

NICNAS releases PEC report on Triclosan

Triclosan (CAS No. 3380-34-5) is included in many consumer products at very low concentrations due to its antimicrobial activity. It is imported into Australia and used in the formulation of cosmetics and personal care products, therapeutic products and cleaning agents. Triclosan is also used in the treatment of textiles and in plastics manufacture. In addition the chemical is imported as an ingredient in a large number of end products intended for consumer use.

Triclosan was declared a Priority Existing Chemical for full risk assessment (human health and environmental risk assessment) due to environmental concerns. The reason for selection for assessment was that the widespread use of triclosan provided a number of ways for the chemical to enter the environment. In addition, tests showed triclosan to be toxic to aquatic species including algae. The chemical properties of triclosan also indicated that it may be bioaccumulative and persistent in the environment.

NICNAS has completed the draft human health and environmental risk assessment report of triclosan. The draft report has been released to applicants for 28 days, for them to advise the Director of any factual errors. Following the correction of any errors, the report will be released for public comment on 7 October 2008, for 28 days during which requests for variation of the report may be made.



[Dr Nobheetha Jayasekara](#)

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In this issue:

- | | |
|----|--|
| 2 | Message from the Director |
| 3 | Existing Chemicals Program review – Progress scorecard |
| 4 | Voluntary call for information on nanomaterials |
| 5 | Publications updates |
| 6 | Registration renewals |
| | Our training and consultation schedule |
| 7 | Report on uptake of NICNAS PEC recommendations |
| 8 | Submissions on 3 chemicals to NDPSC |
| 9 | OECD New Chemicals Taskforce |
| 10 | Staff news |





Dr Marion Healy
Director, NICNAS

A word from the Director ...

Several national initiatives are under way that are aimed at improving the efficiency and effectiveness of the assessment and management of industrial chemicals, while maintaining protection of human health and the environment.

These initiatives are being progressed by the Council of Australian Governments (COAG), which has recognised the chemicals and plastics sector as a regulatory 'hot spot'. In considering steps to develop a more streamlined and harmonised system, COAG is being informed by a Ministerial Taskforce on Chemicals and Plastics Regulation Reform as well by a Productivity Commission Study into Chemicals and Plastics Regulation.

The report of the Productivity Commission study was released on 7 August, and it includes broad ranging recommendations: national governance arrangements and policy formulation, risk /hazard assessment, management of identified risks in the public health, occupational health and safety and environment sectors, transport safety and the management of chemicals of security concern.

Eight of the recommendations are directed at arrangements involving NICNAS. Three of the recommendations address aspects of NICNAS's internal procedures (recommendations 4.2, 4.5 and 4.6), three address institutional arrangements including the scope of NICNAS responsibilities (recommendations 4.1, 4.3 and 4.4) and two address the safety of consumer products containing chemicals (recommendations 5.4 and 5.5). There are additional recommendations that would impact on NICNAS's activities such as mechanisms to consider national chemicals matters and to develop risk management measures for the environment sector.

The response to these recommendations is currently being considered and is expected to be available before the end of 2008.

Significant steps to improve the operation of regulation in the chemicals and plastics sector have already been taken, with COAG agreeing to the first package of 18 reform initiatives. NICNAS has direct carriage of four of these reforms which address aspects of the notification and assessment system: the work sharing arrangements with Canada, finalising the outstanding reforms from the LRCC initiatives, evaluating the impact of the LRCC initiatives implemented in 2004 to provide an evidence base for further refinements to the LRCC arrangements, and progressing the review of the regulatory arrangements for hard surface disinfectants.

Several of the other reform initiatives involve chemicals that fall at the interface of agricultural and veterinary chemicals and may have implications for future NICNAS activities.

We have entered a period of significant national reform and change and NICNAS is actively engaged in these activities. There are considerable opportunities to improve the functioning of the regulation of industrial chemicals and we will provide regular updates on the progress of the initiatives, as well their impact on NICNAS, via our newsletter.

Please click on the link to access the final report of the [Productivity Commission Study into Chemicals and Plastics Regulation](#).





