GUIDANCE FOR COMPLETING THE NEW CHEMICALS ASSESSMENT FORM

INTRODUCTION

This guidance document should be read in conjunction with guidance provided within the form.

The guidance is intended to help standardise the format, quality and consistency of data provided in notification statements by applicants. The guidance covers the information required under the Industrial Chemicals (Notification and Assessment) Act 1989 (Cwlth) (the Act) for a submission under the Standard and Limited notification categories.

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 information on data requirements.

For a **Standard Notification**, the parts of the schedule to be completed are:

- Chemicals other than polymers: parts A, B and C or
- Polymers: parts A, B, C and D
- Note that for an ultraviolet filter in a cosmetic to be applied to the skin, Schedule part E data requirements apply. In such cases the UV Filter Attachment form should be completed and submitted to NICNAS.

For a **Limited Notification**, the parts of the Schedule to be completed are:

- Chemicals other than polymers: parts A and B or
- Polymers: parts A, B and D

The scheduled items represent a minimum set of data requirements. If additional data is available to the notifier, it should be provided to NICNAS as part of the notification package.

The form consists of 2 parts:

1. Exempt Information: this section should only be completed if exempt information is being applied for and the associated fee paid. Information in this section should not be duplicated in Part 2 (and *vice-versa*).
2. Public Report: This section should contain information that is suitable for publication.

Note: some sections that may be claimed as Exempt Information require generic text for publication in the *Chemical Gazette* and Public Report. In these instances, the generic information should be entered in Part 2 of the form. For example:

1. Use details: while the specific use of a chemical may be claimed as Exempt Information, the chemicals general uses are considered to be basic information.
2. Where numerical information is being claimed as Exempt Information (e.g. Purity, Introduction Volume) a range (e.g. >x%, 10-20 tonnes) is required for publication in the *Chemical Gazette* and Public Report.

The attached guidance document is for Part 2: Public Report only. Guidance for completing the Exempt Information components can be found within the corresponding sections of Part 2.

All headings/sub-headings within the template should not be altered, unless instructed to do so. Text should be entered into the relevant sections within the form in Times New Roman, 10 point font. The form should be filled out completely. Any missing information may result in delays in processing the application. Examples have been included in this guidance document (font style “Arial Narrow”) to illustrate the nature of the responses required. However, the guidance or examples are not exhaustive or exclusive and the user is encouraged to access the NICNAS Public Reports for further examples of the nature of the information required (http://www.nicnas.gov.au/Publications/CAR/New.asp).

The completed application should be submitted to NICNAS in both hardcopy (in duplicate) and electronic form (if possible). With the exception of Schedule E items and certain Schedule C items, hardcopies of all test reports and other relevant information should be submitted to NICNAS in duplicate. The Schedule C items for which only one hardcopy of the test report is required include the human health endpoints (the test reports for the environmental endpoints are required in duplicate).

General instructions for completing the risk assessment sections (sections 5.3 and 6.3): A summary of the occupational health and safety, public health and environmental effects of the chemical is required in all Standard Notifications and Limited Notifications. Notifiers should discuss the effects and hazards of the chemical in light of proposed recommendations for its use.

The summary should highlight the results of the tests that are used to determine the toxic effects of the chemical, including its ecotoxicity; that is, a summary of the most significant results of Part C of the Schedule. In tests where no adverse effects are observed, comments on dosage levels should be made. For Limited Notifications, where test data is not provided (according to Schedule C), adequate detail should be provided in the summaries below regarding the potential health and environmental effects of the polymer.

The summary should also highlight the physical and chemical hazards of the chemical, for example, flammability and reactivity.

Environmental, public and occupational exposure should be briefly discussed, and this should be combined with the information on the hazards associated with the notified chemical to determine any points where a risk to the environment, public health or occupational health and safety are presented by use of the notified chemical.

The summary should also address any information missing from the notification, and justify the omission(s).

Discussion should be in the form of a risk assessment. Additional information is provided in sections 6.3 and 7.3.

FEEDBACK

Your comments and suggestions on how the NICNAS forms may be made more user-friendly are welcome and should be directed to newchemicals@nicnas.gov.au, or:

New Chemicals Program
NICNAS
GPO Box 58
SYDNEY NSW 2001
AUSTRALIA

PART 2: PUBLIC REPORT

Preferred Name for the Notified Chemical/Polymer

This is the name under which the certificate will be issued and is the chemical name unless an application for exemption of the chemical name has been made; Otherwise, this is the tradename by which the chemical/polymer will be known in Australia, e.g. "Acrylic Copolymer in ABC123".

1. IDENTITY OF CHEMICAL

1.1. MARKETING NAME(S)

All trade names used in Australia for the chemical or products incorporating the chemical should be included here. For dyestuffs and pigments, the Colour Index name is sufficient only if marketed under this name alone.

1.2. CAS NUMBER

If a CAS (Chemical Abstracts Service) number has been assigned please include it here, otherwise state "not assigned". Only one CAS number can be given for the notified chemical. If the notified chemical is a mixture of reaction products, give the CAS number (if allocated) for the reaction products mixture, not for the individual components.

If a copy of a CAS "Inventory Expert Service Report" or a result from a CAS online search is available, include it with the submission as an attachment.

