



Australian Government

# Gazette

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**Australian Government**

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

The Australian Government Department of Health and Ageing and Department of Finance and Deregulation are inviting interested parties and individuals to provide written submissions in response to the *Discussion Paper on the Review of the National Industrial Chemicals Notification and Assessment Scheme* (the Discussion Paper).

The review, which is part of a Better Regulation Ministerial Partnership between the Minister for Finance and Deregulation and the Minister for Health, is investigating how regulatory settings may be improved to enhance both the competitiveness of the Australian chemical industry and public health and environmental outcomes. The Discussion Paper takes into account the issues and views raised in public submissions received in December 2011.

Written submissions are sought on the impacts and implications of proposed reform options, and more specifically in relation to the questions raised in the Discussion Paper.

Brief case studies and/or supporting data that illustrate/clarify key issues in relation to each of the proposed reforms would, in particular, assist the review.

Submissions must be received by the Department of Health and Ageing by 5pm, Friday 27 July 2012.

Email: [NICNAS.review@health.gov.au](mailto:NICNAS.review@health.gov.au)

Mail: NICNAS Review (MDP 71)  
Department of Health and Ageing  
GPO Box 9848  
CANBERRA ACT 2601

Submissions will be made public and shared with relevant Commonwealth agencies and consultants engaged to assist with 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 and to access the Discussion Paper please see:  
[http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp\\_nicnas\\_review.htm](http://www.health.gov.au/internet/main/publishing.nsf/Content/ohp_nicnas_review.htm)

## 2      **PRIORITY EXISTING CHEMICAL HEXABROMOCYCLODODECANE - HBCD**

Hexabromocyclododecane (HBCD) has been assessed as a priority existing chemical (PEC) under the Commonwealth *Industrial Chemicals (Notification and Assessment) Act, 1989* (the Act), as amended. Under section 60F of the Act, the final assessment report for HBCD (PEC Report No. 34) is now publicly available from the NICNAS website at:

<http://www.nicnas.gov.au/publications/CAR/PEC.asp>.

An information sheet on HBCD is also available at:

[http://nicnas.gov.au/Publications/Information\\_Sheets/Existing\\_Chemicals\\_Information\\_Sheets.asp](http://nicnas.gov.au/Publications/Information_Sheets/Existing_Chemicals_Information_Sheets.asp).

The publication of this report revokes the declaration of HBCD 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 email [info@nicnas.gov.au](mailto:info@nicnas.gov.au).

### 3 SECONDARY NOTIFICATION OF POLYMER IN MILLFLUID PC-51

In accordance with section 65(2) of the *Industrial Chemicals (Notification and Assessment) Act*, 1989 (the Act), notice is given that the Director requires the secondary notification of the existing chemical, a polymer in the new product Millfluid PC-51.

#### ADDITIONAL INFORMATION AVAILABLE FOR POLYMER IN MILLFLUID PC-51

The polymer was previously assessed as a polymer of low concern for use in a building construction product. The polymer is not manufactured in Australia but imported from overseas countries. Huntsman Corporation Australia intends to manufacture the chemical in Australia and in larger quantities than originally notified. Huntsman also intends to use the polymer for applications other than those originally notified.

#### REASONS FOR SECONDARY NOTIFICATION

The Director has decided that a secondary notification for the polymer in Millfluid PC-51 is required taking into consideration the fact that the polymer will be manufactured in Australia in large quantities for new applications, and noting that this polymer has greater potential for environmental risk than is typical for a polymer of low concern (PLC).

#### REQUIREMENT TO APPLY FOR SECONDARY NOTIFICATION

In accordance with section 65(3) of the Act, an application for secondary notification must be made by all persons who introduce the polymer in Millfluid PC-51 into Australia either by import or manufacture. There is a penalty for failure to comply with the requirement for secondary notification. The penalty for non-compliance may include prohibition from further importation or manufacture.

#### APPLICATION FOR SECONDARY NOTIFICATION AND INFORMATION REQUIRED

Secondary notification must be made to the Director by means of an application for secondary notification assessment for an existing chemical, accompanied by any relevant information relevant to an assessment of the polymer in Millfluid PC-51 which was not originally covered in the previous assessment report.

In addition, importers and manufacturers must provide information on the following:

- Quantities of the polymer and products containing the polymer manufactured or imported into Australia
- Concentration of the polymer in Millfluid PC-51
- Uses of the polymer in Millfluid PC-51 and mode of use
- Any information on assessment/reviews conducted by overseas regulatory authorities.

The secondary notification application form can be found on the NICNAS website at:  
[http://www.nicnas.gov.au/Forms/Existing\\_Chemicals/Form1a\\_SN\\_PEC\\_PDF.pdf](http://www.nicnas.gov.au/Forms/Existing_Chemicals/Form1a_SN_PEC_PDF.pdf)

An application that some or all of this information should be exempt from publication may be made by applying under section 75 of the Act, and using the approved form:  
<http://www.nicnas.gov.au/forms/files/form3.doc>



Applications must be received no later than 3 July 2012.

#### **ADDITIONAL PERSONS WITH RELEVANT INFORMATION**

In addition to the requirement to apply for secondary notification, any persons with information relevant to the assessment of the polymer in Millfluid PC-51 and not covered in the original assessment report are encouraged to submit the information for consideration.

Information collected by NICNAS may be provided to State, Territory or Commonwealth regulatory agencies for the purposes of monitoring compliance under relevant legislation. All information collected is treated in accordance with strict confidentiality guidelines and in compliance with the *Privacy Act 1988*.

For further information applicants are requested to contact Dr Sami Syed by telephone (02) 8577 8845, or fax: (02) 8577 8888.

#### 4 PUBLICATION OF FINAL COST RECOVERY IMPACT STATEMENT

NICNAS has reviewed its cost recovery arrangements and prepared a Cost Recovery Impact Statement (CRIS), in accordance with the Australian Government's Cost Recovery Guidelines. The CRIS outlines NICNAS fees and charges for the period 2012-13 to 2015-16.

The change in fees and charges is to:

- better align fees and charges with the cost of delivering the services; and
- recover the cost of stage one of the accelerated assessment and prioritisation of existing chemicals.

