## Application for Low Volume Chemical Permit

Australian Government
Department of Health and Ageing
NICNAS

**FORM LVC-1**

Use this form if applying for a Low Volume Chemical Permit: LVC up to 100 kg/year (LVC 100) or LVC 100-1000 kg/year (LVC 1000) pursuant to section 21S of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

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*):

Introduction volume: ☐ ≤100 kg ☐ 100-1000 kg

| | | |
|---|---|---|
| Has this chemical been notified overseas?<br>If so by which competent authority and in what year? | ☐ Yes | ☐ No |
| Has this chemical been assessed, or is it currently being assessed by another Australian regulatory agency (e.g. TGA, APVMA)?<br>If yes, provide details: | ☐ Yes | ☐ No |
| Is the chemical an industrial nanomaterial under the NICNAS definition?<br>*(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<br>☐ 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 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<br>**Credit card no.** | | | |
| | **Amount:** | $ _____ | **Expiry Date:** | _____ |
| | **Print Name:** | _____ | | |
| | **Authorised Signature:** | | | |
| | | | | |
| ☐ Cheque | Enclosed ☐ Yes ☐ No<br>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.** | | | | |

# Low Volume Chemical 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 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. In cases where the proposed introduction volume exceeds 100 kg/year, data (test data, literature data, read across data, modelled data) is required to demonstrate that the low-hazardous criteria are met where a structural alert exists for a certain human health endpoint, e.g. sensitisation. (A list of structural alerts is included in Appendix 15 of the Handbook for Notifiers). In cases where the proposed introduction volume exceeds 100 kg/year, data (test data, literature data, read across data, modelled data) are required for each environmental hazard criterion to demonstrate that that the low-hazardous criteria are met. Other studies may be required where they are deemed necessary to determine no unreasonable risk.

**Provision of original studies to NICNAS**: A copy of all available ecotoxicological data should be provided to NICNAS. Where a repeat dose study has been conducted, a copy of the study summary (not the full study report) should be provided to NICNAS. For all other endpoints, the 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.

**LOW VOLUME CHEMICAL PERMIT ELIGIBILITY CHECKLIST**

Complete the following checklist. In cases where the proposed introduction volume exceeds 100 kg/year, each of the following criteria must be met (ticked 'Yes'). If you tick 'No' to any criterion, the chemical/polymer may be eligible for an LVC permit but the quantity will be restricted to 100 Kg. Supporting information to demonstrate criteria should be included in section 4/6."

***Chemicals including polymers with a NAMW <1000***

| | *Criterion* | *Criterion met?* |
|---|---|---|
| Acute oral toxicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Acute dermal toxicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Acute inhalation toxicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Skin irritation | Not classified as hazardous* or classified* with the risk phrase R38 (Irritating to skin). Irritation must be reversible. | Yes ☐ No ☐ |
| Eye irritation | Not classified as hazardous* or classified* with the risk phrase R36 (Irritating to eyes). | Yes ☐ No ☐ |
| Sensitisation | Not classified as hazardous* | Yes ☐ No ☐ |
| Repeat dose toxicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Mutagenicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Carcinogenicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Developmental and reproductive toxicity | Not classified as hazardous* | Yes ☐ No ☐ |
| Other toxicological endpoints | Not classified as hazardous* | Yes ☐ No ☐ |
| Aquatic toxicity | Toxicity to fish (i.e. $LC_{50}$), as determined using the Fish Acute Toxicity Test, is > 100 mg/L | Yes ☐ No ☐ |
| | Toxicity to aquatic invertebrates (i.e. $EC_{50}$), as determined using the *Daphnia* sp, Acute Immobilisation Test, is > 100 mg/L | Yes ☐ No ☐ |
| | Toxicity to algae (i.e. $EC_{50}$), as determined using the Algal Growth Inhibition Test, is > 100 mg/L | Yes ☐ No ☐ |
| Physical-chemical properties | Not a dangerous good **OR** classified as class 3 flammable liquid only | Yes ☐ No ☐ |
| Persistence/bioaccumulation | Not persistent and bioaccumulative, or have breakdown products with these characteristics ** | Yes ☐ No ☐ |