1.3. CHEMICAL NAME

Enter the Chemical Abstracts (CA) Preferred Index name for the notified chemical. If the CA Preferred Index name is not available, enter the International Union for Pure and Applied Chemistry (IUPAC) name..

If the notified chemical is not a pure chemical, enter a chemical name that describes it as completely as possible in the CA format. For example, the name can be in the form of a "reaction products" type or a "polymer with" name, as indicated below. A name indicating a mixture is not acceptable – this would require more than one notification.

e.g. fatty acids, tall-oil, reaction products with formaldehyde or phenol, polymer with formaldehyde

If the notified chemical is a biopolymer or other biological product, ensure that you identify its biological source.

e.g. jasmine, *jasminum officinale*, extract

If A CAS number has not been assigned, indicate whether or not the chemical name provided was assigned by CAS.

1.4. OTHER NAME(S)

This item should include all other names, e.g. synonyms, names used in study reports.

1.5. MOLECULAR FORMULA

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 (order the monomers from highest to lowest carbon numbers).

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

It may not be possible to provide a formula for complex natural products. In addition, it may be necessary to describe features such as variation in counter-ions, possibility of isomers etc.

1.6. STRUCTURAL FORMULA

A structural formula must be included unless it is impossible to assign one, e.g. for complex natural products. The structural formula should indicate the location of atoms, ions or groups, and the nature of bonds joining them. Ionic charges and stereochemistry should also be shown.

For polymers or reaction products, a structural formula showing the essential details of the types of bonds present should be drawn. In addition, the range and typical values for the number of repeating units as well as the

type of polymerisation (graft, block or random) should be shown. Provide approximate relative mole ratios of precursors.

The formula may be embedded in the document, and preferably also separately submitted electronically. A structure in ChemDraw.cdx format is preferred.

1.7. / 1.8. MOLECULAR WEIGHT

Delete the first molecular weight table if the notified chemical is a polymer. Enter the gram-molecular weight of the notified chemical. For UVCB substances, enter an estimate or range if known. If the molecular weight is being claimed as confidential enter actual values in Part 1: Exempt Information and a range for publication in Part 2: Full Public Report, e.g. <1,000, >10,000.

Delete the second molecular weight table if the notified chemical is not a polymer. Information 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).

1.9. ANALYTICAL DATA

This section should be used to provide details of both spectra (e.g. NMR, UV-Vis, IR etc) as well as methods of detection (e.g. HPLC, GC). Copy and Paste additional tables as necessary. Attach clear copies of spectra (rather than originals) to the submission, with scales properly marked. For ^{1}H NMR spectra, also provide integration curve. On the curve, concentrations used should ensure most intense substance-related peaks approach full-scale mark, increase vertically the intensity of weak NMR peaks and expand complex patterns. List the type(s) of analysis used to confirm chemical structure. Also give, according to type(s) of analysis:

- UV/Visible: solvent/ concentration, peak position, epsilon (ε) value of main peaks, and pH.

e.g. 1,
λmax = 207 nm, $\varepsilon = 6.70 \times 10^4$
λmax = 233 nm, $\varepsilon = 3.80 \times 10^4$
λmax = 326 nm, $\varepsilon = 1.38 \times 10^4$(pH 7)

λmax = 214 nm, $\varepsilon = 6.99 \times 10^4$
λmax = 253 nm, $\varepsilon = 3.56 \times 10^4$
λmax = 336 nm, $\varepsilon = 1.44 \times 10^4$ (pH 1)

λmax = 223 nm, $\varepsilon = 4.16 \times 10^4$
λmax = 366 nm, $\varepsilon = 1.07 \times 10^4$ (pH 10) (in aqueous solution)

- IR or Raman: peaks in wave numbers in descending order. If peak width is >100 specify in parenthesis "broad".

e.g. 2, 3350, 3203 (broad), 2951, 2863, 1910, 1687, 1595, 1559, 1496, 432, 416 cm^{-1}.

- NMR: nucleus and result. Indicate if signals correspond to solvent or impurities.

e.g. 3, ^{1}H, 9.74, 9.7-9.5, 9.37, 9.18, 9.00, 8.81,8.78,8.72, 8.58, 7.91*, 4.91, 4.88, 1.08, 0.88 ppm.
*residual undeuterated chloroform.

- mass spectrum: mode (e.g. electron impact), M/Z values or assignments.

e.g. 4,
m^+ peak isotopic splitting
m/e (relative intensity in brackets) 1022.5(9) 1024.5(32) 1013.5(64) 1020.5(100) 1030.5(92) 1042.5(63) 1033.5(30) 1066.1(6).

For types not mentioned, give sufficient information to confirm structural formula.

List analytical method(s) used to detect and determine (assay) the notified chemical in full.
e.g., The notified chemical may be precipitated by reaction with dimethylglyoxime under basic conditions after digestion, and determined gravimetrically.

In the Remarks section: comment on whether the spectral data confirm the structural formula of the notified chemical.

In the Test Facility section: Enter the name of the test facility and the year the report was produced. It is acceptable to enter an abbreviated name for the test facility.