Existing Chemicals Program Review: progress report on implementation of recommendations

The scorecard for implementing the recommendations which arose from the Existing Chemicals Program Review is provided below (as at 31 August 2008) with each recommendation categorised and current status indicated by shading:

Green shading: completed in 2007-08

Yellow shading: in progress

Pink shading: not begun

Communications
3.1 Promote community awareness / education/ participation in Existing Chemicals Assessment Program
3.2 Publish 'Who's Who Guide' for industrial chemicals safety assessment & management
3.3 Develop current awareness bulletin on international chemical safety information & issues relevant to program
5.1 Develop, modify and publish process to filter out & re-direct non-NICNAS matters & determine level of response and/or assessment required
Screening, Prioritisation & Assessment Products
4.1 Develop an overall framework for screening of chemicals of concern
4.2 Screen AICS listed chemicals for hazard and/or risk indicators elements
4.4 Develop a framework to identify the circumstances under which down-stream use information is sought as being necessary for prioritisation
5.2 Develop scientifically based criteria for prioritisation of chemicals for assessment
5.3 Publish the prioritisation process and decisions
5.4 Streamline the secondary notification process for existing chemicals originally assessed as new chemicals
6.1 Develop new types of assessment products based on intended output and purposes
6.2 Develop information requirements for each new assessment type

Monitoring

4.3 Examine the feasibility of a nationally co-ordinated system of surveillance monitoring and post market reporting

Consultation

5.5 Explore with States & Territories improved processes for coordination & cooperation including under its MOU group

5.6 Explore an extension of the Bilateral Agreement with Canada to include existing chemicals

5.7 Explore the development of similar arrangements with other major trading countries

Refer to COAG Ministerial Taskforce

5.11 Refer the proposal to investigate the barriers to effective implementation of NICNAS recommendations to Ministerial Taskforce on Chemicals and Plastics [Regulation Reform] for their consideration.

7.0 Refer the range of issues related to the ban, severe restriction and/or the control of certain chemicals to Ministerial Taskforce on Chemicals and Plastics [Regulation Reform]

Currently improving practice

5.6 Continue to participate in chemicals management forums to ensure harmonised & streamlined regulation of industrial chemicals at national level

5.9 Increase & broaden consultation with stakeholders during assessment process & before recommendations are finalised

5.10 Recommendations are action statements that are evidence based, specific to the needs identified, achievable, and practical and be directed to the most appropriate body for implementation





NICNAS Voluntary Call for Information: industrial nanomaterials

Nanotechnology presents Australia with potential for innovation that must be balanced with health, safety and environmental considerations.

NICNAS is aware of these considerations and is acting at national and international levels to maintain appropriate regulatory oversight and ensure continued safe and sustainable use of industrial nanomaterials.

NICNAS is undertaking a voluntary **Call for Information** on the use and data holdings of industrial nanomaterials in Australia. The call is expected to go out in October and will close three months later. It will be publicised in the October *Chemical Gazette*.

This **Call for Information** follows a similar [Call in 2006](#) on the use of industrial nanomaterials by businesses in Australia, which was published as [aggregate data in early 2007](#). However, the current Call is being extended to include not only business, but also public sector researchers. Moreover, the Call will also ask respondents to state whether they hold physico-chemical and toxicological data for their nanomaterials, but will not require respondents to report the details of the data nor generate new data.

The Call has been developed with the assistance of the NICNAS Nanotechnology Advisory Group, as well as the community, and public and private sector stakeholders. NICNAS is working through industry associations, the [CSIRO Niche Manufacturing Flagship](#) and the [Australian Research Council's National Nanotechnology Network](#) to circulate the Call to potential respondents.

The aims of the Call are to:

- determine what industrial nanomaterials are introduced and used in Australia
- determine the volumes of these industrial nanomaterials
- understand how industrial nanomaterials are used in industry and in public sector research, and
- identify what physico-chemical and toxicological data is available on these industrial nanomaterials.

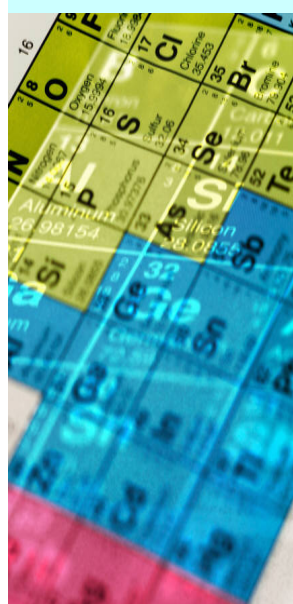
NICNAS encourages businesses and public sector researchers to participate in the **Call for Information** to assist NICNAS in developing appropriate regulatory processes to manage any risks posed by industrial nanomaterials.