***Polymers with a NAMW that is 1000 or greater***

| | | *Criterion* | *Criterion met?* |
|---|---|---|---|
| Low molecular weight species | | % of Low MW Species < 500 is less than 10% **AND** % of Low MW Species < 1000 is less than 25% | Yes ☐ No ☐ |
| Hazard classification | | Not classified* 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 ☐ |
| Low charge density | A | Polymer is not cationic or is not likely to become cationic in the pH range 4-9; **OR** | Yes ☐ No ☐ |
| | B | Polymer is a solid that is not soluble or dispersible in water and is used only in its solid phase; **OR** | *Criterion met* |
| | C | The total combined cationic functional group equivalent weight (FGEW) for a polymer is ≥ 5000. | A ☐ B ☐ C ☐ |
| Persistence/bioaccumulation | | Not persistent and bioaccumulative, or have breakdown products with these characteristics** | Yes ☐ No ☐ |

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

** Persistence and bioaccumulation criteria are set out in the *Handbook for Notifiers*.

**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*
*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*

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
% 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*
…%

**Comment [N2]:** Page: 5
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 [N3]:** Page: 5
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; duration of the p... [1]

**Comment [N4]:** Page: 5
The chemical name should be provided in CA Preferred Index Name format (eg as obtained from a CAS Registry search). Th... [2]

**Comment [N5]:** Page: 5
Other names include any other names by which the chemical is known apart from the CA Index name and trade names whi... [3]

**Comment [N6]:** Page: 5
All trade names used in Australia for the chemical or products incorporating the chemical should be included here. The prefe... [4]

**Comment [N7]:** Page: 5
If a CAS number has been assigned please include it here. The CAS number will not appear in the *Chemical Gazette*.

**Comment [N8]:** Page: 5
Include a molecular formula for the notified chemical if it is possible to assign one; for polymers or reaction produ... [5]

**Comment [N9]:** Page: 5
A structural formula must be included unless it is impossible to assign one, eg for complex natural products. For polymers or ... [6]

**Comment [N10]:** Page: 5
Enter the gram-molecular weight of the notified chemical. For UVCB substances, enter an estimate or range if known.

**Comment [N11]:** Page: 5
This can be taken from molecular weight characterisation report. If taken from a method such as light scattering which does not g... [7]

**Comment [N12]:** Page: 6
In the space below, write the methods used for characterising the notified chemical.

**Comment [N13]:** Page: 6
Please enter details of the typical weight percentage purity of the notified chemical (and not the formulation) here.

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS *Not for publication*

*[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 *Not for publication*

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

## 4. PHYSICAL/CHEMICAL PROPERTIES *Not for publication*

Complete all sections **where information is available** for the notified chemical.

| | |
|---|---|
| **Appearance at 20°C and 101.3 kPa** | |
| **Melting Point/Glass Transition Temp** | …°C |
| **Boiling Point** | …°C |
| **Density** | … kg/m$^3$ at …°C *(Note: units are kg/m3; density in kg/m3 is 1000 x density in g/cm3)* |
| **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 |
| **Adsorption/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 |
| **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 in particular physico-chemical hazards such as flammability, explosive properties and reactivity. NICNAS may request copies of original data for endpoints where physico-chemical classification may be appropriate.*

## 5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL FOR THE DURATION OF THE PERMIT (INCLUDING TRANSPORT AND PACKAGING) *Not for publication*

INTRODUCTION VOLUME OF NOTIFIED CHEMICAL *Not for publication*

| *Year* | *1* | *2* | *3* |
|---|---|---|---|
| *Kilograms* | | | |

USE **Confidential**

**Comment [N14]:** Page: 6
If the notified chemical has no known or reasonably anticipated hazardous impurities or hazardous residual monomers, write 'None'. Otherwise, enter the chemical name(s), CAS number (if available), weight percentage and toxic or hazardous properties of all known (or reasonably anticipated) hazardous impurities or residual monomers, including isomers and by-products, even if these are below the relevant cut offs listed in the *List of Designated Hazardous Substances*.