If claimed as confidential, provide details in Part 1: Exempt Information and then in Part 2: Full Public Report, provide a list of the spectra that were provided to NICNAS but delete data tables.

2. COMPOSITION

2.1. DEGREE OF PURITY

Enter details of the typical weight percentage purity of the chemical, together with upper and lower limits of purity for typical commercial batches of the substance. Where possible enter batch number.

If the notified chemical is a complex reaction mixture, enter the typical percentage purity and upper and lower limits of purity for each of the main components, if known. Otherwise give an approximate purity for the overall mixture, excluding known impurties.

If claiming the degree of purity as confidential, enter the actual values in Part 1: Exempt Information and provide a non-confidential value in Part 2: Full Public Report, e.g. for 95% purity in Part 1, enter >90% in Part 2, or for 50% purity in Part 1, enter <60% in Part 2.

2.2. HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

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* should be provided. Include any impurities which have Australian exposure standards.

Minor or even trace impurities should be included if they have, or may reasonably be suspected to have, toxicological importance. Certain chemicals are designed to be reactive on exposure to air (such as acid chlorides producing HCl) and the properties of the reaction products which will be formed under normal conditions of exposure should also be discussed. Impurities which have not been classified in Australia but are reasonably expected to be hazardous should also be included, together with a short statement of the expected hazard from referenced literature sources.

If claiming Hazardous Impurities/Residual Monomers as Exempt Information, please note that it may be necessary to disclose the identity of these in the Full Public Report.

- If the hazardous impurities or residual monomers are all present at levels below the cut offs for classification of the notified chemical or polymer as a hazardous substance (taking into account additive effects), all details may be claimed as confidential. In such cases, enter the details in the relevant boxes in Part 1: Exempt Information, and enter the statement "All hazardous impurities [and residual monomers] are present at below the relevant cut offs for classification of the notified chemical [polymer] as a hazardous substance" in the relevant Part 2 Section.
- If the hazardous impurities or residual monomers are present at levels above the cut offs for classification of the notified chemical or polymer as a hazardous substance, but the notified chemical or polymer is not classified as Type I hazardous substance (that is, classification as carcinogenic, mutagenic, teratogenic, as a skin or respiratory sensitiser, as very corrosive, corrosive, causing severe eye damage, toxic or very toxic, as a harmful substance which can cause irreversible effects after acute exposure or a harmful substance which can cause serious damage to health after repeated or prolonged exposure), details can be claimed as confidential information but generic text must be provided in Part 2: Full Public Report.
- If the presence of the hazardous impurities or residual monomers leads to classification of the notified chemical or polymer as a Type I hazardous substance or if the impurity has an Australian exposure standard and is present under conditions which may lead to the exposure level being reached in practice, no exemption may be claimed. Note that although the notified chemical may have an Australian exposure standard, in practice it may not be present under conditions which may lead to this level of exposure being reached. For example, if an impurity has an exposure standard as a dust but it is only present in solution, the exposure level in air is not expected to reach the exposure standard.

If the notified chemical has more than one hazardous impurity or residual monomer, copy and paste the relevant

boxes until there is a sufficient number.

2.3. NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)
If the notified chemical does not have any non-hazardous impurities or residual monomers at 1% by weight or more, write 'None'. Otherwise, enter the chemical name(s), CAS number (if available) and weight percentage of all non-hazardous impurities or residual monomers, including isomers and by-products, present at 1% by weight or more.

2.4. ADDITIVES/ADJUVANTS
Additives and adjuvants are deliberately introduced into a product and include stabilisers, inhibitors, emulsifiers, antioxidants and solvents used in the production process which are not separated from the final product.

If no additives or adjuvants are introduced into the product, write 'None'. Otherwise, enter the chemical name(s), CAS number (if available) and maximum weight percentage of all additives and adjuvants. Exclude substances added subsequently to make a formulation or a preparation.

Details of the 'ADDITIVES/ADJUVANTS' may be claimed as confidential information similarly to hazardous impurities.

2.5. POLYMER CONSTITUENTS
For polymers only (delete if not required). Provide the identity and percentage of starting monomers and other reactants (e.g. 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.

2.6. LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
For polymers only (delete if not required). Information on the natural loss of monomers, reactants, additives and impurities from the polymer is required in order to assess health and environmental effects during use of the polymer. This data should include:

- loss by volatility, for example, monomer;
- loss by exudation, for example, additive; and
- loss by leaching, for example, by water or oil.

The conditions under which such loss may occur should be indicated.

2.7. DEGRADATION PRODUCTS
For polymers only (delete if not required). Information on all products resulting from the degradation, decomposition or depolymerisation of the polymer is required, including identification of the products. Details should include the conditions under which degradation, decomposition or depolymerisation take place. The rate and mode of degradation, decomposition or depolymerisation should be provided, together with the likely proportion of products formed. In particular, information on all dangerous and hazardous products should be provided. Information on the degradation products likely to be produced during or after the disposal of the polymer should be included.

3. PHYSICAL AND CHEMICAL PROPERTIES

Provide a summary of the physical and chemical properties in the table provided.

If applying for a Variation of Scheduled Data Requirements, check the appropriate boxes for these items. In such cases, state "Not determined" in the appropriate row of the Value column of the table. If the value is not for the notified chemical/polymer (e.g. is for the imported product) indicate this in the table.