For details of **other NICNAS activities in nanotechnology**, please see page XX



For further information on what is nanotechnology, please see: the [June 2008 edition of NICNAS Matters](#), and our [information sheet on nanomaterials](#) (of September 2006) or contact: [Dr Matthew Gredley](#).

Other NICNAS activities in nanotechnology are outlined on page 5.



NICNAS Matters



Australian Government
Department of Health and Ageing
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ISSUE > 02 2008

Assessing chemicals for your protection

New NICNAS publications

REPORTS

[OLOA 270 Secondary Notification Report](#)

BROCHURES

[NICNAS Business Plan 2008-09](#)

[NICNAS Fees and Charges 2008-09](#)

CHEMICAL GAZETTES

[September 2008](#)
[August 2008](#)
[July 2008](#)

NEWSLETTERS

[Community Engagement Bulletin Winter 2008](#)

OTHER PUBLICATIONS

[Uptake of NICNAS's Priority Existing Chemicals recommendations by Government Chemical Management Bodies](#)

[European Union "REACH" legislation: Pre-registration for chemicals by 1 December 2008](#)

Other NICNAS activities in nanotechnology (from page 4)

The current Call is one of a number of activities that NICNAS is undertaking in the area of industrial nanomaterials. Other initiatives currently underway or being considered include:

- Contributing to the [Australian Government Approach to the Responsible Development of Nanotechnology](#), as well as considering the issues raised in the independent report [A Review of the Possible Impacts of Nanotechnology on Australia's Regulatory Framework](#) commissioned by the [Australian Office of Nanotechnology](#)
- Developing guidance to industry on how NICNAS determines whether an industrial nanomaterial is equivalent to the bulk form of the chemical, which is a critical step in determining whether the nanomaterial is on the Australian Inventory of Chemical Substances, and can therefore be lawfully introduced into Australia
- Facilitating the development of Australian interest in the OECD Sponsorship Program for the Testing of a Representative Set of Nanomaterials under the OECD [Working Party on Manufactured Nanomaterials](#). Australia is currently contributing data towards the testing of cerium oxide, zinc oxide and silver nanoparticles, and
- Participating in capacity building workshops with other Australian regulators, such as the TGA, FSANZ and the APVMA, to train our chemical assessors in the area of nanotechnology.

New Cyanide Management handbook from DRET

In May 2008, the Australian Government Department of Resources, Energy and Tourism (DRET) published a handbook on *Cyanide Management* under the *Leading Practice Sustainable Development Program for the Mining Industry*.

Managing cyanide to minimise risks to human health and environmental health represents one of the key challenges facing the mining industry. The handbook addresses principles and procedures for effective and safe cyanide management. It takes a risk management approach and is closely based upon the leading practice principles contained in the International Cyanide Management Code.

Other handbooks in the series include *Stewardship, Community Engagement and Development, Mine Closure and Completion, Mine Rehabilitation, Biodiversity Management, Managing Acid and Metalliferous Drainage, Tailings Management, Working With Indigenous Communities, Water Management and Risk Assessment and Management*.

Handbooks are provided free of charge. To obtain a copy of the *Cyanide Management* handbook, or any of the other handbooks in the series, please send an email to sdmining@ret.gov.au.



Community Engagement updates

NICNAS's *Community Engagement Forum* publishes a *quarterly bulletin*.

For information about subscriptions, please go to the [NICNAS Community page](#).

5





NICNAS Registration renewals 2008-09

If you would like either:

- more information about NICNAS Registration
- or
- to report any unregistered introducers of industrial chemicals

please contact
 NICNAS on
 1800 638 528

The 2008-09 NICNAS Registration renewal cycle has seen an overall increase in the number of companies that have renewed their registration on time, which is a very positive result and greatly assists in administration of the scheme.

NICNAS Director, Dr Marion Healy has acknowledged the high level of cooperation from the industry and thanks all of the people who paid their registration renewal by the due date.


NICNAS is an industry-funded Government organisation, with a collaborative approach to regulating the safe use of chemicals for everyone's benefit. We produce a wealth of useable information to support a sustainable chemical industry and ensure that the community and environment is protected from the harmful effects of chemicals.