The CRIS was developed with extensive stakeholder consultation, including two phases of public consultation- a discussion paper outlining issues to be canvassed through the CRIS and the draft CRIS. Stakeholder consultation mechanisms included written submissions, public workshops, NICNAS consultative committees and a stakeholder survey. Stakeholder views were taken into account in finalising the CRIS.

The [Final CRIS](#) and a summary ([Final CRIS – At a Glance](#)) are available on the NICNAS website.

New NICNAS fees and charges apply from **1 July 2012**. Key changes for 2012-13 include:

##### [NICNAS registration fees and charges](#)

- Increase in registration fee and charge for tier 2 and tier 3 registrants (tier 1 fee remains unchanged);
- Changes in late penalty charges.

##### [New chemicals fees](#)

- Changes to new chemicals assessment fees;
- Introduction of a non-refundable screening fee;
- Removal of template rebate; and
- Variable fee rebates replaced with set fees.

##### [Fees relating to Australian Inventory of Chemical Substances \(AICS\)](#)

- Changes to confidential and early listing fees.

For further information please contact NICNAS via:

Freecall: 1800 638 528

Phone: 02 8577 8800

Fax: 02 8577 8888

Email: [info@nicnas.gov.au](mailto:info@nicnas.gov.au)

## 5 NOTICE OF CHANGES TO NICNAS FEES AND CHARGES - 2012-13

As outlined in the NICNAS Cost Recovery Impact Statement (CRIS), the fees and charges for 2012-13 are being amended to better align with the cost of delivering the services and recover the cost of stage one of the accelerated assessment and prioritisation of existing chemicals. The overall charging structure, that is, category specific new chemicals fees and a three tier registration charging arrangement, remains unchanged.

NICNAS fees and charges are specified in the *Industrial Chemicals (Notification and Assessment) Regulations 1990* (the Regulations). The regulations have been amended to give effect to the revised fees and charges established through the CRIS. These come into effect on **1 July 2012**. This notice provides the list of fees and charges that are to apply from that date.

Note: All NICNAS fees and charges are in Australian dollars and are GST free.

### NICNAS registration fees and charges

Changes to registration fees and charges for 2012-13 are:

- increase in registration fee and charge for tier 2 and tier 3 registrants (tier 1 fee remains unchanged) (see Table 1); and
- changes in late penalty charges (see Table 2).

**Table 1 – Registration fees and charges**

Registration Fees & Charges		
Tier	Applicable Introduction Value	Registration Fee and Charges 2012-13
1	\$1- \$499,999	\$395
2	\$500,000- \$4,999,999	\$1,857
3	\$5,000,000 or more	\$14,300

**Table 2 – Late penalty charges**

Late Penalty Charges		
Tier	Applicable Introduction Value	Late Penalty Charge
1	\$1- \$499,999	\$100
2	\$500,000- \$4,999,999	\$185
3	\$5,000,000 or more	\$1,430

### New chemicals fees

Changes to New Chemicals fees for 2012-13 include:

- amendments to fees for new chemicals categories and associated administrative processes, (see Table 3);
- replacement of variable fee rebates with set fees (see Table 4); and
- introduction of a non-refundable screening fee of 15% (included in the specified notification fee) for all notifications. The fee is intended to encourage notifiers to submit applications which contain the scheduled information required to enable an

adequate assessment. If deficiencies identified during the preliminary assessment of an application cannot be rectified within an agreed timeframe, the application may be returned to the applicant, minus the screening fee.

**Table 3 - New chemicals application fees<sup>1</sup>**

<b>New Chemical Certificate Applications</b>		
<b>Code</b>	<b>Name</b>	<b>Fee</b>
<b>STD</b>	Standard Assessment	\$16,800
<b>LTD</b>	Limited Assessment	\$12,000
<b>PLC</b>	Polymer of Low Concern	\$5,600
<b>EX</b>	Application for Extension of Assessment Certificate	\$5,100
<b><i>New Chemical Self-Assessment Certificate Applications</i></b>		
<b>SANHC</b>	Self-Assessment Application Non-hazardous Chemical	\$10,400
<b>SANHP</b>	Self-Assessment Application Non-hazardous Polymer (other than PLC)	\$9,700
<b>SAPLC</b>	Polymer of Low Concern (SAPLC) Self-Assessment Application	\$3,900
<b><i>Approved Foreign Scheme</i></b>		
<b>FS-STD</b>	Standard Assessment	\$12,300
<b>FS-LTD</b>	Limited Assessment	\$9,000
<b>FS-PLC</b>	Polymer of Low Concern	\$3,500
<b><i>Reassessment of New Chemicals – Secondary Notifications</i></b>		
<b>SN</b>	Other than a synthetic PLC	\$9,600
<b>SNPLC</b>	A synthetic PLC	\$4,200
<b>New Chemical Permit Applications</b>		
<b>Code</b>	<b>Name</b>	<b>Fee</b>
<b>CEC</b>	Commercial Evaluation Permit Application	\$4,000
<b>LVC</b>	Low Volume Chemical Permit Application	\$4,000
<b>EOP</b>	Controlled Use Permit Application (Export Only)	\$4,000
<b>CUP</b>	Controlled Use Permit Application (Other)	\$4,000
<b>EIP</b>	Application for Early Introduction Permit (EIP)	\$2,300

<sup>1</sup> All New Chemical Notification Fees include a non-refundable screening fee (equivalent to 15% of the fee).

-	Section 30 Permit Application	\$8,500
<b>Permit Renewal Applications</b>		
<b>CER</b>	Commercial Evaluation Renewal Application	\$2,000
<b>LVCR</b>	Low Volume Chemical Permit Renewal Application	\$2,000
<b>EOPR or CUPR</b>	Controlled Use Permit Renewal Application (Export Only or Other)	\$2,000
<b>Other Fees</b>		
Variation of Schedule Data Requirements		\$2,600
Nomination of Foreign Scheme		\$7,100
Application to Vary Assessment Report		\$4,100
Application to Vary Public Report		\$4,100
Application for Exempt Information		\$1,100
Alternate State Law Application**		\$10,400

\*\*Whilst fees have been set for this application, at present there are no Alternate State Laws in Australia

**Table 4 - New chemicals fees to replace rebates<sup>1</sup>**

<b>Assessed by Comparable Agency</b>		
<b>CA-STD</b>	Standard Assessment	\$13,400
<b>CA-LTD</b>	Limited Assessment	\$9,600
<b>CA-PLC</b>	Polymer of Low Concern	\$4,500
<b>Similar to Chemical Previously Assessed by NICNAS</b>		
<b>SC-STD</b>	Standard Assessment	\$10,100
<b>SC-LTD</b>	Limited Assessment	\$7,200
<b>SC-PLC</b>	Polymer of Low Concern	\$3,400
<b>Group Assessment</b>		
<b>GA-STD</b>	Standard Assessment	\$4,000
<b>GA-LTD</b>	Limited Assessment	\$2,500
<b>GA-PLC</b>	Polymer of Low Concern	\$2,500
<b>Electronic Template</b>		
Application with draft assessment report (electronic template)*		N/A

\*To date, the provision of a rebate for electronic template notifications has not resulted in the reduction of administrative effort by NICNAS. The template rebate has therefore been replaced by set fees for specific notification categories.

