of the chemical to outside of the workplace, (4) emergencies at storage facilities outside the workplace.
This information should include the possibility of recovery, containment, neutralisation and destruction, for example, incineration.

Page 2: [15] Comment [N30] **NICNAS**

State whether or not the notified chemical is classified as a hazardous substance. Under the NOHSC Standard Control of Workplace Hazardous Substances: National Model Regulations and National Code of Practice, a hazardous substance is defined as: (1) a substance which is listed on the NOHSC List of Designated Hazardous Substances; or (2) a substance which has been classified as a hazardous substance by the manufacturer or importer in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances (Approved Criteria).
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 2: [16] Comment [N31] **NICNAS**

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 2: [17] Comment [N32] **NICNAS**

Provide comment on whether the chemical is likely to be persistent or bioaccumulative, or have breakdown products with these characteristics

Page 2: [18] Comment [N33] **NICNAS**

Taking into account the hazards related to human health and occupational health and safety (eg toxicity, reactivity), the likely routes of exposure and the protective/control measures present, discuss the level of risk to workers handling the notified chemical under these conditions. A legislative condition of the permit is that there be low risk to occupational health and safety, public health and the environment.

Page 2: [19] Comment [N34] **NICNAS**

Taking into account the public exposure (indirect and accidental) and the hazards to human health posed by the notified chemical, discuss the level of risk to the public posed by introduction of the chemical. A legislative condition of the permit is that there be low risk to occupational health and safety, public health and the environment.

Page 2: [20] Comment [N35] **NICNAS**

Taking into account the environmental hazards posed by the notified chemical; the likely environmental release and the environmental fate such as distribution between water, air and soil, and degradation of the notified chemical, discuss whether the notified chemical will be released to any environmental compartment in concentrations which are likely to result in environmental risk. A legislative condition of the permit is that there be low risk to occupational health and safety, public health and the environment.

Page 2: [21] Comment [N36] **NICNAS**

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. Attach a copy of the proposed label.

Page 2: [22] Comment [N37] **NICNAS**

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. Attach a copy of the proposed MSDS for the notified chemical and each product in which it is present. All ingredients of a product should be listed (totalling 100 %) although generic names may be used where allowed by the Code of Practice.

Page 2: [23] Comment [N38] **NICNAS**

The Material Safety Data Sheet (MSDS) for the chemical and products containing it should carry advice that the chemical is being imported or manufactured under a permit granted under section 22F of the *Industrial Chemicals (Notification and Assessment) Act 1989*.