For those people who have not renewed their registration or notified NICNAS that they are no longer introducing relevant industrial chemicals, a mandatory Late Penalty will be issued.

Team Leader, NICNAS Compliance and Reporting Team, Mr Nick Walton said that if a person introduces any relevant industrial chemicals while they are not registered with NICNAS, they can face severe fines and potential seizure of their chemicals. NICNAS has the capacity to follow up on complaints about unregistered companies and conducts audits throughout the year to ensure the maximum level of compliance.

Anyone who intends to introduce relevant industrial chemicals during the NICNAS registration year must be registered.

The NICNAS [Register of Chemical Introducers](http://www.nicnas.gov.au) is a publicly available document and can be viewed on the NICNAS website: www.nicnas.gov.au.

 02 8577 8800 / 1800 638 528

NICNAS 2008-09 Training and Consultation Schedule 2008-09

October 2008	Briefings following 7 October release of Triclosan report
7	Sydney
8	Melbourne
10	Brisbane / Gold Coast
November 2008	Introduction to NICNAS Cosmetics Regulation Notifiers Training
December 2008	LRCC Training
February 2009	Notifiers Update





NICNAS assesses chemicals on a **priority** basis – in response to concerns about their health and/or environmental effects – because there are over 38,000 existing chemicals in use in Australia.

Chemicals undergoing such assessment are referred to as **Priority Existing Chemicals (PECs)** and PEC assessment reports contain – as a major output – recommendations directed to State/ Territory and Commonwealth regulatory authorities, and to industry and others, on ways to reduce the risk of adverse effects to human health or the environment, and/or measures to improve safe use of chemicals.

PEC Recommendations can cover occupational health and safety, environmental and/or public health issues. To date, NICNAS has assessed 72 chemicals as PECs and eight secondary notifications.

These findings relate to Recommendation 5.11 of the ECR Scorecard report (see p. 3 of this newsletter)

NICNAS Priority Existing Chemicals: report on uptake of recommendations by Government Chemical Management Bodies

NICNAS commissioned a consultancy to investigate the uptake of its PEC recommendations by Commonwealth and State/ Territory bodies, as part of an overall evaluation of the PEC program. A survey consisting of a representative sample of PEC recommendations was circulated to all relevant State/ Territory and Commonwealth regulatory authorities (over 30 departments and agencies). The recommendations selected related to approximately 40 chemicals, and risk management subjects, and included both recommendations directed to government and also the surveillance of recommendations directed to industry.

The survey aimed to identify, where applicable, the extent and timing of uptake of recommendations, barriers to the implementation of recommendations where these have not been taken up, and potential strategies to improve the timely implementation of the PEC recommendations. Each agency was contacted by telephone to discuss and finalise survey responses.

The study found that the proportion of NICNAS PEC recommendations adopted varied between the national bodies such as the Australian Safety and Compensation Council (ASCC), Environment Protection and Heritage Council (EPHC) and the National Drugs and Poisons Schedule Committee (NDPSC). The time between release of the recommendation and final adoption varied greatly between recommendations, and ranged from 1 to 6 years. Recommendations to Commonwealth regulatory agencies such as the Therapeutic Goods Administration (TGA), Australian Pesticides and Veterinary Medicines Authority (APVMA), Food Standards Australia New Zealand (FSANZ) and the Australian Competition and Consumer Commission (ACCC) were infrequent. Where recommendations were made to regulatory agencies they reported that these were considered but there was no need to take specific action as these were addressed independently of the NICNAS reports.

Actions proposed in PEC recommendations were not generally directly adopted by the States and Territories. However, often the intent of the recommendation was addressed in broader projects or generic actions and legislation. This is particularly the case for those chemicals for which a significant risk or priority had been established by a jurisdiction. Jurisdictions did not generally undertake monitoring of implementation of PEC recommendations directed specifically to industry.

Where PEC recommendations were not adopted agencies identified barriers for implementation.



The full report can be found on the NICNAS website:
www.nicnas.gov.au/Industry/Existing_Chemicals/The_PEC_Assessment_Report.asp





OLOA 270

NICNAS has completed a secondary notification assessment report on 'Chemical in OLOA 270' (referred to as OLOA 270). A new study on reproductive toxicity had been provided to NICNAS, warranting a secondary notification.