**Comment [N15]:** Page: 6
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 … [8]

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

**Comment [N17]:** Page: 6
If no data is available, an indication of likely solubility based on structural considerations can be provided.

**Comment [N18]:** Page: 6
If no data is available, an estimate based on structural considerations can be provided.

**Comment [N19]:** 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 [N20]:** Page: 7
Indicate if the notified chemical is introduced by import or local manufacture. Give formulation details if the notified chemical is not introduced in 100% form. Describe how the notified chemical or formulation(s) … [9]

**Comment [N21]:** Page: 7
Volume (of notified chemical, not formulated product) to be introduced per annum for each year of the permit.

**Comment [N22]:** Page: 7
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 als … [10]

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

OPERATION DESCRIPTION *Not for publication*

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

STORAGE *Not for publication*

## 6. HUMAN HEALTH *Not for publication*

### 6.1. Occupational Exposure

OCCUPATIONAL EXPOSURE
*Number and Category of Workers*

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

EXPOSURE DETAILS

SAFETY PROCEDURES

EDUCATION AND TRAINING

HEALTH CONDITIONS

OCCUPATIONAL HEALTH MONITORING

### 6.2. Public Exposure

EXPOSURE DETAILS

### 6.3 Summary of human health effects

SUMMARY OF TOXICOLOGICAL INFORMATION

All available toxicological data (test data, literature data, read across data, modelled data) should be summarised in the table below. In cases where the proposed introduction volume exceeds 100 kg/year, data is required to demonstrate that the low-hazardous criteria are met where a structural alert exists for a certain human health endpoint, e.g. sensitisation. A list of structural alerts is included in the Handbook for Notifiers.

For endpoints where no data is available, the potential for the chemical to cause adverse health effects should be discussed in the section '**SUMMARY OF EXPECTED HEALTH EFFECTS FOR ENDPOINTS WHERE NO TOXICOLOGICAL DATA AVAILABLE'** below.

| | Acute oral toxicity | Acute dermal toxicity | Acute inhalation toxicity | Skin irritation/ corrosion | Eye irritation | Skin sensitisation |
|---|---|---|---|---|---|---|
| Structural | ☐ Yes | ☐ Yes | ☐ Yes | ☐ Yes | ☐ Yes | ☐ Yes |

**Comment [N23]:** 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.

**Comment [N24]:** 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.

**Comment [N25]:** Page: 7
Describe the manner of storage for the products containing the notified chemical; include any information on storage requirements, such as the need for storage in a cool, ventilated place.

**Comment [N26]:** 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 e ... [11]

**Comment [N27]:** Page: 7
Describe the activities carried out by each category of workers and the types of exposure to the notified chemical that may result; include the concentration of notified chemical in the ... [12]

**Comment [N28]:** Page: 7
Describe the safe work practices which will be used, such as automated enclosed systems or codes of practice, engineering controls such as local exhaust ventilation, and any perso ... [13]

**Comment [N29]:** Page: 7
Briefly describe the training and education given to workers to ensure proficiency in safe working practices related to the notified chemical.

**Comment [N30]:** Page: 7
Include detail on any health conditions which indicate that the worker should not handle the notified chemical.

**Comment [N31]:** Page: 7
Include particulars of any procedures proposed for atmospheric or health effects monitoring for the notified chemical.