**Fees relating to Australian Inventory of Chemical Substances (AICS)***Table 5 – AICS fees*

AICS Fees	
Application for Confidential Listing	\$3,500
Application to Retain Confidential Listing	\$3,500
Application for Early Non-Confidential Listing after 28 days	\$750
Application to be a Holder of a Confidence	\$700
Transfer to Confidential Listing	\$2,100

More information can be found in the following fact sheets on the NICNAS website

[www.nicnas.gov.au](http://www.nicnas.gov.au)

- List of NICNAS Fees and charges
- Changes to New Chemicals Fees
- Changes to NICNAS Registration Fees and Charges
- Changes to AICS Fees

For further information please contact NICNAS via:

Freecall: 1800 638 528

Phone: 02 8577 8800

Fax: 02 8577 8888

Email: [info@nicnas.gov.au](mailto:info@nicnas.gov.au)

## 6 ACCELERATED ASSESSMENT AND PRIORITISATION OF EXISTING CHEMICALS – STAGE 1

As part of the reform regarding assessment of Existing Chemicals, NICNAS is implementing a new framework for the assessment and prioritisation of chemicals on the Australian Inventory of Chemical Substances (AICS). The new [Inventory Multi-tiered Assessment and Prioritisation \(IMAP\) framework](#) will be implemented in a staged manner, with a focus on a subset of chemicals on the AICS meeting characteristics supported by stakeholders. This new program will deliver more timely information about the hazards and risks associated with the use of industrial chemicals and identify chemicals which require risk mitigation to ensure safe use.

From July 2012, NICNAS will begin assessing around 3,000 existing chemicals on AICS using the IMAP framework. The chemicals in the first group to be assessed are called “Stage 1 chemicals”. These 3,000 chemicals have been selected for assessment in Stage 1 based on the following characteristics agreed by stakeholders as priorities for early consideration:

- chemicals for which NICNAS already holds exposure information,
- chemicals identified as a concern or for which regulatory action has been taken overseas, and
- chemicals found in cord blood.

The Stage 1 chemicals will be published on the NICNAS website on the week commencing 11 June 2012.

For further information on the new program visit the [NICNAS website](#) or contact via:

Telephone: (02) 8577 8870

Email: [imap@nicnas.gov.au](mailto:imap@nicnas.gov.au)

Address: Existing Chemicals Program,  
NICNAS,  
GPO Box 58,  
Sydney NSW 2001

## **7 NOTICE OF INCLUSION ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES OF COSMETIC INGREDIENTS IN PRODUCTS PREVIOUSLY REGULATED BY THE THERAPEUTIC GOODS ADMINISTRATION**

In accordance with Subsection 15AB(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), this notice is to advise that the Director, NICNAS, has included on the public section of the Australian Inventory of Chemical Substances (AICS) seven chemicals for cosmetic use only (see Table 1).

### **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.

The Director, NICNAS proposed, via Notice 4 published in the *Chemical Gazette* of 7 February 2012, the seven chemicals subject to this notice for transfer to the AICS as listed in Table 1, along with associated conditions of use in accordance with subsections 15AA(1) and 15AA(2) of the Act.

### **The Decision**

No statements objecting to the proposal for transfer to the AICS of the seven chemicals listed in Table 1 were received within the 28 day statutory time period. Therefore, the Director, NICNAS decided to include each of these chemicals in the public section of the AICS for cosmetic use only, together with an associated condition of use.

Notice of this decision was given in the *Chemical Gazette* of 3 April 2012 (Notice 2). Included in this Notice was advice that, under subsection 15AB(1) of the Act, each decision to include a chemical on the AICS was subject to appeal to the Administrative Appeals Tribunal (AAT). No applications for review of the decisions were received.

### **Inclusion of Chemicals on the AICS**

Under Section 15AB, after at least 28 days has passed since the publication of the Director's decision and if 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 public section of the AICS, along with any conditions of use, and give notice of this action in the *Chemical Gazette*.

Notice is hereby given that each of the chemicals listed in Table 1 have been placed on the non-confidential section of the AICS for cosmetic use only. No other conditions of use are specified.

### **Consequence of inclusion on the AICS**

#### Status as an existing chemical when introduced within condition of use

The chemicals listed in Table 1 will be regarded as existing chemicals within the context of the conditions of use. Under section 15A of the Act, failure to comply with these conditions of use



when introducing as an existing chemical is an offence. As such, these chemicals are now no longer subject to new chemical annual reporting requirements under Section 21AA when used in cosmetics and within the specified conditions of use.

Status as a new chemical when introduced outside condition of use

Introduction of the chemicals listed in Table 1 for uses other than those specified (namely, for a non-cosmetic use) results in the chemical being considered a new chemical as defined under Section 5 of the Act. The introduction of such a new chemical is subject to Section 21 of the Act and the associated requirements prescribed in the Industrial Chemicals (Notification and Assessment) Regulations 1990.

