



Australian Government

Gazette

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Notification and Assessment Scheme - NICNAS

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Australian Government

Department of Health and Ageing
NICNAS

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) commenced on 17 July 1990. As required by Section 5 of the Act, a Chemical Gazette is published on the first Tuesday in any month or on any days prescribed by the regulations.

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1 PUBLIC CONSULTATION ON IMPROVING ACCESS TO INFORMATION TO SUPPORT INTRODUCERS OF NICNAS ASSESSED CHEMICALS TO NOTIFY THE DIRECTOR OF CHANGED CIRCUMSTANCES – CLOSING 29 FEBRUARY 2012

Purpose

To inform stakeholders that NICNAS is seeking public comment on a proposal to provide introducers of NICNAS assessed chemicals with improved access to information to facilitate fulfilling obligations to notify the Director of NICNAS when a significant change in circumstances occurs relative to the original assessment. Comments should be submitted by 29 February 2012.

Background

The *Industrial Chemicals (Notification and Assessment Act) 1989* (the Act) specifies circumstances in which secondary notification of a previously assessed chemical may be required. This relates to significant changes in the risks posed by the chemical due to circumstances that have occurred since the chemical was first assessed, for example, a chemical that was imported at the time of assessment, and then is subsequently manufactured locally, poses a potential occupational health and safety risk that would not have been assessed. To enable a determination by introducers as to whether such changes are significant, introducers need to know the circumstances under which the chemical was first assessed.

However, approximately a high proportion of assessment reports for new chemicals published on the NICNAS web site do not contain the identity of the assessed chemical as an application for exemption from publication has been submitted and accepted. The record for the chemical on the Australian Inventory of Chemical Substances (AICS) contains the chemical name and number and indicates that the chemical has been assessed, however it is often difficult to know the circumstances of that assessment. Linking the AICS record (which contains the proper chemical name and number) directly to the public assessment (which often only contains a trade name) may undermine the confidentiality of the information exempted from publication in some circumstances.

Proposal

NICNAS is therefore proposing to provide information on the AICS records of previously assessed chemicals to aid potential introducers in fulfilling their obligations under the Act. For chemicals where the public assessment report contains the proper chemical name (ie it has not been exempted from publication), it is proposed that there would be a direct link from the AICS record to the assessment report taking the form of a hyperlink in the AICS record. For other chemicals, certain particulars are not published and the identity of the chemical cannot normally be found in the published report. In these cases, sufficient information will be provided on the AICS record for an introducer to determine the circumstances under which a secondary notification may be required without linking directly to the public assessment report.

NICNAS is consulting on this proposal to provide introducers of previously assessed chemicals access to information regarding conditions under which secondary

notification may be required, to assist them to better meet their obligations under the Act with regard to secondary notification. The proposal contains a number of points for discussion on the above access issues, noting that introducers may not be fully aware of how their chemicals are utilised by downstream users. This public consultation document is published on the consultation section of the NICNAS website at <http://www.nicnas.gov.au/Consultations.asp> and on the Australian Government Business website at <https://consultation.business.gov.au/consultation>.

Submissions

Written submissions can be provided to:

Dr Bill Diver

Reform Section

NICNAS

Phone 02 8577 8862

Fax: 02 8577 8888

e-mail: bill.diver@nicnas.gov.au

Submissions should be received by **29 February 2012**.

All submissions will be published on the NICNAS website. If you wish to have material exempt from publication, you must provide a reason for claiming confidentiality and clearly mark any confidential material contained within your submission.

2 NICNAS HAS RELEASED A DRAFT COST RECOVERY IMPACT STATEMENT (CRIS) AND INVITES FEEDBACK FROM STAKEHOLDERS

The purpose of the CRIS is:

- To transparently demonstrate compliance with the Government's Cost Recovery and Guidelines; and
- To outline proposed changes to the existing cost recovery arrangements based on review outcomes.
- Key proposed changes include:
 - better alignment of fees with costs associated with delivering the services;
 - transition to a four tiered registration structure to provide for more equitable charging arrangements;
 - arrangements to recover the cost of the first stage of the accelerated assessment and prioritisation of existing chemicals.

[Draft Cost Recovery Impact Statement](#) (CRIS) (PDF 663 Kb)

[Draft CRIS - At a Glance](#) (PDF 78 Kb)

STAKEHOLDER CONSULTATION

Closing date: **30 November 2011**

Written submissions

The Draft CRIS is open for written comments until 5pm on 30th November.

Please submit your feedback along with the [Consultation Submission Form](#) to:

E-mail: CRIS@nicnas.gov.au

Mail: CRIS
NICNAS
PO Box 58
Sydney NSW 2001
Fax: 02 8577 8888

Note: all submissions will be published on the NICNAS website. If you wish to have any material exempt from publication, you must provide a reason for claiming confidentiality in the Consultation Submission Form and clearly mark any confidential material contained within the submission.

Public meetings

Public consultation workshops have been scheduled for:

- **Sydney** – Friday 11 November 2011
- **Melbourne** – Monday 14 November 2011

Meetings in other states will be determined by demand.

If you wish to attend a meeting, please complete the [Expression of Interest Form](#) to register your interest and to receive information on venues and times.

3 PUBLIC SUBMISSIONS TO THE REVIEW OF THE NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

The Commonwealth Department of Health and Ageing and Department of Finance and Deregulation are inviting interested parties and individuals to provide written submissions to the review of the National Industrial Chemicals Notification and Assessment Scheme.