3.1. PHYSICAL STATE AND APPEARANCE AT 20 °C AND 101.3 kPa:	e.g. Light yellow crystalline solid. Describe the appearance of the chemical in terms of its colour, physical state (solid, liquid or gaseous), state (e.g, powder, viscous, crystalline, compact), general appearance (e.g. cloudy, oily), odour, odour threshold (if known), and volatility (if

known).

3.2. DISCUSSION OF PROPERTIES

Reactivity

Include general remarks on stability under normal conditions, for example reactivity with water or air.
e.g. Stable to water and stable to air at temperatures below 295°C.

4. INTRODUCTION AND USE INFORMATION

4.1. MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Indicate if the notified chemical will be introduced by import or local manufacture and if it will be introduced as the chemical itself, or as a component of a formulation/solution.

Also describe any foreseeable circumstances that may impact on either the scale of manufacture or the volume of the notified chemical imported. For example, the chemical may initially be imported, but manufacture may be anticipated at a later date, or use of the chemical may be phased out after a number of years due to the implementation of local ozone protection laws.

4.2. MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS *

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

If claiming the 'MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS' as confidential information, then enter the confidential values in the appropriate table in Part 1: Exempt Information and then enter non-confidential values in the appropriate table in Part 2: Public Report (e.g. for 70 tonnes, enter 30-100).

4.3. PORT OF ENTRY

If the notified chemical is imported, identify the proposed port(s) of entry.

4.4. IDENTITY OF MANUFACTURER/RECIPIENTS

Enter the company name and locations of all sites at which manufacture, storage, reformulation, and/or end use of the notified chemical will occur. Where there is widespread end use, for example, in the commercial or consumer sectors, it is not necessary to give locations of end uses.

If claiming IDENTITY OF MANUFACTURER/RECIPIENTS as confidential, then enter the required information into the appropriate table in Part 1: Exempt Information and enter generic text (including the district(s) name(s) and State(s)/Territory(s) of the manufacturers or recipients of the notified chemical) in Part 2: Full Public Report.

4.5. TRANSPORTATION AND PACKAGING

Describe how the notified chemical or formulation(s) will be transported to and from the port(s) of entry, the manufacturing sites, storage facilities, processing sites and end use sites. Indicate the quantity transported, the mode of transport and the potential for environmental exposure.

Also describe how the chemical or formulation(s) will be packaged. Give details on the packaging size, type and material of construction, for example, 60 g plastic tubes, 4 L high-density polyethylene container, polyethylene lined 20 L steel drum or 1000 L isotank, road tanker.

Describe the safe transportation requirements, including details of UN Number, Dangerous Goods Class(es) and the Hazchem Code.

4.6. USE

For each intended use of the notified chemical:

- describe its function and application. Function refers to the inherent physical and chemical properties of the chemical, for example, degreaser, catalyst, plasticiser, ultraviolet absorber, surfactant, dyestuff, adhesive. Application refers to the use of the substance in particular processes or products.
- give the approximate percentage of total manufacture or import volume for each use.

- indicate the percentage of total manufacture or import volume introduced by each applicant, where there is more than one applicant.
- give information on which sector(s) will use the chemical or formulation(s), and in what proportion.
- If the notified chemical/polymer is an ingredient in cosmetics, please provide specific uses and maximum concentrations intended in various cosmetic types. Also provide methods of application (e.g. spray).

If claiming 'USE' as confidential information then enter commercially sensitive information regarding processes into the appropriate table in Part 1: Exempt Information (this may include exact percentage of the notified polymer in products, or the precise function of the polymer – e.g. 'the notified polymer is an anti-oxidant used at 7% in marine diesel engine oils'. A generic description of each identified use that is claimed as confidential should be entered in Part 2: Full Public Report (note that sufficient information should be provided for the risk assessment).

4.7. STORAGE

Describe all intended storage facilities, including details on the size, type and capacity of containers used to store the notified chemical or formulation(s), and the potential for environmental exposure.

Also describe safe storage requirements taking into account the hazards of the notified chemical or formulation(s). Such requirements may include details of the required location, ventilation or temperature, or details of any incompatibilities the notified chemical has. If dust explosivity is likely, describe the precautions that will be taken.

List any relevant national codes of practice, (e.g. the NOHSC National Code of Practice for the Control of Major Hazard Facilities), any relevant industry codes of practice or guidance notes or any relevant Australian Standards [e.g. The storage and handling of hazardous chemical materials - Class 5.2 substances (organic peroxides)] applicable to the storage of the notified chemical or formulation.

4.8. EMERGENCY PROCEDURES – OCCUPATIONAL

Describe procedures required to render the chemical harmless in the workplace, include:

- environmental emergencies, e.g., spillage or release of the notified chemical in the workplace
- personnel emergencies, e.g., inhalation of leaking vapours by workers

4.9. EMERGENCY PROCEDURES – ENVIRONMENTAL

Describe procedures required to render the chemical harmless outside the workplace include:

- workplace emergencies affecting the public at large, e.g., a gas release affecting nearby residents
- transport emergencies
- environmental emergencies, e.g., spillage or release of the chemical outside of the workplace
- emergencies at storage facilities outside the workplace

Include the possibility of recovery, containment, neutralisation and destruction, e.g., incineration.

