

Advice of introduction of a new chemical for cosmetic: introduced at 10 kg to 100 kg per 12-month period



Australian Government
Department of Health and Ageing
NICNAS

Complete this form if you intend to manufacture or import a new chemical for cosmetic use at 10 kg to 100 kg per annum under subsection 21(4)(b)(i) of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

FORM 15

GUIDANCE NOTES

-The exemption applies only if

- the chemical does not pose an unreasonable risk to occupational health and safety, public health or the environment; and
- the chemical is not used in the cosmetic product as a preservative, a colouring agent or an ultraviolet filter; and
- the chemical is not restricted for use as a cosmetic or in cosmetic products in the European Union or the United States of America; and
- the chemical meets the requirements of relevant Commonwealth, State and Territory laws.

-Persons who introduce the chemical must keep in writing, for 5 years after the introduction, all information available to the person about occupational health and safety, public health matters and the environmental effects of the chemical.

- Exemptions are also available for import or manufacture of a new chemical for cosmetic use introduced at 10 kg per annum or less. Chemicals introduced at less than 10 kg/12 months must be included in the annual report to the Director (section 21AA of the Act).

Please complete forms in BLOCK LETTERS and ensure that the Material Safety Data Sheet (MSDS), Label and any supporting documents are enclosed.

Return to: Director
NICNAS
GPO Box 58, Sydney NSW 2001
Telephone (02) 8577 8800 / 1800 638 528 Fax (02) 8577 8888

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

Chemical Name

Marketing or Other Name(s)

CAS Number (if known) - -

Claim(s) on cosmetic product label and advertising material

Function of new chemical in cosmetic product

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
- 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)
 Yes No

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

- Will the new chemical be used in the cosmetic product as (i) a preservative, (ii) a colouring agent, or (iii) a ultraviolet filter?
(Note: New chemicals used for these purposes in cosmetic products are not subject to an exemption from notification and assessment.)
 Yes No
- Is the new chemical prohibited or restricted for use as a cosmetic or in cosmetic products in the European Union or the United States of America?
(Note: Chemicals prohibited or restricted are not subject to an exemption from notification and assessment.)
 Yes No
- Does the new chemical or cosmetic products containing the chemical meet the requirements of relevant Commonwealth, State and Territory laws?
(Note: Chemicals are not subject to an exemption unless all such laws are complied with.)
 Yes No

- Where the concentration of the new chemical in a cosmetic product exceeds 1%, is information available that the chemical will be safe for use by potentially high-risk groups (including infants, the elderly, and those predisposed to hypersensitivity or allergic conditions) consistent with the intended use pattern of the cosmetic product?
 Yes No Not applicable as will not exceed 1%
- Is the Material Safety Data Sheet for the chemical / cosmetic product attached?
 Yes No
- Is the label for the chemical / cosmetic product attached?
 Yes No

State reasons why the introduction of the new chemical should not pose an unreasonable risk to the following:
 Attach additional documentation if insufficient room.

(i) occupational health and safety

(ii) public health

(iii) the environment

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.

Is your company a small business with less than 20 employees? YES NO

If yes, please provide an estimate of the time taken to complete this form:

hrs mins