**Comment [N32]:** Page: 7
Include all routes by which the public will be exposed; indicate the likely frequency of exposure and the expected quantities; include the concentration of the notified chemical in the e ... [14]

| | | | | | | |
|---|---|---|---|---|---|---|
| alert? [1] | ☐ No | ☐ No | ☐ No | ☐ No | ☐ No | ☐ No |
| Data available? | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| Data Source (e.g. study, read across, journal, model) | | | | | | |
| Effects observed? [2] | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No<br>☐ 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 [N33]:** 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? [1] | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| Data available? | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No | ☐ Yes<br>☐ No |
| Data Source (study, read across, journal, model) | | | | | | |
| Effects observed? [2] | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No<br>☐ NA | ☐ Yes [3]<br>☐ No [4]<br>☐ NA | ☐ Yes [5]<br>☐ No<br>☐ NA | ☐ Yes<br>☐ No<br>☐ NA | ☐ Yes<br>☐ No<br>☐ NA |
| Result (if study conducted) | positive/negative/ equivocal | positive/negative/ equivocal | positive/negative/ equivocal | NOEL/NOAEL/ LOAEL = | NOEL/NOAEL / LOAEL = | |

**Comment [N34]:** 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

[1] *Where there is a structural alert, NICNAS will require that a study has been conducted for this endpoint to demonstrate that this chemical is eligible for the LVC 1000.*
[2] *NICNAS may request copies of original data for endpoints where effects are seen, even below classification levels, depending on the severity of the effects and the exposure conditions.*
[3] *If effects are seen, complete the relevant table below.*
[4] *If effects are seen in the in vitro genotoxicity studies, complete the table for in vivo genotoxicty even if no effects were observed.*
[5] *If effects are observed, a summary report must be provided to NICNAS.*

***Acute Oral Toxicity*** *(Complete if any effects observed, otherwise delete)*

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

***Acute Dermal Toxicity*** *(Complete if any effects observed, otherwise delete)*

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

***Acute Inhalation Toxicity*** *(Complete if any effects observed, otherwise delete)*

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

***Eye Irritation Scores*** *(Complete if any effects observed, otherwise delete)*

| *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*** *(Complete if any effects observed, otherwise delete)*

| *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*** *(Complete if any effects observed, otherwise delete)*

| *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* | | |

***Bacterial Mutagenicity*** *(Complete if any effects observed, otherwise delete)*

| |
|---|
| |

**Comment [N35]:** Page: 9
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*** *(Complete if any effects observed, otherwise delete)*

***In Vivo Genotoxicity*** *(Complete if any effects are seen in the in vitro genotoxicity studies otherwise delete)*

OBSERVATION ON HUMAN EXPOSURE

SUMMARY OF EXPECTED HEALTH EFFECTS FOR ENDPOINTS WHERE NO TOXICOLOGICAL DATA AVAILABLE

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

JUSTIFICATION FOR READ ACROSS/MODELLED DATA

## 7. ENVIRONMENT *Not for publication*

### 7.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

RELEASE OF CHEMICAL FROM USE

RELEASE OF CHEMICAL FROM DISPOSAL

### 7.2 Summary of Environmental Toxicology

SUMMARY OF ECOTOXICOLOGICAL INFORMATION

All available ecotoxicological data (test data, literature data, read across data, modelled data) should be summarised in the table below. For chemicals (including polymers with a NAMW <1000) in cases where the proposed introduction volume exceeds 100 kg/year, data (test data, literature data, read across data, modelled data) are required for each of the environmental hazard criteria to demonstrate that that the low-hazardous criteria are met.

For endpoints where no data is available, the potential for the chemical to cause adverse environmental effects should be discussed in the section '**SUMMARY OF EXPECTED ENVIRONMENTAL EFFECTS FOR ENDPOINTS WHERE DATA IS NOT AVAILABLE'** below.

| | Fish toxicity | Daphnia toxicity | Algal toxicity | Other (describe): | Other (describe): |
|---|---|---|---|---|---|
| Result | EC50 … mg/L | EC50 … mg/L | EC50 … mg/L | | |

**Comment [N36]:** Page: 9
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. … [15]

**Comment [N37]:** Page: 10
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 … [16]

**Comment [N38]:** Page: 7
Include detail on any known human health hazards eg information from overseas use of the notified chemical.

**Comment [N39]:** Page: 10
Discuss the potential for the chemical to cause adverse local (irritation and sensitisation) and systemic (acute and chronic) effects.