The review, part of a Better Regulation Ministerial Partnership between the Minister for Finance and Deregulation and the Minister for Health and Ageing, will investigate how the regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry and public health and environmental outcomes. The review will have particular regard to the recommendations of the Productivity Commission Research Report: *Chemicals and Plastics Regulation*, July 2008 and relevant commitments made under the Council of Australian Governments' *Seamless National Economy National Partnership Agreement*, 2009.

Written submissions should address:

- the role and functions of NICNAS as set out in the *Industrial Chemicals (Notification and Assessment) Act 1989* and the extent to which they adequately reflect stakeholder expectations and international best practice, having regard to the broader context of chemicals regulation in Australia;
- the governance and consultation arrangements of NICNAS and the extent to which they support the effective delivery of NICNAS's functions;
- the efficiency and effectiveness of NICNAS's operating arrangements and business processes, with particular regard to the protection of human and environmental health, the management of risk, and compliance costs for business; and
- any implications for and constraints on, transferring risk management functions to alternate agencies.

Brief case studies and/or supporting data that illustrate/clarify key issues raised should be provided.

Submissions must be received by the Department of Health and Ageing by **5pm, Wednesday 14 December 2011**.

E-mail: NICNAS.review@health.gov.au

Mail: NICNAS Review
Department of Health and Ageing
MDP 88
GPO Box 9848
CANBERRA ACT 2609

Submissions will be made public and shared with relevant Commonwealth agencies and the consultant engaged to undertake the review. Submissions, or parts thereof, that are intended to remain confidential should be clearly marked as such and justifications

provided. Submitters should be aware that confidential submissions may still be subject to access under Freedom of Information law.

For more information on the review please see:

http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp_nicnas_review.htm

4 PRIORITY EXISTING CHEMICAL ASSESSMENT REPORT FOR DIETHYL PHTHALATE

Diethyl phthalate (DEP) has been assessed as a priority existing chemical (PEC) under the Commonwealth *Industrial Chemicals (Notification and Assessment) Act, 1989* (the Act), as amended. No requests to vary the report were received during the public comment period. Under section 60F of the Act, the final assessment report for DEP (PEC Report No. 33) is now publicly available from the NICNAS website at: <http://www.nicnas.gov.au/publications/CAR/PEC.asp>.

An information sheet on DEP is also available at: http://nicnas.gov.au/Publications/Information_Sheets/Existing_Chemicals_Information_Sheets.asp.

The publication of this report revokes the declaration of diethyl phthalate as a priority existing chemical under section 62 of the Act.

The report will also be available (free) on request to:
NICNAS
GPO Box 58
Sydney NSW 2001
Australia

Toll free 1800 638 528 or may be requested by fax: (02) 8577 8888 or e-mail info@nicnas.gov.au.

5 NOTICE OF PROPOSED TRANSFER TO THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES OF CERTAIN COSMETIC INGREDIENTS IN PRODUCTS PREVIOUSLY REGULATED BY THE THERAPEUTIC GOODS ADMINISTRATION (TGA)

In accordance with sections 15AA(1) and 15AA(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) the Director proposes to include the chemicals listed in Table 1 in the public section of the Australian Inventory of Chemical Substances (AICS) for cosmetic use only, along with certain conditions of use. These chemicals are currently regulated by NICNAS as new chemicals.

Background

The regulatory responsibility for chemicals in certain cosmetic products that were previously regulated by the Therapeutic Goods Administration (TGA) was transferred to NICNAS under the cosmetic reforms in 2007. As a result of the transfer, those chemicals not already on the AICS were recognised as new industrial chemicals and therefore required notification and assessment as new chemicals before being imported or manufactured, and/or are subject to post market reporting.

The intent of the cosmetic reform was that the transfer of responsibility would occur whilst maintaining health and safety standards and without posing unnecessary burden on industry. Therefore, it was envisioned that those chemicals not already on the AICS would be recognised as existing industrial chemicals by listing them on the public AICS subject to controls that are not less stringent than those previously required by the TGA.

A mechanism to list certain chemicals on the public section of the AICS that were previously regulated by another Commonwealth regulator came into force on 27 September 2011. This occurred following modification of the Act by the Industrial Chemicals (Notification and Assessment) Amendment (Inventory) Bill 2011. NICNAS published a notice in the October 2011 *Chemical Gazette* detailing the resulting changes to the Act and how NICNAS will be implementing those changes.

Requirements for proposing to list chemicals on the AICS

In order to be considered by the Director, NICNAS for possible transfer onto the AICS under the cosmetic reforms, chemicals need to meet two sets of criteria.

The first set of criteria is legislated under Section 15AA of the Act, and applies to any group of chemicals proposed by the Director, NICNAS for listing on the AICS as a result of regulatory reform. These criteria are:

- the chemical was previously regulated by another Commonwealth regulator, or was in a product regulated by another Commonwealth regulator; and
- there is no NICNAS assessment certificate in force for the chemical; and
- the chemical is currently in use in Australia.

In addition, consideration must be given as to whether the chemical poses an unreasonable risk to occupational health and safety, public health or the environment.

The second set of criteria is specific to the particular circumstances of the cosmetic reforms. These criteria are:

- the chemical was an ingredient in at least one of the products that were regulated under TGA; and
- the product(s) meets the definition of a cosmetic under the Act and any requirements in the *Cosmetic Standard 2007*; and
- the product(s) was in commerce at some time during the three-year period preceding the cosmetic reforms, that is, September 2004 to September 2007; and
- the chemical is not currently listed on the AICS.