OLOA 270 is mainly used as an ingredient in lubricant oils for marine diesel engines. It is imported as a component of additive packages, which are then formulated into final lubricating oil products in Australia. A maximum of 60% of OLOA 270 is present in the additive packages.

OLOA 270 is not directly marketed to the public – hence direct contact with OLOA 270 by members of the public is unlikely.

The full assessment report for 'Chemical in OLOA 270' can be found on NICNAS website:
www.nicnas.gov.au/Publications/CAR/Other/OLOA_270_PDF.pdf

NICNAS makes submissions on three chemicals to NDPSC

NICNAS has made submissions to the National Drugs and Poisons Schedule Committee (NDPSC) for three chemicals not previously scheduled. Two of these were prompted by concerns over public safety arising from investigations into the chemicals by NICNAS following media reports, and governmental and public enquiries.

1,4-Butanediol is an industrial solvent and intermediate used in the production of various plastics and polymers. 1,4-Butanediol was reported to have caused the hospitalisation of children following ingestion of toy beads containing the chemical. After oral or intravenous administration, 1,4-butanediol is rapidly and efficiently metabolised in the liver to form γ -hydroxybutyrate (GHB), a chemical that exerts potent depressant effects on the central nervous system. Following an assessment a submission was made to the NDPSC's June 2008 meeting recommending the listing of 1,4-butanediol (in the monomer form) for use in toys in Appendix C of the Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP) to prohibit sale, supply and use. The free form 1,4-butanediol is now listed in Appendix C for all domestic use, including toys.

Diethylene glycol (DEG) is an industrial chemical used in brake fluids, glues and as an anti-freeze agent. In 2007, diethylene glycol (DEG) was found in certain brands of imported toothpaste. In conjunction with advice from NICNAS, the Australian Competition and Consumer Commission (ACCC) issued recall notices for toothpastes containing DEG. Besides the mandatory general labelling requirements for cosmetics under the *Trade Practices Act 1974* and the interim ACCC Consumer Protection Notice on maximum limits of DEG in toothpastes, no regulations existed for the use of DEG in oral cosmetic products in Australia. In humans DEG causes neurological impairment, metabolic acidosis and acute renal failure. Following an assessment NICNAS made a submission to the NDPSC's June 2008 meeting recommending the listing of DEG for intentional oral cosmetic use in Appendix C of the SUSDP to prohibit sale, supply and use. DEG for use in toothpastes and mouthwashes is now listed in Appendix C, with a low level cut-off of 0.25 per cent.

Methyldibromo glutaronitrile (MDBGN), a preservative and biocide used in a wide range of consumer products including cosmetics, was of concern to NICNAS due to its skin sensitising potential. As a result of a NICNAS submission to the NDPSC, MDBGN is now listed in Appendix C of the SUSDP and prohibited for use in preparations involving skin contact (including cosmetics). For other uses, it is now also listed as a Schedule 6 Poison requiring appropriate warning statements.





OECD New Chemicals Taskforce

Among many things, NICNAS is committed to maximising the use of its resources by:

- work sharing
- reducing duplication of effort
- unnecessary animal testing
- supporting global innovation and
- marketing of new chemicals.

Through active participation in international activities, more effective and efficient environmental and human health decisions could be achieved by sharing assessment approaches and outcomes on the assessment of risk of industrial chemicals.

NICNAS has been a lead player in the work of the OECD New Chemicals Task Force and has strongly supported the principle of Mutual Acceptance of Notifications (MAN). One of the work areas of the taskforce involves work towards the MAN principle.

The Parallel Process is a notification process whereby a company would submit the same notification package to two or more countries – which has the potential to reduce government and industry resource burdens, increase transparency in decision-making, and improve information transfer without compromising environmental and human health protection.

The other work area of the taskforce aims to harmonise key definitions used in the regulation of industrial chemicals and polymers, and to work towards a common approach for substances which are either exempt from notification or subject to reduced regulatory requirements (such as polymers of low concern). NICNAS is the lead participant in taking forward the work on sharing polymer data and reporting back to OECD new chemicals taskforce meetings. A draft report – the product of data sharing between participating countries – was presented at a recent OECD meeting in San Diego. The report further strengthens the application of the polymer of low concern criteria in new chemicals and aims to provide scientific evidence so as to build confidence among countries that are not currently using the polymer of low concern criteria. Presently US, Canada and Australia are aligned in the application of the criteria.