4.10. OPERATION DESCRIPTION

A process flow diagram may be useful to assist the description. Where a process flow diagram is available, it can be inserted or included with the submission as an attachment. The operation description is split into 3 section: i) manufacture; ii) reformulation/repackaging; and iii) end-use.

Describe the manufacturing, processing, reformulation, repackaging and/or end use operations involving the notified chemical or formulation. Identify the major unit operation steps and chemical conversions, including secondary operations involving the notified chemical, such as interim storage and transport containers (give size and type). Note that "unit operation" means a functional step in a manufacturing, processing or end-use operation where substances undergo chemical changes and/or changes in location, temperature, pressure, physical state, or similar characteristics. Include in your description:

- steps in which the notified chemical is formulated, for example into gels, mixtures, suspensions or solutions
- steps where the notified chemical is packaged (give size and type of packaging)

Indicate the entry and exit point of all:

- feedstocks (eg reactants, solvents, catalysts) used in the operation

- products
- recycle streams and
- wastes

Specify the approximate weight of the notified chemical fed into the process. Provide this information as "kg per batch" for batch operations or "kg per day" for continuous operations, also the batch size in kg or L, or the amount of product per day for continuous operations.

Indicate the location of the points of release from which the notified chemical and mixtures containing it will be released to the environment or to control equipment. Include small or intermittent releases (e.g. some cleaning releases, drum residues) and trace amounts of the notified chemical. Accidental releases need not be included. Describe measures taken to control release, such as bunding or control of surface runoff.

Where applicable, describe the degree of containment for each unit operation, for example,

- destructive use (e.g. fuel additives, intermediates)
- contained use (e.g. catalysts used in closed systems, capacitor fluids)
- open use
- non-dispersive use (e.g. printing inks, textiles, dyes, plasticisers, adhesives, paints, resins)
- dispersive use (e.g. cutting fluids)
- highly dispersive use (e.g. spray paints)

Estimate the maximum amount of the notified chemical (on a 100% basis) manufactured, processed, or used in the operation. Basing the estimates on the maximum 12-month introduction volume, provide this information "per batch" for batch operations and "per day" for continuous operations. Also estimate the duration of the operation.

If the same manufacturing, processing and/or end use operations are performed at more than one site, describe the typical operation. If operations or production rates vary substantially among the different sites describe the operations separately for each site, unless it is possible to cover all site operations by several generic process descriptions, e.g. batch operations occur at a number of sites, while others have continuous operations.

Describe operations that occur both at sites you control and sites controlled by others. In most cases, you will have more specific information on sites you control than sites controlled by others. If you do not have specific information on sites controlled by others, describe a typical operation involving the particular processing or end use application based on information available to you or on your experience with similar chemicals.

Manufacturing processes need not be described if they occur outside of Australia. However, it is still necessary to describe further processing and/or end use operations that occur after import of the notified chemical.

Where the notified chemical or formulation is destined for commercial or consumer use, describe how it is used, including estimates on the frequency and mode of application and the amount used at each application. Describe also situations in which release of the notified chemical may occur, including release of the notified chemical through equipment cleaning.

5. HUMAN HEALTH IMPLICATIONS

5.1. Exposure assessment

5.1.1. Occupational exposure

5.1.1.1. CATEGORY OF WORKERS

In the table provided, indicate all categories of workers who will handle the notified chemical/polymer (including transport and storage) or products containing the notified chemical/polymer. For each category, include the predicted length of time that each will handle the chemical, and the frequency of handling the chemical; insert additional rows if required. e.g.

Category of Worker	*Exposure Duration*	*Exposure Frequency*
e.g. Transport workers	4 hours per day	6 days per year
e.g. Distribution workers	2 hours per day	240 days per year
e.g. Warehouse staff	4 hours per day	30 days per year
e.g. Polypropylene process workers	4 hours per day	30 days per year
e.g. Polyacrylate/rubber compounding process workers	4 hours per day	30 days per year
e.g. Laboratory technicians	4 hours per day	30 days per year
e.g. Polypropylene disposal workers	4 hours per day	30 days per year
e.g. Polyacrylate/rubber compounding disposal workers	4 hours per day	30 days per year

5.1.1.2. NATURE OF WORK DONE AND PREVENTION OF WORKER EXPOSURE

Information given here should cover all workers involved from the manufacturing process or importation onwards, and also those involved in storage, handling, transportation and disposal of the notified chemical even where actual exposure is expected to be minimal.

Identify each category of worker that is likely to be exposed to the notified chemical (e.g. technician, plant operator, storeworker) and describe each specific activity during which these workers may be exposed to the notified chemical. Such activities may include transporting the notified chemical, charging reactor vessels, connecting pump lines, performing filtration operations, sampling for quality control, transferring materials from one work area to another, weighing, drumming, bulk loading, changing filters, cleaning equipment and containers, maintenance of equipment or disposal. Activities must be described even if workers wear protective equipment.