To ascertain which chemicals are to be considered for transfer, NICNAS undertook a call for information as outlined in a notice in the February 2010 *Chemical Gazette*. The call contained various eligibility criteria which needed to be fulfilled in order to be considered for possible transfer. NICNAS further clarified the identity of the nominated chemicals through a request for information in the December 2010 *Chemical Gazette*. At the close of nominations on 2 May 2010, NICNAS received nominations for 179 unique chemicals or substances from 14 businesses. As a result of clarifying identity information and applying the two sets of criteria, NICNAS is actively considering 61 chemicals or substances for possible listing on the AICS.

At this time the Director, NICNAS, proposes the listing of a group of 34 chemicals for use in cosmetic products and in accordance with the proposed controls. The specific chemicals or substances proposed for listing are detailed in Table 1.

The additional 27 chemicals are still being considered and further advice will be provided shortly.

Proposal

In accordance with sections 15AA(1) and 15AA(2) of the Act, the Director proposes to include the 34 chemicals and associated conditions of use listed in Table 1 in the public section of the AICS for cosmetic use only.

Section 15AA(5)(e) requires the Director, NICNAS, to state the reasons why these chemicals are proposed for listing on the AICS. These reasons are:

- listing these chemicals on the AICS fulfils the intent of the cosmetic reforms to recognise certain chemicals in cosmetic products previously regulated by the TGA as industrial chemicals whilst maintaining health and safety standards and without posing unnecessary burden on industry;
- the chemicals fulfil the eligibility criteria specific to the cosmetics reforms and legislated criteria for listing as described in Section 15AA(1);
- although these chemicals have not been subject to a full assessment by NICNAS, the Director considers that, when used in cosmetic products only and in accordance with the specified controls, these chemicals do not pose an unreasonable risk to occupational health and safety, public health and the environment.

This notice is published in the Chemical Gazette in accordance with section 15AA(4) of the Act.

Statements about the Proposal

For any of the chemicals listed in Table 1, in accordance with section 15AA(5)(g) of the Act, a person may give a statement to the Director, within 28 days of the date of publication of this notice, giving reasons why the person objects to the Director's proposal.

Persons who wish to make a statement in relation to this proposal should do so in writing by close of business (5.30pm) 29 November 2011. The statement should address specific chemicals (ie not be a generic statement) and provide relevant argument relating to the stated reasons given in this notice as to why the Director, NICNAS, is proposing to list the chemical on the AICS.

Statements should be provided to the contact officer detailed below.

Next Steps

In accordance with section 15AA(7) of the Act, once the 28 days have passed, the Director will, having regard to any statements received, make a final decision to include or not include any chemical and associated conditions of use on the AICS for which a statement has been received.

Under section 15AA(8), the Director will then publish a notice in the Chemical Gazette listing any final decisions that have been made. An application can be made to the Administrative Appeals Tribunal (AAT) for a review of a final decision by the Director. Where a statement has been made, the Director will publish a decision after the Christmas holiday period to minimise disruption to the process.

Under Section 15AB, after at least 28 days has passed since the publication of the Director's decision and an application to the AAT has not been made, or with regard to the finalisation of any appeal that has been made to the AAT, the Director must include the chemical in the AICS, along with any conditions of use, and give notice of this action in the Chemical Gazette.

Following these processes, the relevant chemical will be regarded as an existing chemical within the context of the conditions of use, and so can be introduced into Australia without pre market notification or post market reporting to NICNAS if it is used in accordance with the conditions of use. Under Section 15A of the Act, failure to comply with these conditions of use is an offence, and will require the chemical to be notified to NICNAS as a new industrial chemical, unless an exemption applies.

Arrangements for annually reporting of chemicals proposed for listing on the AICS

The chemicals in Table 1 proposed for transfer to the AICS under section 15AA of the Act are currently considered new chemicals and so are subject to the premarket notification and assessment requirements and/or post market reporting obligations

under Part 3 Division 1 of the Act. These reporting obligations currently apply for these chemicals, however if the chemicals are ultimately transferred to the AICS, annual reports will no longer be required if used in cosmetic products under the specified conditions of use.

In order to reduce the impact of the uncertainty on business about the annual reporting arrangements for 2011-12 while the chemicals are being proposed for transfer to the AICS, the Director, NICNAS, has decided not to seek reports under s21AA for the chemicals in Table 1 that are introduced as new chemicals for cosmetic use within the specified conditions of use during the current registration year between 1 September 2011 and 31 August 2012.

This decision is described in more detail in a separate notice in the November 2011 *Chemical Gazette* for ease of reference.

If you require further information please contact:

Dr Bill Diver
Reform Section
NICNAS
Phone 02 8577 8862
Fax: 02 8577 8888

e-mail: bill.diver@nicnas.gov.au

GPO Box 58
Sydney
NSW 2110

Table 1 Chemicals proposed for inclusion in the public section of the Australian Inventory of Chemical Substances under Sections 15AA(1) and 15AA(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989*