After the meeting NICNAS also participated in discussions (between representatives of other governments and several companies) notification of alternatives to perfluorinated chemicals under the OECD parallel process. This activity is important for NICNAS as perfluorinated chemicals are subject to significant international attention (OECD activity on management of perfluorinated chemicals is a subject of discussion under the Stockholm Convention).

Bilateral and Trilateral Arrangements with US and Canada

The development of bilateral relationships with key countries is one part of NICNAS's strategy to align Australia's practices and processes in the assessment and management of industrial chemicals with international best practice. In June 2008, bilateral and trilateral meetings were held with counterpart agencies from Canada and the USA and also with key stakeholder groups.

The trilateral meeting held with US EPA, Environment Canada and Health Canada was the first occasion that NICNAS has participated in such an initiative. The trilateral meeting focussed on common chemical assessment and management issues and potential collaborations between the three countries.

NICNAS also held bilateral discussions with the US EPA and explored common activities and possible work opportunities that would lead to (among other things) ... *(continued page 10)*



NICNAS Matters



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Assessing chemicals for your protection

Coming events

AUSTRALIA

October

19-25: [Safe Work Australia Week](#)

November

19 NICNAS Community Engagement Forum

26 NICNAS Industry Government Consultative Committee

INTERNATIONAL

October

20-24: *Rotterdam Convention Conference of Parties 4*, Rome, Italy

November

TBC: *OECD Registration Steering Group / Risk Reduction Steering Group / Working Group on Pesticides / Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology*, Paris, France (APVMA/DAFF)

OECD New Chemicals Taskforce *(continued from page 9)*

... reducing duplication, benchmarking risk assessment practices and encouraging a strategic approach to the management of industrial chemicals (eg. perfluorinated chemicals). This is timely as NICNAS is currently implementing the remaining LRCC reforms on new chemicals. Details of a future work-plan between NICNAS and USEPA were also discussed; it will be underpinned by a formal agreement to be finalised during 2008-09.

Bilateral discussions with Canadian officials was aimed at progressing the next phase of the implementation of the recognition of Canada's assessment and management of new chemicals as an Approved Foreign Scheme. The current work-plan for new chemicals was also discussed with a view to identifying priorities for 2008-09 and exploring opportunities to further enhance the arrangements for exchanges of assessment reports.

NICNAS Staff update

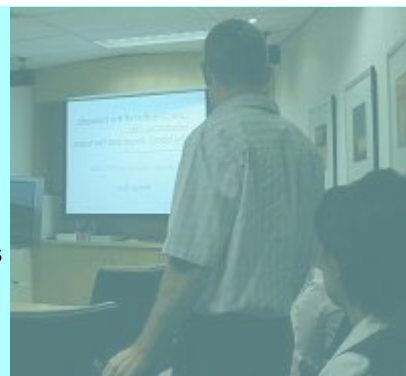
Dr Curtis Crasto has taken up the role of AICS Manager with the NICNAS Reform team.

Dr Trang Pham of the Existing Chemicals team has moved into the Reform team, and commenced duties on NICNAS's nanomaterials-related activities.

Ms Hana Hamdan (Team Leader, New Chemicals) will spend the next 8 months finalising implementation of outstanding reform measures and other activities such as strengthening our bilateral relationships with a view to establishing a cooperative agreement with US EPA.

Dr Sarah Rumble (Sept – Dec 08) and Dr Nobheetha Jayasekera (Jan – April 09) will be acting in the role of Team Leader, New Chemicals for the 8-month period.

NB: In the last issue of *NICNAS Matters*, Ms Natalie Hitoun was inadvertently omitted from the listing of Compliance and Reporting team arrivals.



NICNAS staff continue to arrange and attend regular "Tuesday Tune-up" sessions on a range of professional and scientific topics.

Contacting NICNAS

Do you have an industrial chemicals issue or matter you would like to raise with us?

Please feel free to call or write to us. Our contact points are listed below.

Freecall: 1800 638 528

Email: info@nicnas.gov.au

Post: GPO Box 58, SYDNEY
NSW 2001 AUSTRALIA

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