If you require further information please contact:

Dr Bill Diver  
Reform Section  
NICNAS  
GPO Box 58  
Sydney  
NSW 2110

Phone 02 8577 8862  
Fax: 02 8577 8888  
email: [bill.diver@nicnas.gov.au](mailto:bill.diver@nicnas.gov.au)

**Table 1** Chemicals included in the public section of the Australian Inventory of Chemical Substances under Section 15AB(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989*

INCI name/AAN	CAS name	CAS No.	Conditions of Use
Acetyl Carnitine HCL (AAN: Acetyllevocarnitine hydrochloride)	1-Propanaminium, 2- (acetyloxy)-3-carboxy-N,N,N- trimethyl-, chloride, (2R)-	5080-50-2	For Cosmetic Use Only.
Algae Extract	Laminaria, ext.	92128-82-0	For Cosmetic Use Only.
Butyrospermum Parkii (Shea) Butter Unsaponifiables	Fats and Glyceridic oils, shea butter, unsaponifiable fraction	225234-14-0	For Cosmetic Use Only.
Lauryl laurate	Dodecanoic acid, dodecyl ester	13945-76-1	For Cosmetic Use Only.
Orange roughy oil	Waxes and Waxy substances, orange roughy	91078-99-8	For Cosmetic Use Only.
Sanguisorba Officinalis Root Extract (TGA name: Poterium officinale)	Sanguisorba officinalis, ext.	84787-71-3	For Cosmetic Use Only.
Whey Protein	Glycoproteins, bovine-whey	84082-51-9	For Cosmetic Use Only.

## **8 NOTICE OF DECISION TO INCLUDE ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES CERTAIN COSMETIC INGREDIENTS IN PRODUCTS PREVIOUSLY REGULATED BY THE THERAPEUTIC GOODS ADMINISTRATION**

In accordance with Section 15AA(8) of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), this notice gives the final decision of the Director, NICNAS, to include on the public section of the Australian Inventory of Chemical Substances (AICS) 18 chemicals for cosmetic use only, along with associated conditions of use (see Tables 1 and 2).

### **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. The intent of the reforms is that the transfer of responsibility would occur whilst maintaining health and safety standards and without posing unnecessary burden on industry.

As a result of this transfer, the chemicals in these cosmetic products that were not already on the AICS became new industrial chemicals, and therefore required notification and assessment unless exemptions applied. A mechanism to list certain chemicals on the AICS as existing chemicals came into force on 27 September 2011 with amendments to the Act.

In order to be considered by the Director, NICNAS, for placement on the AICS, these chemicals needed to meet two sets of criteria: a generic set under the amended legislation; and a second set specific to the cosmetic reforms. To ascertain which chemicals were to be considered for transfer, NICNAS undertook a call for information in the February 2010 *Chemical Gazette*. As a result of clarifying identity information and applying the eligibility criteria, the Director, NICNAS identified 62 chemicals or substances for possible listing on the AICS. In addition, the Director, NICNAS must consider whether these chemicals pose an unreasonable risk to occupational health and safety, public health or the environment.

### ***The proposal for listing***

These 18 chemicals were part of the group of 25 chemicals proposed for listing on the AICS via Notice 4 in the *Chemical Gazette* of 7 February 2012.

In this Notice the Director, NICNAS stated reasons why these chemicals were proposed for listing on the AICS in accordance with section 15AA(5)(e) of the Act. Briefly, these reasons were that:

- listing these chemicals on the AICS fulfils the intent of the 2007 cosmetic reforms;
- the chemicals fulfilled eligibility criteria; and
- the Director considers that the chemicals do not pose an unreasonable risk to occupational health and safety, public health and the environment, when used in accordance with the proposed conditions of use.

Statements on the proposal were due within 28 days of the notice, by 6 March 2012.

NICNAS also published a clarification Notice in the 6 March 2012 *Chemical Gazette* (Notice 2) concerning the conditions of use for two of these 25 chemicals and a further 28 days was provided for comment, to 3 April 2012.

### ***Stakeholder response to the proposal for listing the 18 chemicals***

#### *Chemicals for which no statements were received*

Of the 18 chemicals proposed for transfer, no statements were received objecting to the listing of one chemical with the proposed conditions of use.

#### *Chemicals for which statements were received*

Eight statements were received in regard to the remaining 17 chemicals within the 28 day period specified under section 15AA(5)(g) of the Act. The Director, NICNAS, proposed conditions of use for these chemicals, noting that some of the chemicals possessed certain properties that may pose a risk to human health and/or the environment when used outside of the proposed conditions of use. Whilst all eight submissions supported the listing of these chemicals on the AICS, the submissions all objected to the proposed conditions of use on the basis that:

- NICNAS did not present any sound scientific evidence that these ingredients pose an unreasonable risk to public health and/or the environment;
- NICNAS has no power to make risk management decisions in regard to these chemicals;
- the NICNAS restrictions are inconsistent with the use of these chemicals internationally;
- as these proposals will have a significant detrimental impact on the commercial operations of many companies and the supply of product into the market place, an impact assessment is required; and
- the introduction of unique Australian requirements in the absence of any sound scientific evidence will provide a barrier to trade and could lead to challenges through the World Trade Organisation.

Moreover, the submitters did not agree that the chemicals listed in Groups 2, 3 and 4 of Table 1 to the proposal Notice of February 2012 may pose an unreasonable risk when, in the view of submitters, they are used in formulated cosmetic products in small amounts.

Finally, the submissions all included alternative proposed conditions of use within which any unreasonable risk was proposed to be mitigated.

NICNAS sought further information from the submitters and other interested businesses on the use of these chemicals in cosmetic products in Australia in order to give full consideration to the statements received.

## *The Director's consideration of statements received*

### General considerations

In relation to the range of statements provided above by the submitters:

- the Director noted in the proposal Notice 4 of February 2012 that “some of the chemicals possessed certain properties that may pose a risk to human health and/or the environment when used outside of the proposed conditions of use”. This observation was informed by the application of a hazard screening process involving Quantitative Structure Activity Relationship (QSAR) modelling and a review of key literature, along with modelling of the likely volumes of these chemicals when used in formulated cosmetic products in Australia. Finally, in response to the statements received, the Director obtained further information on the likely hazards, volumes and therefore risks posed by these chemicals;
- the new legislative mechanism provides the power for the Director to annotate the AICS with conditions of use under Section 15AA(2);
- introduction of the chemicals proposed for listing outside of the conditions of use means the chemical is a new chemical and that the current Sn21 provisions of the Act then apply (see “Next Steps” further in this Notice); and
- further information on the impact on business was sought and was taken into account in formulating the conditions of use.

### Considerations regarding unreasonable risk

Section 15AA (3) requires the Director to consider whether the use of the chemical poses an unreasonable risk to occupational health and safety, public health or the environment. In relation to submitters' comments that the chemicals in Groups 2, 3 and 4 do not pose an unreasonable risk as they are used in small amounts in formulated cosmetic products, it was noted that the risk posed by a chemical is related to both its intrinsic properties as well as the quantity used.