Also give:

- the physical form of the notified chemical at the time of exposure, for example solid (crystals, granules, powder, dust), liquid, gas, vapour, fume, wet press cake;
- an estimate of the weight percentage of the notified chemical (if in a mixture) at the time of exposure. A range is acceptable if precise data are not available;
- a description on how exposure to the notified chemical may occur (e.g. from drips and spills, splashes, release of vapours) and the route of exposure, that is, eye, skin (hands or whole body) or inhalation. Give this description, even if workers wear protective equipment
- information on the specific types of protective equipment, isolation procedures and engineering controls that will be used to protect the worker from potential exposure to the notified chemical, such as:
  - eye protection
  - gloves and protective clothing (specify design and composition)
  - respirators (specify type)
  - ventilation or exhaust systems
  - spray painting booths
  - closed containment systems
  - nitrogen blankets

Briefly describe safe work practices to be observed in handling the chemical, including precautions during handling, storage and transport of the notified chemical, precautions in handling spills, good housekeeping, and a description of any procedures introduced to reduce the duration and frequency of exposure for employees.

Where measured or modelled exposure data exist they should be discussed and included here.

e.g.
Transport and Storage
The notified chemical will be imported in 16 or 25 kg Dangerous Goods approved packaging (plastic drums) within a container by sea. Transport workers will transport the container from the dockside by road or rail to the warehouse contractor's site where the contents will be emptied for storage in a dangerous goods store.

Distribution staff will then distribute the drums to the customer warehouses. At the warehouse, warehouse workers transport the drums as required, using a forklift or hand trolley from the store to the process peroxide storage and pumping shed, where they will be added to a fully enclosed peroxide storage vessel. The peroxide solution, containing 41-48% of the notified chemical, is semi-automatically pumped via a dip tube from the drums into a storage vessel with capacity of 150L. Workers may come into contact with the peroxide solution as they manually empty the containers or as they connect/disconnect the dip tube and pump to the drums. Incidental exposure to the notified chemical may occur via skin or eye contact from spills and drips or by inhalation of peroxide vapours. Workers involved in transfer will wear overalls, goggles and PVC or rubber gloves.

Transport and other storage workers would only be exposed to the notified chemical in the event of a spill. The nature of the packaging used for transport minimises the likelihood of release or loss of the chemical in incidents.

Polymer Manufacture and Rubber Compounding

Use of the notified chemical during manufacturing processes are similar for polypropylene and polyacrylate and rubber compounds. Typically, polymeric products are manufactured in two stages, primary manufacture (polymerisation) and secondary manufacture (formulation and conversion into plastic products). This section describes exposure during primary manufacture. Polymerisation is an enclosed process where the additives, including the notified chemical, are introduced to the reactor either manually or via an automatic dosing system. The additives are usually weighed and mixed before dosing.

Prior to addition to the reactor, the peroxide solution containing 41-48% of the notified chemical is transferred and weighed into a mixing vessel, either from the peroxide storage vessel or directly from the drum. Exposure of polypropylene process workers or polyacrylate process workers during weighing and transfer to the notified chemical would mainly occur via skin or eye contact from spills and drips or by inhalation. Dosing of the peroxide into the reactor is achieved by contained automatic dosing thereby reducing the potential for spills to occur. Worker exposure during this operation is assumed to be negligible.
After use, the process workers would also rinse the plastic drums of peroxide solution before collection by drum recyclers for disposal. Inhalation and dermal exposure may occur during rinsing.

Exposure estimates were determined by use of the EASE[1] model, information provided by the notifier and information provided in the corresponding risk assessment conducted by the Dutch assessment authority. No personal protection is assumed in the estimates. Assuming the following:

use pattern	-	non-dispersive
pattern of control	-	direct handling, dilution ventilation
volatility	-	low (< 1.5 kPa)
aerosol formation	-	none

Exposure to vapours (inhalation) by process workers is estimated to be 10-50 ppm (108-541 mg/m^3 at 25^{o}C and 101.3 kPa). However, on the basis of very low volatility (vapour pressure 0.004 kPa), 10 ppm is taken to be a reasonable worst-case estimate. Direct handling of the notified chemical has been assumed during weighing and transference procedures, although local exhaust ventilation is expected to normally be used.

Using a respiratory rate of 1.3 m^3/h, the inhalation dose from handling the chemical over a maximum of 4 hours/day is calculated to be 8-mg/kg bw/day (assuming an average body weight of worker as 70 kg).

Similarly, dermal exposure is estimated using the EASE model to be 0.1-1 mg/cm^2/day, assuming non-dispersive, direct handling and intermittent use. The calculated dermal dose, assuming exposure to both hands with skin surface area estimate of 840 cm^2 (following standard US EPA values), is 0.54-5.4 mg/kg bw/day for a solution containing approximately 45% of the notified chemical. In the absence of data, 100% skin absorption was assumed.

Workers handling the notified chemical wear elbow length rubber gloves, eye goggles and rubber aprons. The notifier stated that safe job handling procedures have been developed for production tasks, and workers involved in formulation are trained in the safe handling and use of peroxides.

After reaction, the notified chemical will be either consumed during the polymerisation process or bound within the polymer matrix. At this point, the notified chemical will not be available for exposure or absorption. Therefore, workers involved in the filling and packing operations are not likely to be exposed to the notified chemical.