INCI name/AAN	CAS name	CAS No.	Conditions of Use
Acetyl trifluoromethylphenyl valylglycine	Glycine, N-Acetyl-N-[3-(trifluoromethyl)phenyl]valyl-	379685-96-8	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.5%. It is not to be included in topical products intended for use in the eye.
Aminopropyl Ascorbyl Phosphate	L-Ascorbic acid, 2-(3-aminopropyl hydrogen phosphate) (9CI)	220644-17-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1%. It is not to be included in topical products intended for use in the eye.
Arginine ferulate	L-Arginine, 3-(4-hydroxy-3-methoxyphenyl)-2-propenoate (1:1)	950890-74-1*	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.05% and is not to be used in topical products intended for use in the eye.
Ascorbyl Tetraisopalmitate (AAN: Tetrahexyldecyl ascorbate)	L-Ascorbic acid, tetrakis(2-hexyldecanoate)	183476-82-6	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 1%. It is not to be included in topical products intended for use in the eye.
Ascorbyl Tocopheryl Maleate	L-Ascorbic acid, 2-[(2R)-3,4-dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-2H-1-benzopyran-6-yl (2Z)-2-butenedioate], compd. with 1-propanol (1:1) (9CI)	488109-67-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.0575%. It is not to be included in topical products intended for use in the eye.
Benzylidene camphor sulfonic acid	Benzenesulfonic acid, 4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]-	56039-58-8	For Cosmetic Use Only. For dermal use only. The concentration of this ingredient as an active sunscreen ingredient is 6% (as acid).
Butylene glycol dicaprylate/dicaprate	Decanoic acid, mixed diesters with 1,2-butanediol and octanoic acid	686341-29-7	For Cosmetic Use Only. To be used an excipient ingredient in dermal products only. The concentration is not to exceed 10% and this ingredient is not intended for use in the eye.
C10-30 Cholesterol/Lanosterol Lanolin ester	Fatty acids, C10-30, esters with lanolin alcs.	97862-72-1	For Cosmetic Use Only.
Ceramide 1	9,12-Octadecadienoic acid (9Z,12Z)-, 30-[[[(1S,2R,3E)-2-hydroxy-1-(hydroxymethyl)-3-heptadecen-1-yl]amino]-30-oxotriacontyl ester	156170-27-3	For Cosmetic Use Only.

Ceramide 2	Octadecanamide, N-[(1S,2R)-2-hydroxy-1-(hydroxymethyl)heptadecyl]-	2304-80-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.05%. It is not to be included in topical products intended for use in the eye.
Ceramide 3	Octadecanamide, N-[(1S,2S,3R)-2,3-dihydroxy-1-(hydroxymethyl)heptadecyl]-	34354-88-6	For Cosmetic Use Only.
Decarboxy Carnosine HCl	Propanamide, 3-amino-N-[2-(1H-imidazol-5-yl)ethyl]-, hydrochloride (1:2)	57022-38-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.05%. It is not to be included in topical products intended for use in the eye.
Dipotassium glycyrrhizate	α -D-Glucopyranosiduronic acid, (3 β ,20 β)-20-carboxy-11-oxo-30-norolean-12-en-3-yl-2-O- β -D-glucopyranuronosyl-, potassium salt (1:2)	68797-35-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.2%. It is not to be included in topical products intended for use in the eye.
Disodium Phenyl Dibenimidazole Tetrasulfonate	1H-Benzimidazole-4,6-disulfonic acid, 2,2'-(1,4-phenylene)bis-, disodium salt	180898-37-7	For Cosmetic Use Only. Approved as an active ingredient (UV filter) for use in sunscreen preparations. The concentration level is not to exceed 10% in the final finished product.
Disteardimonium hectorite	Quaternary ammonium compounds, di-C16-18-alkyldimethyl, salts with hectorite	94891-31-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 2%. It is not to be included in topical products intended for use in the eye.
Erythulose	2-Butanone, 1,3,4-trihydroxy	40031-31-0	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 2%. It is not to be included in topical products intended for use in the eye. There was no data submitted examining the effect of Erythulose on the eye, which does not allow for an assessment of its potential ocular irritancy.
Glucosylrutin	4H-1-Benzopyran-4-one, 3-[(O-6-deoxy-.alpha.-L-mannopyranosyl-(1.fwdarw.6)-O-[.alpha.-D-glucopyranosyl-(1.fwdarw.4)]-.beta.-D-glucopyranosyl)oxy]-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-	130603-71-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1%. It is not to be included in topical products intended for use in the eye.

Glyceryl polyacrylate	2-Propenoic acid, homopolymer, ester with 1,2,3-propanetriol	104365-75-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.15%. It is not to be included in topical products intended for use in the eye.
Methyl gluceth-20	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with methyl .beta.-d-glucopyranoside (4:1)	68239-42-9	For Cosmetic Use Only.
Palmitoyl oligopeptide	L-Lysine, N-(1-oxohexadecyl)glycyl-L-histidyl-	147732-56-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.002% and is not intended for use in the eye.
Palmitoyl Pentapeptide-4 (was called Palmitoyl Pentapeptide-3)	L-Serine, N2-(1-oxohexadecyl)-L-lysyl-L-threonyl-L-threonyl-L-lysyl-	214047-00-4	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.0005% and is not intended for use in the eye.
Phytosphingosine	1,3,4-Octadecanetriol, 2-amino-, (2S, 3S, 4R)-	554-62-1	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Polyglyceryl-3 methylglucose distearate	alpha-D-glycopyranoside, methyl, monoether with triglycerol, dioctadecanoate	157175-98-9	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 6.0% and is not to be used in topical products intended for use in the eye.
PPG-20 Methyl Glucose Ether	Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-hydro-.omega.-hydroxy-, ether with methyl .beta.-d-glucopyranoside (4:1)	61849-72-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.5% and is not to be used in topical products intended for use in the eye.
Retinyl Linoleate	Retinol, 15-[(9Z,12Z)-9,12-octadecadienoate]	631-89-0	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Sodium carbomer	Carbomer, sodium salt	73298-57-4	For Cosmetic Use Only.
Sodium Carboxymethyl Betaglucan	.beta.-D-Glucan, (1.fwdarw.3)-, carboxymethyl ether, sodium salt	9050-93-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.005% and is not to be used in topical products intended for use in the eye.
Sodium Carboxymethyl Dextran	Dextran, carboxymethyl ether, sodium salt	39422-83-8	For Cosmetic Use Only.
Sodium DNA	DNA, sodium complexes	438545-06-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Sodium Lauroyl Lactylate	Dodecanoic acid, 2-(1-carboxyethoxy)-1-methyl-2-oxoethyl ester, sodium salt	13557-75-0	For Cosmetic Use Only.
Sodium stearyl glutamate	L-Glutamic acid, N-(1-oxooctadecyl)-, monosodium salt	38517-23-6	For Cosmetic Use Only. Approved for dermal use only as an excipient ingredient. The concentration is not to exceed 2.5% in the finished product and is not be used in topical preparations intended for the eye.