For one chemical, the data provided addressed the concerns regarding its environmental impacts to some extent, but concerns regarding aquatic chronic toxicity remained. For another chemical, submitters agreed with the Director's concerns regarding the toxicity of a predicted metabolite.

For the remaining 15 chemicals, the Director considered that the additional information was insufficient to conclude that these chemicals do not pose an unreasonable risk to human health and the environment within the conditions of use proposed by submitters. As a result, the Director decided, on the basis of the available information, that the original view about the risk to human health and the environment which may be posed by these chemicals remains unchanged, and therefore appropriate conditions of use to mitigate this risk should be maintained.

Submitters also noted the practical difficulties in complying with a condition of use limiting introduction of the chemical to one product type. The Director determined

that an adequate mitigation of risk could be achieved by extending the introduction of these chemicals to all cosmetic products, as requested by submitters, whilst:

- limiting the annual volume a company could introduce for chemicals or
- limiting the concentration of the chemical in products either based on that previously imposed by the original regulator (TGA) or on the levels that companies indicated were being used in Australia.

## **The Decision**

The Director makes the following decisions regarding the listing of chemicals on the public AICS in accordance with Section 15AA(7):

### ***Decision on chemical for which no statements were received (Table 1)***

Table 1 of this Notice contains the Director's decision on the chemical for which no statements were received. The Director has decided to include the chemical on the public section of the AICS with the condition of use identical to that originally proposed, namely that the chemical be available for cosmetic use only.

### ***Decision on chemicals for which statements were received***

Table 2 contains the Director's decisions on the 17 chemicals for which statements were received. Having taken account of the statements received, the Director has decided to include the chemicals in Table 2 in the public section of the AICS.

Table 2 is divided into groups of chemicals in accordance with the groupings used in the February proposal Notice 4. Moreover, each group is prefaced with a statement concerning how the Director took account of statements received.

For ease of reference, Table 2 contains:

- the CAS number and INCI name/AAN in the first column;
- the original conditions of use proposed by the Director in the February/March Notices along with the conditions proposed in the stakeholder submissions in the second column; and
- the final conditions of use decided by the Director in the third column.

## **Your right to apply for a review of this Decision**

Under Section 15AB(1) of the Act, for each decision to include a chemical listed in Tables 1 and 2 on the AICS, a period of at least 28 days is allowed for persons to apply to the Administrative Appeals Tribunal (AAT) for a review of that decision. Information concerning the right to apply to the AAT and the means of doing so is included in an attachment to this notice. In particular, you must apply to the AAT **within 28 days of the date of this notice**.

## **Next Steps**

Under Section 15AB, after at least 28 days has passed since the publication of the Director's decision and if 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 public section of the AICS, along with any conditions of use, and give notice of this action in the *Chemical Gazette*. Pending any application for review to the AAT, NICNAS expects these processes to occur in August 2012.

If listed on the AICS, the 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.

Introduction of a chemical for such other uses (for example, for a non-cosmetic use; or for a cosmetic use but at a higher concentration or volume than specified in the condition of use) would mean the chemical is a new chemical as defined under Section 5 of the Act. The introduction of such a new chemical is subject to Section 21 of the Act and the associated requirements prescribed in the *Industrial Chemicals (Notification and Assessment) Regulations 1990*.

In order to reduce the impact of the uncertainty on business about the annual reporting arrangements for 2011-12 while the chemicals are in the process of proposed transfer to the AICS, the Director, NICNAS, has decided not to seek reports under s21AA for the chemicals in Tables 1 and 2 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.

If you require further information please contact:

Dr Bill Diver  
Reform Section  
NICNAS  
GPO Box 58  
Sydney  
NSW 2110

Phone 02 8577 8862  
Fax: 02 8577 8888  
email: [bill.diver@nicnas.gov.au](mailto:bill.diver@nicnas.gov.au)

**Table 1** Chemicals decided for inclusion in the public section of the Australian Inventory of Chemical Substances under Section 15AA(7) of the *Industrial Chemicals (Notification and Assessment) Act 1989*

*Chemical for which existing TGA controls are considered adequate and for which no statements were received*

INCI name/AAN	CAS name	CAS No.	Conditions of Use Decided
Octyldodecyl Neopentanoate	Propanoic acid, 2,2-dimethyl-, 2-octyldodecyl ester	158567-66-9	For Cosmetic Use Only



**Table 2** Chemicals decided for inclusion in the public section of the Australian Inventory of Chemical Substances under Section 15AA(7) of the *Industrial Chemicals (Notification and Assessment) Act 1989*

*Chemicals for which statements were received*

The following chemicals were proposed for listing with a condition of use based on the controls imposed by the previous regulator (the Therapeutic Goods Administration). Statements received requested an increase in the concentration limit, based on the limit of 1% in the Sn 21(6)(c) exemption provisions under the *Industrial Chemicals (Notification and Assessment) Act 1989* for the introduction of non-hazardous chemicals in cosmetics. Sufficient data were not provided by submitters to support that the chemicals do not pose an unreasonable risk to human safety and the environment. Therefore a change to the proposed condition of use is not considered warranted, and the decision is to maintain the conditions of use imposed by the previous regulator.

**Group 1      Chemicals for which existing TGA controls are adequate**

CAS No. INCI name/AAN	Conditions of Use: 1. As originally proposed 2. As proposed in statements received	Conditions of Use Decided
244023-78-7 Cholesteryl/beheryl/ octyldodecyl lauroyl glutamate	1. 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. 2. For Cosmetic Use Only. The concentration of this ingredient in the final product should be 1% or less.	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.
81065-76-1 Ethylbisiminomethyl guaiacol manganese chloride	1. For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.002%. It is not to be included in topical products intended for use in the eye. 2. For Cosmetic Use Only. The concentration of this ingredient in the final product should be 1% or less.	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.002%. It is not to be included in topical products intended for use in the eye.
158765-79-8 Micrococcus lysate (AAN	1. For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.002% and is not	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed

Micrococcus luteus lysate)	intended for use in the eye. 2. For Cosmetic Use Only. The concentration of this ingredient in the final product should be 1% or less.	0.002% and is not intended for use in the eye.
528855-60-9 Palmitoyl hydroxypropyltrimonium amylopectin/glycerin crosspolymer	1. For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.01% and is not to be used in topical products intended for use in the eye. 2. For Cosmetic Use Only. The concentration of this ingredient in the final product should be 1% or less.	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 0.01% and is not to be used in topical products intended for use in the eye.