[1] Estimation and Assessment of Substance Exposure (EASE). The EASE system was developed by the UK Health and Safety Executive in conjunction with the Artificial Intelligence Applications Institute. For a further description see: Marquart et al., Evaluation of Methods of Exposure Assessment for Premarket Notifications, TNO Report V 94.229 TNO Nutrition and Food Research (Zeist), 1994.

Laboratory Analysis
Exposure to the notified chemical may occur mainly via skin contact or inhalation while sampling and testing the peroxide solution, however exposure is expected to be minor, as small samples will be handled. In addition, testing is performed in fume hoods and laboratory technicians are required to wear personal protective equipment.

Drum Recycling
The empty plastic containers are either pierced and disposed of to an industrial landfill by polypropylene disposal workers or polyacrylate disposal workers, or are collected by contractors who shred and granulate them. Residues of peroxide in empty containers are expected to be minimal as process workers rinse the drums before collection and recycling or disposal. Therefore, inhalation and dermal exposure are not expected during these operations.

Plastic Product Production
This is described as secondary manufacture. As the notified chemical is either consumed during the polymerisation process or bound within the polymer matrix, it will not be available for worker exposure during plastics production. Any residues of the notified chemical will be consumed in the compounding or extrusion processes, under heat (temperatures range between 50-185^{o}C depending on process) and pressure. Exposure to the notified chemical in this instance is not expected.

5.1.1.3. Education & Training
Briefly describe the training and education that will be given to workers to ensure proficiency in safe working practices related to the notified chemical.

5.1.1.4. Prevalence of Work-Related Injuries & Diseases
For chemicals already in use, any effect on the occupational health of workers exposed to the chemical may be known before introduction of the chemical into Australia or during its prior use in Australia under a NICNAS permit or exemption. The type, frequency and severity of all work-related injuries and diseases resulting from worker exposure to the notified chemical are required, for example, the incidence of health effects or diseases, total work time lost. Where available, details on the duration, frequency and levels of exposure of workers to the chemical should be indicated. Exposure to other chemicals or other relevant factors should also be mentioned.

5.1.1.5. Other Occupational Hazards
Give information on possible occupational hazards that are not covered elsewhere, including information on conditions that may increase the hazard of the chemical. State any relevant national or industry codes of practice or guidance notes or Australian Standards (e.g. Safe working in a confined space) that may be applicable to use of the notified chemical or formulation.

5.1.1.6. Occupational Health Monitoring
Give details of the atmospheric monitoring and biological monitoring procedures that are proposed to be adopted to give a measure of worker exposure to the notified chemical and the effects of the notified chemical. Where applicable, also provide information on existing or proposed exposure limits. If no monitoring procedures are proposed, this should be justified in terms of the health and safety hazards of the chemical and extent of worker exposure to the chemical.

For importers who may not use the chemical, some indication of proposed monitoring procedures should be obtained from the user and described.

5.1.2. Public exposure
Public exposure may occur by:

- exposure during industrial use as the result of contamination of air, water, soil or food
- exposure as the result of an industrial accident
- exposure by domestic use of the chemical

Describe potential public exposure to the notified chemical, based on the proposed uses of the notified chemical, the physical and chemical properties, the site of manufacture or reformulation in Australia and the release of the chemical into the environment at that site, the quantity, concentration and frequency of release of the notified chemical for each use of the chemical, the conditions of safe storage, the disposal procedures, and the consequences of accidental spillage. Where it is possible (such as for cosmetics applied to the skin), quantify the exposure in terms of number of applications per day and amount used per application.

e.g. 1
The imported product is intended for industrial use only. After application to the edge of windshields, the notified chemical cures and becomes an inert part covered by urethane adhesive material. While members of the public may make contact with the primer layer, the notified chemical is unlikely to be bioavailable in this form.

Public exposure to the notified chemical (in products) as a result of transportation within Australia is unlikely unless there is an accident. The material safety data sheets (MSDS) supplied for the products containing the notified chemical have adequate instructions for clean-up and disposal of any accidental spills and therefore public exposure as a result of a transport accident is likely to be negligible.

e.g. 2
Widespread public exposure to the notified chemical is expected. Members of the public are likely to make dermal and possibly ocular contact with the notified chemical at a concentration of <2% as a result of use of the shower gel product. Typically the shower gel is used once or twice a day with 5ml of shower gel being applied each use.

Public exposure to the notified chemical as imported as a component of fragrance composition could only occur in the event of transport accident or spillage. The packaging will protect the contents from being released during normal handling. Similarly, public exposure during the reformulation process is unlikely.

5.2 Human health effects assessment

The table provided contains Schedule Data Requirements for a Standard (STD) notification. If data is available for chemicals/polymers that will be assessed in the Limited (LTD) notification category, then the table should be completed to the extent possible.

A summary of the properties should be included in the table provided. If applying for a Variation of Scheduled Data Requirements, check the appropriate boxes for these items. In such cases, state "Not determined" in the appropriate row of the Result column of the table. If the value is not for the notified chemical/polymer (e.g. is for the imported product) indicate this in the table.

In 5.2.1 OBSERVATIONS ON HUMAN EXPOSURE SECTION, include details on any known human health hazards, e.g. information from overseas use of the notified chemical.