Tetrahydroferuloylmethane	3,5-Heptanedione, 1,7-bis(4-hydroxy-3-methoxyphenyl)-	36062-04-1	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Tridecyl salicylate	Benzoic acid, 2-hydroxy-, tridecyl ester	19666-16-1	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 5% and is not to be used in topical products intended for use in the eye.
Trioctyldodecyl citrate	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, 1,2,3-tris(2-octyldodecyl) ester	126121-35-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 12% and is not to be used in topical products intended for use in the eye.

6 ANNUAL REPORTING ARRANGEMENTS FOR NEW INDUSTRIAL COSMETIC CHEMICALS PROPOSED FOR TRANSFER TO THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES

This notice is directed to those persons or companies with an interest in chemicals in products affected by the cosmetic reforms, i.e. those involved with chemicals in products previously regulated by the Therapeutic Goods Administration (TGA), that are now regulated by NICNAS as cosmetics.

This notice applies ONLY:

- To chemicals in certain products that were previously regulated under the TGA and, as a result of the introduction of the reforms to the cosmetic-therapeutic interface in September 2007, are now regulated under NICNAS, and
- the product contains an ingredient(s) not listed on the Australian Inventory of Chemical Substances (AICS).

This notice does not apply to:

- chemicals in other products regulated under the TGA, i.e. categories that were not affected by the cosmetic reforms, and remain therapeutic.
- chemical ingredients already listed on the Australian Inventory of Chemical Substances (AICS).

Purpose

To inform introducers that the chemicals listed at Table 1 which are proposed for transfer to the AICS under sections 15AA(1) and 15AA(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) will not be required to be annually reported in the 2011-12 reporting period whilst being introduced as new chemicals.

Background

Following the reforms to therapeutic-cosmetic interface that occurred in 2007, NICNAS published a notice in the February 2010 Chemical Gazette, entitled *Call for Information on Chemicals in Cosmetic Products Previously Regulated as Therapeutics*. The purpose of the notice was to seek nominations from industry of chemicals in certain cosmetic products previously regulated by the TGA, which are currently not on the AICS, and which met certain criteria, that they wished to have recognised as an existing industrial chemical by listing onto the AICS.

The *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) was amended on 27 September 2011 to create a new mechanism to place onto AICS chemicals that were previously regulated by another Commonwealth regulator (see a notice in the October 2011 Chemical Gazette explaining this amendment). As a result, NICNAS is now able to propose certain cosmetic chemicals for listing on the AICS under the new mechanism.

At the close of nominations on 2 May 2010, NICNAS had received nominations for 179 unique chemicals or substances from 14 businesses. Of these, 118 do not meet the criteria required for proposal to transfer to the inventory under sections 15AA(1) of the Act and under criteria specific to the cosmetic reforms. The remaining 61 chemicals are under active consideration and of these, an initial 34 have been proposed for transfer to the public section of AICS. See the separate notice in the November 2011 *Chemical Gazette* for more information on the criteria and the legislated process for the listing of chemicals on the AICS under this new mechanism. NICNAS is still considering the remaining 27 chemicals, and further advice will be provided shortly.

The chemicals currently proposed for transfer to the AICS and which are subject to this notice are listed in Table 1.

Arrangements for annually reporting of these chemicals proposed for listing on the AICS

The chemicals in Table 1 proposed for transfer to the AICS under section 15AA of the Act are currently considered new chemicals and so are subject to the premarket notification and assessment requirements and/or post market reporting obligations under Part 3 Division 1 of the Act. These reporting obligations currently apply for these chemicals, however if the chemicals are ultimately transferred to the AICS, annual reports will no longer be required in so far as they relate to the use of the chemical in cosmetic products under the specified conditions of use.

In order to reduce the impact of the uncertainty on business about the annual reporting arrangements for 2011-12 while the chemicals are being proposed for transfer to the AICS, the Director, NICNAS, has decided not to seek reports under s21AA for the chemicals in Table 1 that are introduced as new chemicals for cosmetic use within the specified conditions of use during the current registration year between 1 September 2011 and 31 August 2012.

Please note that the above arrangements do not apply to chemicals introduced during the 2010-11 registration year which were required to be reported to the Director, NICNAS by 28 September 2011. Nor will these arrangements continue to apply to any chemical in Table 1 that is not ultimately listed on the AICS under this new mechanism and that is introduced past the current registration year finishing 31 August 2012.