The following chemicals were proposed for listing with a condition of use based on the controls imposed by the previous regulator. Statements received requested the removal of certain conditions. Sufficient data were not provided by submitters to support the removal of these aspects of the condition. Therefore a change to the proposed condition of use is not considered warranted. The decided conditions of use maintain the controls imposed by the previous regulator

123465-35-0 Phospholipids	1. For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 20% and is not to be used in topical products intended for use in the eye. 2. For Cosmetic Use Only. The concentration is not to exceed 20%.	For Cosmetic Use Only. For dermal use only. The concentration is not to exceed 20% and is not to be used in topical products intended for use in the eye.
125275-25-4 Polyquaternium-51	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. 2. For Cosmetic Use Only. The concentration is not to exceed 5%.	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.

## Group 2 Chemicals which may pose an unreasonable risk to the environment

The following four chemicals were calculated to have a Risk Quotient (RQ) >1 and hence have the potential to pose an unacceptable risk to the environment. In the absence of data the RQ was derived using modelled data for chronic aquatic toxicity and physico chemical endpoints, and assumptions on the volumes introduced into Australia. The original proposed conditions of use were intended to restrict these chemicals to the product class in which they were nominated so that the risk is mitigated. The condition of use also incorporated any controls imposed by the previous regulator. Statements received provided more accurate estimates of import volumes to allow the RQ to be revised and also provided information on the difficulties of complying with a product based condition of use. The decided conditions of use expands the range of cosmetic products in which the chemicals can be introduced, whilst limiting the volume of chemical which can be introduced per company per annum so as to reduce the predicted concentration in the environment to below that calculated to be of concern derived from the chronic aquatic toxicity data. The Director views this combination of conditions of use as suitably mitigating the risk to the environment.

<b>CAS No. INCI name/AAN</b>	<b>Conditions of Use: 1. As originally proposed 2. As proposed in statements received</b>	<b>Conditions of Use Decided</b>
302776-68-7 Diethylamino Hydroxybenzoyl Hexyl Benzoate (Uvinul A Plus)	<ol style="list-style-type: none"> <li>1. For Cosmetic Use Only. For use in topical (dermal) sunscreen products with an SPF up to 15 only. The concentration is not to exceed 10%.</li> <li>2. For Cosmetic Use Only. The concentration is not to exceed 10%.</li> </ol>	For Cosmetic Use Only. Not to be introduced in an amount exceeding one tonne per annum per introducer. The concentration is not to exceed 10%.
28510-23-8 Neopentyl Glycol Diethylhexanoate	<ol style="list-style-type: none"> <li>1. For Cosmetic Use Only. To be used only as an ingredient in topical sunscreen products with an SPF up to 15. The concentration of this ingredient in the final product should be 5% or less. It should not be used in topical preparations intended for the eye.</li> <li>2. For Cosmetic Use Only. The concentration of this ingredient in the final product should be 5% or less.</li> </ol>	For Cosmetic Use Only. Not to be introduced in an amount exceeding one tonne per annum per introducer. The concentration of this ingredient in the final product should be 5% or less. It should not be used in topical preparations intended for the eye.

135326-54-4 Propylene Glycol Myristyl Ether Acetate	<ol style="list-style-type: none"> <li>1. For Cosmetic Use Only. For use only in sunscreen products with an SPF up to 15.</li> <li>2. For Cosmetic Use Only.</li> </ol>	For Cosmetic Use Only. Not to be introduced in an amount exceeding one tonne per annum per introducer.
131276-37-4 Trihydroxypalmitamido hydroxypropyl Myristyl Ether	<ol style="list-style-type: none"> <li>1. For Cosmetic Use Only. For dermal use only. For use only in sunscreen products with an SPF up to 15. The concentration is not to exceed 0.02% and is not to be used in topical products intended for use in the eye.</li> <li>2. For Cosmetic Use Only. The concentration of this ingredient in the final product should be 1% or less.</li> </ol>	For Cosmetic Use Only. Not to be introduced in an amount exceeding 100 kg per annum per introducer. For dermal use only. The concentration is not to exceed 0.02% and is not to be used in topical products intended for use in the eye.

The following chemicals contain components which were identified as having potential for endocrine disrupting activity and estrogen receptor binding. This potential, in the absence of further information, leads to uncertainty about the likely impact on human health and the environment if the use of these chemicals is to become more widespread in cosmetic products. The original proposed condition of use was intended to restrict these chemicals to the product class in which they were nominated so that the risk is mitigated. Statements received provided information on the concentrations in cosmetic products at which these chemicals are typically used in Australia, and also provided information on the difficulties of complying with a product based condition of use. The decided conditions of use expand the range of cosmetic products in which the chemicals can be introduced, whilst limiting the concentration of chemical in the product close to that reported as being used by industry in Australia. The Director views this combination of conditions of use as suitably mitigating the risk to the environment.

160965-04-8 Bertholletia Excelsa Extract	<ol style="list-style-type: none"> <li>1. For Cosmetic Use Only. For use in sunscreen products with an SPF up to 15.</li> <li>2. For Cosmetic Use Only.</li> </ol>	For Cosmetic Use Only. The concentration of this ingredient in the final product should be 0.013% or less.
90083-09-3 Potentilla erecta root extract	<ol style="list-style-type: none"> <li>1. For Cosmetic Use Only. For use in sunscreen products with an SPF up to 15.</li> <li>2. For Cosmetic Use Only.</li> </ol>	For Cosmetic Use Only. The concentration of this ingredient in the final product should be 0.04% or less.

### Group 3 Chemicals which may pose an unreasonable risk to health or the environment

The following chemicals contain components which were identified as having a potential for endocrine disrupting activity and estrogen receptor binding. This potential, in the absence of further information, leads to uncertainty about the likely impact on human health and the environment if the use of these chemicals is to become more widespread in cosmetic products. The original proposed condition of use was intended to restrict these chemicals to the product class in which they were nominated so that the risk is mitigated. Statements received provided information on the concentrations in cosmetic products at which these chemicals are typically used in Australia, and also provided information on the difficulties of complying with a product based condition of use. The decided conditions of use expand the range of cosmetic products in which the chemicals can be introduced, whilst limiting the concentration of chemical in the product close to that reported as being used by industry in Australia. The Director views this combination of conditions of use as suitably mitigating the risk to health or the environment to a reasonable level.