5.3. Human health risk assessment

5.3.1. Occupational health and safety
Include a brief discussion of hazards related to human health and occupational health and safety (e.g. toxicity, reactivity), the likely routes of exposure, appropriate protective measures, and the level of risk to workers handling the notified chemical under these conditions. For additional details see introductory remark section.

5.3.2. Public health
Discuss the public exposure (direct, indirect and accidental) and relate this to the hazards to human health posed by the notified chemical; discuss the level of risk to the public posed by introduction of the chemical. For additional details see introductory remark section.

6. ENVIRONMENTAL IMPLICATIONS

6.1. Environmental exposure Assessment

6.1.1. RELEASE OF CHEMICAL AT SITE
For each point of release identified under "OPERATION DESCRIPTION",

- estimate the amount of the notified chemical that will be released directly into either the environment or into control technology. Provide this information as "kg per day" for continuous operations or repetitive batch operations and "kg per batch" for less frequent batch operations. Base the estimates on the maximum 12-month introduction volume. Take into consideration releases from cleaning of equipment, storage and residues remaining in transport containers.
- identify the medium (air, soil or water) to which the notified chemical is released. provide this information, whether or not control technology is used.

- describe the type of technology used to control release of the notified chemical, and the efficiency of the control technique. Examples of control technologies include carbon filters, scrubbers and biological treatment (primary, secondary etc). If no control technology is used, state this.
- identify the destination(s) of releases to water, e.g. ground water, natural waterways.

6.1.2. RELEASE OF CHEMICAL FROM USE
Provide information on any release not covered in "RELEASE OF CHEMICAL AT SITE".

For each use situation give the quantity (kg/day), expected concentration and media of release in which environmental release of the chemical may occur, for example:

- to ambient air, e.g. through smoke stack emissions, car exhaust fumes, incineration gases, aerosols and fugitive refrigerant gases.
- in water, e.g. natural waterways or ground water, including release to waste water treatment facilities, e.g. through washing off of cosmetic products.
- to the surrounding land, e.g. through overspray of paints, general wear and tear and deposition.
- to landfill from disposal of containers after domestic use, disposal of material used to capture overspray at paint users premises, disposal of printed pages covered in ink containing the notified chemical or similar scenarios.

6.1.3. RELEASE OF CHEMICAL FROM DISPOSAL
Describe all disposal procedures, including disposal procedures for all contaminated packaging. Include in your description:

- route of disposal (e.g. landfill or incineration, including details where necessary, e.g. secure landfill or high temperature incineration).
- quantities (in kg/year) to be disposed of by each route, including residues in contaminated packaging (e.g. empty drums, plastic bottles).
- identity and hazards of any degradation products resulting from disposal.

State whether disposal needs to be in accordance with government regulations.

6.2. Environmental effects assessment

The table provided contains Schedule Data Requirements for a Standard (STD) notification. If data is available for chemicals/polymers that will be assessed in the Limited (LTD) notification category, then the table should be completed to the extent possible.

A summary of the properties should be included in the table provided. If applying for a Variation of Scheduled Data Requirements, check the appropriate boxes for these items. In such cases, state "Not determined" in the appropriate row of the Result column of the table. If the value is not for the notified chemical/polymer (e.g. is for the imported product) indicate this in the table.

6.3. Environmental risk assessment
Include a brief discussion of the environmental hazards posed by the notified chemical; relate this to the likely environmental release. Discuss the environmental fate such as distribution between water, air and soil, and degradation of the notified chemical. Identify whether the notified chemical will be released to any environmental compartment in concentrations which are likely to result in environmental risk.

7. SUMMARY OF HOW THE CHEMICAL MEETS THE DEFINITION OF A HAZARDOUS SUBSTANCE (CLASSIFICATION)
State whether or not the notified chemical is classified as a hazardous substance.

If the notified chemical is a hazardous substance, list the appropriate classifications (or risk and safety phrases) for the notified chemical and products containing the notified chemical. In addition, provide the basis of the classification in terms of the toxicological endpoints considered. No new data for the chemical should be introduced in this section, However, data for other chemicals can be included, to demonstrate similarities or

differences.

8. (M)SDS AND LABEL

8.1. 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 the application. The label should be compiled in accordance with the Safe Work Australia Code of Practice for the *Labelling of Workplace Hazardous Chemicals* or the NOHSC *National Code of Practice for the Labelling of Workplace Substances*. Check the label checklist items as appropriate.

8.2. (Material) Safety Data Sheet

A copy of the (M)SDS for the chemical and the chemical in the form(s) that is intended to be introduced should be attached to the 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 (M)SDS (either by its full chemical name or generic name), then (M)SDS for those products should also be attached. The (M)SDS should be compiled in accordance with the Safe Work Australia Code of Practice for the *Preparation of Safety Data Sheets for Hazardous Chemicals* or the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets*. Check the MSDS checklist items as appropriate.

11. BIBLIOGRAPHY/LIST OF ATTACHMENTS

A list of attachments that will accompany the notification is required (e.g. study reports). The list should also identify any publications referred to in the statement. Note that any publications (e.g. literature sources) referred to in the statement should be provided as attachments, unless they are standard test methods, codes of practice etc.