

## For introducers of new chemicals under non-cosmetic exemption provisions



Australian Government  
Department of Health and Ageing  
NICNAS

This guide can be used by persons intending to manufacture/import a new chemical under the non-cosmetic exemption (NCE) and at volumes not exceeding 100 kg per 12-month period under subsection 21(4)(b) of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

**NCE -1**

This form is for use as an aid in determining no unreasonable risk and must be kept by the introducer for record keeping purposes with supporting documentation. This form can be sent to NICNAS for data entry purposes relating to annual reporting requirements.

### Applicant

Business Name	ABN	
Business Address	Postcode	
Postal Address (if same as Business Address, state AS ABOVE)	Postcode	
Phone ( )	Fax ( )	Email

### Technical Contact

Name	Position	Company
Business Address (if different to above)	Postcode	
Postal Address (if same as Business Address, state AS ABOVE)	Postcode	
Phone ( )	Fax ( )	Email

### Chemical Identity

Chemical Name
Marketing or Other Name(s)
CAS Number (if known) - -

Amount of the new chemical intended to be introduced under this exemption for a 12-month period

- Is the new chemical classified as *hazardous* according to the *NOHSC* Approved Criteria for Classifying Hazardous Substances?  
 Yes  No
- Will the new chemical be present in a formulated product at a concentration, which causes the product to be classified as *hazardous* according to *NOHSC* Approved Criteria?  
 Yes  No
- Will the new chemical be present in a formulated product which itself is classified as *hazardous* according to the *NOHSC* Approved Criteria irrespective of the chemical?  
 Yes  No
- Is the chemical or the breakdown products likely to be persistent and/or bioaccumulative?  
 Yes  No

Please refer to the Handbook for Notifiers Section 2.6 for further information regarding the above questions and implications.

- Is the chemical an industrial nanomaterial under the NICNAS definition?  
(Note: for the working definition please consult the guidance document, *Guidance on New Chemical Requirements for Notification of Industrial Nanomaterials*, available from the NICNAS website:  
[http://www.nicnas.gov.au/Current\\_Issues/Nanotechnology/Guidance%20on%20New%20Chemical%20Requirements%20for%20Notification%20of%20Industrial%20Nanomaterials.pdf](http://www.nicnas.gov.au/Current_Issues/Nanotechnology/Guidance%20on%20New%20Chemical%20Requirements%20for%20Notification%20of%20Industrial%20Nanomaterials.pdf))

Yes     No

If yes, the chemical is not subject to an exemption from notification and assessment and must be notified to NICNAS.

***Use: In this box describe what the chemical is used for***

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Example: The new chemical will be used as paint additive for industrial and home applications.

State reasons why the introduction of the new chemical should **not** pose an unreasonable risk to the following:

(i) occupational health and safety

**Include details of:**

1. **How the chemical is transported and in what type of packaging/containers**
2. **How the chemical is handled for example is the chemical manually poured into a hopper**
3. **What concentration of the chemical workers will be exposed to at different stages eg. manufactured at 50%, concentration and after reformulation the chemical is present at a concentration 20%**
4. **What personal protective equipment is used such as gloves, eye protection, coveralls etc to minimize exposure to the chemical**
5. **What engineering controls are in place to minimize worker exposure to the chemical such as local exhaust ventilation**
6. **Any toxicological data if available**

Example: The new chemical will be imported in 20 kg polyethylene lined cardboard boxes or bags. The new chemical will be moved by forklift from the warehouse to the plant blending production area. The new chemical will be weighed out manually and added manually to a mixer. After blending the new chemical is present only at a concentration of <1%. Quality control samples (20 mL) are taken of the new mixture. Following blending the equipment must be cleaned by washing down with water. Following mixing the reformulated product is packaged by automated means into 4L and 20L plastic containers for distribution to customers.

The main routes of exposure are dermal, ocular and inhalation to workers during the weighing out of the notified chemical (100%) however the workers will be wearing appropriate personal protective equipment (PPE) such as dust masks, coveralls, gloves and eye protection. Exposure is further minimised by the use of local exhaust ventilation at the weighing area. The new chemical is not respirable (particle size >10 µm). Following blending (produces a liquid) the main routes of exposure are dermal and ocular. Again, PPE, engineering controls and the low concentration will minimize exposure to the new chemical. Furthermore limited toxicity testing has shown that the product is not hazardous. The new chemical is of low acute oral toxicity (LD50>2000 mg/kg) and is not a skin sensitiser (Guinea pig maximization test).

The Occupational Health and Safety risk presented by the new chemical is expected to be low under the settings described herein.

(ii) public health

**Include details of:**

1. **The availability of the new chemical to the public**
2. **Any public exposure to articles containing the notified chemical**
3. **The bioavailability of the new chemical in articles the public may handle containing the new chemical**

Example: Exposure to the new chemical will be widespread. The new chemical will be available to the public in paints at a concentration of <1%. The most likely routes of exposure are dermal and ocular. The new chemical is of low toxicity and under normal conditions of use exposure should be minimal. Once the paint is dry the new chemical is trapped within an inert matrix and not bioavailable. There is low risk to the public when handling products (paints) containing the new chemical.

(iii) the environment

**Include details of:**

- 1. Possible routes for release of the new chemical from accidental spillage (ie. during transport by road)**
- 2. Possible routes for release of the new chemical during manufacture and/or reformulation**
- 3. Disposal of the waste product and/or articles containing the new chemical**
- 4. Any ecotoxicological data that is available**

Example: The new chemical will not be manufactured in Australia. During transport only when packaging is accidentally breached would the new chemical be released. After blending, residual chemicals are washed out with water and treated at a wastewater plant, although the new chemical is present at low concentration and unlikely to pose an environmental hazard. As the final product will be distributed widely and will be highly diluted when it enters the aquatic environment through washing of paint trays the release is highly dispersed. Environmental concern is extremely low in view of the amount of chemical involved (less than 100 kg/yr). Ecotoxicological data further supports the low toxicity of the new chemical. The new chemical is of low acute toxicity to fish (LC50>1000 mg/L).

**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 which is false or misleading.

Under the Regulations, manufacturers and importers must maintain a dossier of safety information on non-cosmetic chemicals/products which are exempt under subsection 21(4)(b) of the Act from notification and assessment.

Companies are also required to complete annual reporting under subsection 21AA of the act.

December 2010