**Comment [N40]:** Page: 10
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 Cl* … [17]

**Comment [N41]:** Page: 10
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 properti … [18]

**Comment [N42]:** ♦Page: 10
Discuss the releases during activities described under "**Operation Description e.g.** manufacturing or reformulation processes. For each situation give quantity (kg/day), expected concentration and media … [19]

**Comment [N43]:** Page: 10
Give information on releases not covered above.
For each situation give quantity (kg/day), expected concentration and media of release in which environmental release of the notified chemical may oc … [20]

**Comment [N44]:** Page: 10
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 … [21]

| | | | | | |
|---|---|---|---|---|---|
| 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:

SUMMARY OF EXPECTED ENVIRONMENTAL EFFECTS (WHERE DATA IS NOT AVAILABLE)

JUSTIFICATION FOR READ ACROSS/MODELLED DATA

## 8. 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*.

**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*.

**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

**Comment [N45]:** Page: 10
Indicate Test guideline used e.g. OECD TG 405, similar to OECD TG 405, in-house, etc

**Comment [N46]:** Page: 11
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.

**Comment [N47]:** Page: 11
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).

Full details of the QSAR model used (including version), as well as all input values used by the model including the SMILES string should be provided.

**Comment [N48]:** Page: 11
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.

**Comment [N49]:** Page: 11
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.

**Page 6: [1] Comment [N3]** **NICNAS**

Page: 5

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; duration of the permit (maximum three years); and general use of the chemical.

**Page 6: [2] Comment [N4]** **NICNAS**

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*.

**Page 6: [3] Comment [N5]** **NICNAS**

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*.

**Page 6: [4] Comment [N6]** **NICNAS**

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.

**Page 6: [5] Comment [N8]** **NICNAS**

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.

**Page 6: [6] Comment [N9]** **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, 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.

**Page 6: [7] Comment [N11]** **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). Attach a copy of the molecular weight characterisation report (paper copy or electronic)..

**Page 7: [8] Comment [N15]** **NICNAS**

Page: 6

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: [9] Comment [N20]** **NICNAS**

Page: 7

Indicate if the notified chemical is introduced by import or local manufacture. Give formulation details if the notified chemical is not introduced in 100% form. 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 how the chemical or formulation(s) will be packaged.

**Page 7: [10] Comment [N22]** **NICNAS**

Page: 7

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 8: [11] Comment [N26]** **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: [12] Comment [N27]** **NICNAS**

Page: 7

Describe the activities carried out by each category of workers and the types of exposure to the notified chemical that may result; include the concentration of notified chemical in the formulation at each step. 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). Give these details even if protective equipment which will minimise exposure is used.

**Page 8: [13] Comment [N28]** **NICNAS**

Page: 7

Describe the safe work practices which will be used, such as automated enclosed systems or codes of practice, engineering controls such as local exhaust ventilation, and any personal protective equipment which will be used by workers during each step.

**Page 8: [14] Comment [N32]** **NICNAS**

Page: 7

Include all routes by which the public will be exposed; indicate the likely frequency of exposure and the expected quantities; include the concentration of the notified chemical in the consumer products.

**Page 11: [15] Comment [N36]** **NICNAS**

Page: 9

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.

**Page 11: [16] Comment [N37]** **NICNAS**

Page: 10

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 11: [17] Comment [N40]** **NICNAS**

Page: 10

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 11: [18] Comment [N41]** **NICNAS**

Page: 10

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).

Full details of the QSAR model used (including version), as well as all input values used by the model including the SMILES string should be provided.

**Page 11: [19] Comment [N42]** **NICNAS**

- Page: 10
  Discuss the releases during activities desciribed under "**Operation Description e.g.** manufacturing or reformulation processes. For each situation give quantity (kg/day), expected concentration and media of release in which environmental release of the notified chemical may occur

**Page 11: [20] Comment [N43]** **NICNAS**

Page: 10

Give information on releases not covered above.
For each situation give quantity (kg/day), expected concentration and media of release in which environmental release of the notified chemical may occur.

**Page 11: [21] Comment [N44]** **NICNAS**

Page: 10

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.