<b>CAS No. INCI name/AAN</b>	<b>Conditions of Use: 1. As originally proposed 2. As proposed in statements received</b>	<b>Conditions of Use Decided</b>
776295-36-4 Aspalathus linearis Extract	1. For Cosmetic Use Only. For use in sunscreen products with an SPF up to 15. 2. For Cosmetic Use Only.	For Cosmetic Use Only. The concentration of this ingredient in the final product should be 0.01% or less.
97952-72-2 Boswellia serrata extract	1. For Cosmetic Use Only. For use in sunscreen products with an SPF up to 15. 2. For Cosmetic Use Only.	For Cosmetic Use Only. The concentration of this ingredient in the final product should be 0.3% or less.
168456-53-9 Poria Cocos Sclerotium Extract (TGA name: Poria cocos)	1. For Cosmetic Use Only. For use in sunscreen products with an SPF up to 15. 2. For Cosmetic Use Only.	For Cosmetic Use Only. The concentration of this ingredient in the final product should be 0.2% or less.
94279-99-9 Scutellaria Baicalensis Extract/Root Extract	1. For Cosmetic Use Only. For use in sunscreen products with an SPF up to 15. 2. For Cosmetic Use Only.	For Cosmetic Use Only. The concentration of this ingredient in the final product should be 0.5% or less.

#### Group 4      Chemicals which may pose an unreasonable risk to health

The following chemical was proposed for listing with a condition of use based on concerns relating to developmental toxicity of a predicted metabolite. The chemical is predicted to metabolise, *in vivo*, to 2-ethylhexanoic acid which has been shown to be a developmental toxicant in animal studies. 2-Ethylhexanoic acid is classified as hazardous, Reproductive toxicant category 3 with a risk phrase R63 at concentrations greater than 5%, under the Safe Work Australia *Approved Criteria for Classifying Hazardous Substances*. The concentration limit in the original proposed condition of use is based on previous risk assessments by the Therapeutic Goods Administration and NICNAS of other esters which metabolise to 2-ethylhexanoic acid.

Statements received requested a removal of the concentration limit. Data on the developmental toxicity of 2-ethylhexyl terephthalate (DEHT) were provided to support that cetearyl octanoate could not present a risk of developmental toxicity. The data were not sufficient to warrant a change to the proposed condition of use due to differences in metabolic profiles between cetearyl octanoate and DEHT, and the absence of a consistent trend.

CAS No. INCI name/AAN	Conditions of Use: 1. As originally proposed 2. As proposed in statements received	Conditions of Use Decided
90411-68-0 Cetearyl octanoate	1. For Cosmetic Use Only. The concentration is not to exceed 5%. 2. For Cosmetic Use Only.	For Cosmetic Use Only. The concentration is not to exceed 5%.

## Attachment

### REVIEW RIGHTS INFORMATION

If you think this decision is wrong you have the right to apply to the Administrative Appeals Tribunal (AAT) for a review of this decision. The AAT is independent of NICNAS.

If you want the AAT to review the decision, you must apply to the AAT within 28 days of the date the decision was published or you received the decision. If you have good reason for not meeting the time limit, you can write to the AAT and ask for an extension of time, giving details of your reason(s).

Application forms are available from the AAT's website: [www.aat.gov.au](http://www.aat.gov.au). Alternatively you can make an application by writing a letter to the AAT. The letter should include:

- your full name
- your residential and postal address(es)
- your telephone number(s) and email address
- the date you received the decision you want reviewed
- brief reason(s) why you think the decision is wrong.

If you can, send a copy of the decision with your letter. If you can't, include the following details in your letter:

- a brief description of the decision
- the name and address of the person or organisation that made the decision
- the date the decision was made
- the reference number of the decision

For further information you can phone the AAT on (02) 9391 2400. If you live outside a metropolitan area you can phone the AAT on 1300 366 700, for the cost of a local call. If you are deaf or have a hearing or speech impairment, you can call through the National Relay Service ([www.relayservice.com.au](http://www.relayservice.com.au)).

The AAT's office is at:

Level 7, City Centre Tower  
55 Market Street  
Sydney NSW 2000

The address for mail is:

Administrative Appeals Tribunal  
GPO Box 9955  
Sydney NSW 2001  
Fax (02) 9283 4881

An application fee of \$777 is normally payable. However, you might not have to pay all of it. For example, if you hold a health care card or a Commonwealth seniors health card you only pay a reduced fee of \$100. If you believe you can't afford to pay the full fee, you can apply to pay the reduced fee of \$100.

If you pay the full application fee and the application is resolved in your favour, you will receive a partial refund. There is no refund if you have paid a reduced fee. If the application is not resolved in your favour, you will not have to pay NICNAS' costs.

Legal Aid offices, Community Legal Centres, or a lawyer may be able to help you with your application. You can phone or visit the AAT to receive information about these organisations.

Under the *Freedom of Information Act 1982*, any person has the right to seek access to documents about the decision(s).

## **9 NOTICE OF PROPOSED TRANSFER TO THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES OF CERTAIN COSMETIC INGREDIENTS IN PRODUCTS PREVIOUSLY REGULATED BY THE THERAPEUTIC GOODS ADMINISTRATION**

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 chemical 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. This chemical is currently regulated by NICNAS as a new chemical.

### **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 62 chemicals or substances for possible listing on the AICS.

In the *Chemical Gazette* of 7 February 2012, the Director, NICNAS, advised that an initial group of 34 chemicals for use in cosmetic products along with proposed controls had been listed on the AICS.

The Director, NICNAS, proposed the listing of a further group of 25 chemicals for use in cosmetic products along with proposed conditions of use in the 7 February 2012 *Chemical Gazette*. Of the remaining three chemicals, two are proposed not to be transferred and are the subject of a separate notice. This current notice proposes the transfer of the remaining chemical.