Table 1 Chemicals for which NICNAS will not seek annual reports under Section 21AA of the *Industrial Chemicals (Notification and Assessment) Act 1989*, and which are proposed for inclusion in the public section of the Australian Inventory of Chemical Substances under Sections 15AA(1) and 15AA(2)

INCI name/AAN	CAS name	CAS No.	Conditions of Use
Acetyl trifluoromethylphenyl valylglycine	Glycine, N-Acetyl-N-[3-(trifluoromethyl)phenyl]valyl-	379685-96-8	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.5%. It is not to be included in topical products intended for use in the eye.
Aminopropyl Ascorbyl Phosphate	L-Ascorbic acid, 2-(3-aminopropyl hydrogen phosphate) (9CI)	220644-17-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1%. It is not to be included in topical products intended for use in the eye.
Arginine ferulate	L-Arginine, 3-(4-hydroxy-3-methoxyphenyl)-2-propenoate (1:1)	950890-74-1*	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.05% and is not to be used in topical products intended for use in the eye.
Ascorbyl Tetraisopalmitate (AAN: Tetrahexyldecyl ascorbate)	L-Ascorbic acid, tetrakis(2-hexyldecanoate)	183476-82-6	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 1%. It is not to be included in topical products intended for use in the eye.
Ascorbyl Tocopheryl Maleate	L-Ascorbic acid, 2-[(2R)-3,4-dihydro-2,5,7,8-tetramethyl-2-[(4R,8R)-4,8,12-trimethyltridecyl]-2H-1-benzopyran-6-yl (2Z)-2-butenedioate], compd. with 1-propanol (1:1) (9CI)	488109-67-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.0575%. It is not to be included in topical products intended for use in the eye.
Benzylidene camphor sulfonic acid	Benzenesulfonic acid, 4-[(4,7,7-trimethyl-3-oxobicyclo[2.2.1]hept-2-ylidene)methyl]-	56039-58-8	For Cosmetic Use Only. For dermal use only. The concentration of this ingredient as an active sunscreen ingredient is 6% (as acid).
Butylene glycol dicaprylate/dicaprate	Decanoic acid, mixed diesters with 1,2-butanediol and octanoic acid	686341-29-7	For Cosmetic Use Only. To be used an excipient ingredient in dermal products only. The concentration is not to exceed 10% and this ingredient is not intended for use in the eye.
C10-30 Cholesterol/Lanosterol Lanolin ester	Fatty acids, C10-30, esters with lanolin alcs.	97862-72-1	For Cosmetic Use Only.
Ceramide 1	9,12-Octadecadienoic acid (9Z,12Z)-, 30-[[[(1S,2R,3E)-2-hydroxy-1-(hydroxymethyl)-3-heptadecen-1-yl]amino]-30-oxotriacontyl ester	156170-27-3	For Cosmetic Use Only.

Ceramide 2	Octadecanamide, N-[(1S,2R)-2-hydroxy-1-(hydroxymethyl)heptadecyl]-	2304-80-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.05%. It is not to be included in topical products intended for use in the eye.
Ceramide 3	Octadecanamide, N-[(1S,2S,3R)-2,3-dihydroxy-1-(hydroxymethyl)heptadecyl]-	34354-88-6	For Cosmetic Use Only.
Decarboxy Carnosine HCl	Propanamide, 3-amino-N-[2-(1H-imidazol-5-yl)ethyl]-, hydrochloride (1:2)	57022-38-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.05%. It is not to be included in topical products intended for use in the eye.
Dipotassium glycyrrhizate	α -D-Glucopyranosiduronic acid, (3 β ,20 β)-20-carboxy-11-oxo-30-norolean-12-en-3-yl-2-O- β -D-glucopyranuronosyl-, potassium salt (1:2)	68797-35-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.2%. It is not to be included in topical products intended for use in the eye.
Disodium Phenyl Dibenimidazole Tetrasulfonate	1H-Benzimidazole-4,6-disulfonic acid, 2,2'-(1,4-phenylene)bis-, disodium salt	180898-37-7	For Cosmetic Use Only. Approved as an active ingredient (UV filter) for use in sunscreen preparations. The concentration level is not to exceed 10% in the final finished product.
Disteardimonium hectorite	Quaternary ammonium compounds, di-C16-18-alkyldimethyl, salts with hectorite	94891-31-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 2%. It is not to be included in topical products intended for use in the eye.
Erythulose	2-Butanone, 1,3,4-trihydroxy	40031-31-0	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 2%. It is not to be included in topical products intended for use in the eye. There was no data submitted examining the effect of Erythulose on the eye, which does not allow for an assessment of its potential ocular irritancy.
Glucosylrutin	4H-1-Benzopyran-4-one, 3-[(O-6-deoxy-.alpha.-L-mannopyranosyl-(1.fwdarw.6)-O-[.alpha.-D-glucopyranosyl-(1.fwdarw.4)]-.beta.-D-glucopyranosyl)oxy]-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-	130603-71-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1%. It is not to be included in topical products intended for use in the eye.

Glyceryl polyacrylate	2-Propenoic acid, homopolymer, ester with 1,2,3-propanetriol	104365-75-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.15%. It is not to be included in topical products intended for use in the eye.
Methyl gluceth-20	Poly(oxy-1,2-ethanediyl), .alpha.-hydro-.omega.-hydroxy-, ether with methyl .beta.-d-glucopyranoside (4:1)	68239-42-9	For Cosmetic Use Only.
Palmitoyl oligopeptide	L-Lysine, N-(1-oxohexadecyl)glycyl-L-histidyl-	147732-56-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.002% and is not intended for use in the eye.
Palmitoyl Pentapeptide-4 (was called Palmitoyl Pentapeptide-3)	L-Serine, N2-(1-oxohexadecyl)-L-lysyl-L-threonyl-L-threonyl-L-lysyl-	214047-00-4	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.0005% and is not intended for use in the eye.
Phytosphingosine	1,3,4-Octadecanetriol, 2-amino-, (2S, 3S, 4R)-	554-62-1	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Polyglyceryl-3 methylglucose distearate	alpha-D-glycopyranoside, methyl, monoether with triglycerol, dioctadecanoate	157175-98-9	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 6.0% and is not to be used in topical products intended for use in the eye.
PPG-20 Methyl Glucose Ether	Poly[oxy(methyl-1,2-ethanediyl)], .alpha.-hydro-.omega.-hydroxy-, ether with methyl .beta.-d-glucopyranoside (4:1)	61849-72-7	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.5% and is not to be used in topical products intended for use in the eye.
Retinyl Linoleate	Retinol, 15-[(9Z,12Z)-9,12-octadecadienoate]	631-89-0	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Sodium carbomer	Carbomer, sodium salt	73298-57-4	For Cosmetic Use Only.
Sodium Carboxymethyl Betaglucan	.beta.-D-Glucan, (1.fwdarw.3)-, carboxymethyl ether, sodium salt	9050-93-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.005% and is not to be used in topical products intended for use in the eye.
Sodium Carboxymethyl Dextran	Dextran, carboxymethyl ether, sodium salt	39422-83-8	For Cosmetic Use Only.
Sodium DNA	DNA, sodium complexes	438545-06-3	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Sodium Lauroyl Lactylate	Dodecanoic acid, 2-(1-carboxyethoxy)-1-methyl-2-oxoethyl ester, sodium salt	13557-75-0	For Cosmetic Use Only.

Sodium stearoyl glutamate	L-Glutamic acid, N-(1-oxooctadecyl)-, monosodium salt	38517-23-6	For Cosmetic Use Only. Approved for dermal use only as an excipient ingredient. The concentration is not to exceed 2.5% in the finished product and is not be used in topical preparations intended for the eye.
Tetrahydrodiferuloylmethane	3,5-Heptanedione, 1,7-bis(4-hydroxy-3-methoxyphenyl)-	36062-04-1	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.1% and is not to be used in topical products intended for use in the eye.
Tridecyl salicylate	Benzoic acid, 2-hydroxy-, tridecyl ester	19666-16-1	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 5% and is not to be used in topical products intended for use in the eye.
Trioctyldodecyl citrate	1,2,3-Propanetricarboxylic acid, 2-hydroxy-, 1,2,3-tris(2-octyldodecyl) ester	126121-35-5	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 12% and is not to be used in topical products intended for use in the eye.

7 NEW DATA ON 2-ANTHRACENESULFONIC ACID, 4-[[4-(ACETYLMETHYLAMINO)-2-SULFOPHENYL]AMINO]-1-AMINO-9,10-DIHYDRO-9,10-DIOXO-, DISODIUM SALT (CAS 72152-54-6)

2-Anthracenesulfonic acid, 4-[[4-(acetylmethylamino)-2-sulfophenyl]amino]-1-amino-9,10-dihydro-9,10-dioxo-, disodium salt (CAS 72152-54-6) was assessed by NICNAS as a limited notification and a public report published. The chemical is now listed on AICS. A company recently advised NICNAS of the intention to import a fully compounded, consumer packed and labelled washing machine powder containing 2-Anthracenesulfonic acid, 4-[[4-(acetylmethylamino)-2-sulfophenyl]amino]-1-amino-9,10-dihydro-9,10-dioxo-, disodium salt (CAS 72152-54-6) at a concentration below 1%. The proposed import volume is < 1 Kg.

Based on the available toxicological data previously assessed by NICNAS, the chemical was not classified as a hazardous substance under the *Approved Criteria for Classifying Hazardous Substances*.

The chemical was considered not to pose a concern to occupational health and safety, public health and the environment based on its reported use pattern.

No new toxicity data have been provided.

The proposed new use of 2-Anthracenesulfonic acid, 4-[[4-(acetylmethylamino)-2-sulfophenyl]amino]-1-amino-9,10-dihydro-9,10-dioxo-, disodium salt in washing machine powder at low concentrations and volume would not significantly increase occupational, public or environmental exposures, and therefore does not change the conclusions of the original risk assessment. On this basis, NICNAS concludes that a secondary notification is not required at this time under Section 65 of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

8 NEW CHEMICALS FULL PUBLIC REPORTS

Reference Number	Applicant	Chemical or Trade Name	Hazardous Substance	Introduction Volume (per annum)	Use
PLC/998*	DKSH Australia Pty Ltd	Polymer in Chemipearl	No	≤10 tonnes p/a	Component of paints & printing inks
STD/1391*	Sylan Chemical Co Inc.	Hyperform HPR-803	ND	≤100 tonnes p/a	Component of plastic articles
LTD/1550*	Karpelo Holdings Pty Ltd	Aliphatic Urethane Acrylate Polymer	ND	≤15 tonnes p/a	Component of industrial coatings, adhesives & inks
PLC/990*	Hewlett Packard Australia Pty Ltd	Polymer in CN 623 Series	No	<1 tonne p/a	Component of printer ink in inkjet printer cartridges
LTD/1532*	ResChem Technologies Pty Ltd	Polymer in NeoCryl AF-10	ND	≤10 tonnes p/a	Component of anti-graffiti coatings for concrete & metal for industrial use

N.D.: not determined; insufficient data available to effect a health effects classification under Approved Criteria [NOHSC:1008(2004)]

***Select link to view Full Public Report**

9 ACCESS TO FULL PUBLIC REPORT

NICNAS publishes a Full Public Report for each new chemical assessed. These reports are available for inspection at our NICNAS office by appointment only at Level 7, 260 Elizabeth St SURRY HILLS NSW 2010.

Reports can also be viewed and downloaded free of charge from our website at <http://www.nicnas.gov.au/>. Copies of these reports may also be requested, free of charge, by contacting the Administration Section of NICNAS by phone: (02) 8577 8800 or fax: (02) 8577 8888.

10 EARLY INTRODUCTION PERMITS FOR NON-HAZARDOUS INDUSTRIAL CHEMICALS

The permits listed in Table 1 were issued to import or manufacture the following chemicals prior to the issue of their respective assessment certificates under section 30A of the Act.

Table 1**Early Introduction Permits**

PERMIT NUMBER	COMPANY NAME	CHEMICAL OR TRADE NAME	USE
777	PPG Industries Australia Pty Limited	Polymer in Synolac 1001	Component of coatings

11 LOW VOLUME CATEGORY PERMITS

The permits listed in Table 2 were issued to import or manufacture the following chemicals under section 21U of the *Industrial Chemicals (Notification and Assessment) Act 1989*. Low Volume Category Permits are approved for 36 months.

Table 2
Low Volume Category Permits

PERMIT NUMBER	COMPANY NAME	COMPANY POSTCODE	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	USE
944	Givaudan Australia Pty Ltd	2153	1H-Inden-1-one, 2,3-dihydro-2,3,3-trimethyl-	Yes	Fragrance ingredient
945	Canon Australia Pty Ltd	2113	CIM 27	No	Component of inkjet printer
946	Canon Australia Pty Ltd	2113	CIM 28	No	Component of inkjet printer
947	Symrise Pty Ltd	2099	Nonanoic acid, C16-18-alkyl esters (INCI: cetearyl nonanoate)	No	Moisturiser in cosmetics

12 NOTICE OF CHEMICALS ELIGIBLE FOR LISTING ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES FIVE YEARS AFTER ISSUING OF ASSESSMENT CERTIFICATES

Notice is given in accordance with section 14(1) of the *Industrial Chemicals (Notification and Assessment) Act 1989*, that the following chemicals have been added to the Australian Inventory of Chemical Substances.

Table 3

Chemicals Eligible for Listing on the Australian Inventory of Chemical Substances

CHEMICAL NAME	MOLECULAR FORMULA	CAS NUMBER
2-Propenoic acid, 2-methyl-, butyl ester, polymer with 2-(dimethylamino)ethyl 2-propenoate, 2-hydroxyethyl 2-propenoate, methyl 2-methyl-2-propenoate and methyl 2-propenoate, compd. with methyl 4-methylbenzenesulfonate	$(C_8H_{14}O_2.C_7H_{13}NO_2.C_5H_8O_3.C_5H_8O_2.C_4H_6O_2)_x.xC_8H_{10}O_3S$	710320-09-5
Copper, [29H,31H-phthalocyaninato(2-)-.kappa.N29,.kappa.N30,.kappa.N31,.kappa.N32]-, sulfo [[4-[[2-(sulfoxy)ethyl]sulfonyl]phenyl]amino]sulfonyl derivs., sodium salts, reaction products with polyethylene glycol mono(4-aminophenyl) ether	Unspecified	1332877-76-5
Piperidine, 1-acetyl-4-(3-dodecyl-2,5-dioxo-1-pyrrolidinyl)-2,2,6,6-tetramethyl-	$C_{27}H_{48}N_2O_3$	106917-31-1
Manganese, [[2,2',2''-[nitrilotris[2,1-ethanediyl(nitrilo-.kappa.N)methylidyne]]tris[phenolato-.kappa.O]](3-)]-,	$C_{27}H_{27}MnN_4O_3$	61007-89-4
Bicyclo[2.2.1]heptane, 2,5 (or 2,6) -bis(isocyanatomethyl)-	$C_{11}H_{14}N_2O_2$	74091-64-8
Propanoic acid, 3-hydroxy-2-(hydroxymethyl)-2-methyl-, polymer with 2,2'-[1,2-ethanediylbis(oxy)]bis[ethanol], .alpha.-hydro-.omega.-hydroxypoly(oxy-1,4-butanediyl) and 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane compd. with N,N-diethylethanamine	$(C_{12}H_{18}N_2O_2.C_6H_{14}O_4.C_5H_{10}O_4.(C_4H_8O)nH_2O)_x.xC_6H_{15}N$	872830-26-7
L-Aspartic acid, homopolymer, sodium salt	$(C_4H_7NO_4)_x.xNa$	34345-47-6
Poly(oxy-1,4-phenyleneoxy-1,4-phenylenecarbonyl-1,4-phenylene)	$(C_{19}H_{12}O_3)_n$	31694-16-3

1H-Indole-5,6-diol, 2,3-dihydro-, hydrobromide (1:1)	$C_8H_9NO_2 \cdot BrH$	138937-28-7
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13 NOTICE OF CHEMICALS ELIGIBLE FOR IMMEDIATE LISTING ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES AFTER ISSUING OF ASSESSMENT CERTIFICATES

Notice is given in accordance with section 13B of the *Industrial Chemicals (Notification and Assessment) Act 1989*, that the following chemicals have been added to the Australian Inventory of Chemical Substances.

Table 4

Chemicals Eligible for Immediate Listing on the Australian Inventory of Chemical Substances

CHEMICAL NAME	MOLECULAR FORMULA	CAS NUMBER
1-Propene, polymer with ethene, maleated, potassium salts	Unspecified	403616-29-5
Magnesium hydroxide sulfate (Mg ₆ (OH) ₁₀ (SO ₄)), hydrate (1:3)	H ₂ O.1/3HO.1/3Mg.1/3O ₄ S	12508-61-1