## Proposal

In accordance with sections 15AA(1) and 15AA(2) of the Act, the Director proposes to include a chemical and associated conditions of use as 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 this chemical is proposed for listing on the AICS. These reasons are:

- listing this chemical 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 chemical fulfils the eligibility criteria specific to the cosmetics reforms and legislated criteria for listing as described in Section 15AA(1);
- although this chemical has not been subject to a full assessment by NICNAS, the Director considers that, when used in cosmetic products only and in accordance with the proposed conditions of use, this chemical does not pose an unreasonable risk to occupational health and safety, public health and the environment.

In determining that this chemical poses no unreasonable risk when used within the proposed conditions of use, the Director noted that certain components of the extract have possible endocrine disrupting activity and estrogen receptor binding effects, in addition to other biological effects. However, the uncertainty in these effects on human health or the environment may be mitigated at low concentrations, as similar chemicals are commonly found in food at low levels.

The Director proposes conditions of use for this chemical that cover its use in a broad range of cosmetic products, but which limits its concentration in those products. The concentration limit proposed is that which poses no unreasonable risk to health or the environment, and is close to the concentrations known to be currently in use in Australia.

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

### **Statements about the Proposal**

For the chemical 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) Tuesday 3 July 2012<sup>2</sup>. The statement should 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 the chemical and associated conditions of use on the AICS for which a statement has been received.

<sup>2</sup> The Acts Interpretation Act 1901 requires that a time period commences with day 1 being the day after the publication of a notice. Therefore 28 days from publication of this notice is 3 July 2012.

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. Given the close of comments is COB 3 July 2012, the earliest opportunity to publish the notice will be the August 2012 *Chemical Gazette*.

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 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.

In determining that the chemical will pose no unreasonable risk when used within the conditions of use listed on the AICS, the Director has noted that the chemical possesses certain toxicological properties that may pose a risk to human health or the environment when used outside of these conditions. Introduction of a chemical for such other uses (for example, for a non-cosmetic use; or for a cosmetic use but at a higher concentration than specified in the condition of use) would mean the chemical is a new chemical as defined under Section 5 of the Act. The introduction of such a new chemical is subject to Section 21 of the Act and the associated requirements prescribed in the Industrial Chemicals (Notification and Assessment) Regulations 1990.

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

The chemical in Table 1 proposed for transfer to the AICS under section 15AA of the Act is currently considered a new chemical and so is 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 the chemical, however if the chemical is 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 chemical is being proposed for transfer to the AICS, the Director, NICNAS, has decided not to seek reports under s21AA for the chemical in Table 1 that is introduced as a new chemical for cosmetic use within the specified conditions of use during the current registration year between 1 September 2011 and 31 August 2012.

This decision was 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  
GPO Box 58  
Sydney  
NSW 2110

Phone 02 8577 8862  
Fax: 02 8577 8888  
email: [bill.diver@nicnas.gov.au](mailto:bill.diver@nicnas.gov.au)

**Table 1** Chemical 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
Morus Bombycis Root Extract	Mulberry, Morus bombycis, ext.	1174920-93-4	For Cosmetic Use Only. The concentration in products is not to exceed 0.015%.

## **10 NOTICE OF PROPOSAL NOT TO TRANSFER TO THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES CERTAIN COSMETIC INGREDIENTS IN PRODUCTS PREVIOUSLY REGULATED BY THE THERAPEUTIC GOODS ADMINISTRATION**

In accordance with section 15AA(1) of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) the Director proposes not to include the chemicals listed in Table 1 in the Australian Inventory of Chemical Substances (AICS). 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 62 chemicals or substances for possible listing on the AICS.

In the *Chemical Gazette* of 7 February 2012, the Director, NICNAS, advised that an initial group of 34 chemicals for use in cosmetic products along with proposed controls had been listed on the AICS.

The Director, NICNAS, proposed the listing of a further group of 25 chemicals for use in cosmetic products along with proposed conditions of use in the 7 February 2012 *Chemical Gazette*. Of the remaining three chemicals, one is proposed to be transferred and is the subject of a separate notice. The current notice relates to the remaining two chemicals.

## Proposal

In accordance with section 15AA(1) of the Act, the Director proposes not to include the chemicals listed in Table 1 on the AICS.

Section 15AA(5)(e) requires the Director, NICNAS, to state the reasons why these chemicals are not proposed for listing on the AICS. The reason is that the Director considers that:

- when used in cosmetic products only, these chemicals may pose an unreasonable risk to occupational health and safety, public health and the environment; and
- there is insufficient information available to determine conditions under which risk mitigation could be achieved.

Further details relating to this view are given in Table 1.

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

### **Statements about the Proposal**

For 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) Tuesday 3 July 2012<sup>3</sup>. The statement should provide relevant argument relating to the stated reasons given in this notice as to why the Director, NICNAS, is proposing not to list the chemicals on the AICS. The statement should address a specific chemical (ie not be a generic statement).

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. Given the close of comments is COB 3 July 2012, the earliest opportunity to publish the notice will be the August 2012 Chemical Gazette. An application can then be made to the Administrative Appeals Tribunal (AAT) for a review of a final decision by the Director.

### **Arrangements for annually reporting of chemicals under Sn15AA process**

The chemicals in Table 1 not 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 the 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.

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<sup>3</sup> The Acts Interpretation Act 1901 requires that a time period commences with day 1 being the day after the publication of a notice. Therefore 28 days from publication of this notice is 3 July 2012.



Given the chemicals in Table 1 are not proposed for listing on the AICS, the Director has decided to continue seeking reports under Sn21AA for these chemicals when introduced as new chemicals for cosmetic use during the current registration year between 1 September 2011 and 31 August 2012.

If you require further information please contact:

Dr Bill Diver  
Reform Section  
NICNAS  
GPO Box 58  
Sydney  
NSW 2110

Phone 02 8577 8862  
Fax: 02 8577 8888  
email: [bill.diver@nicnas.gov.au](mailto:bill.diver@nicnas.gov.au)

**Table 1** Chemicals proposed not to be included on the Australian Inventory of Chemical Substances under Section 15AA(1) and 15AA(2) of the *Industrial Chemicals (Notification and Assessment) Act 1989*

INCI name/AAN	CAS name	CAS No.	Reasons for proposal
Ajuga Turkestanica Extract	Ajuga turkestanica, ext.	329360-59-0	<p>Based on the potential for severe developmental effects to insects and in the absence of information to alleviate these concerns, the addition of Ajuga turkestanica to AICS is not proposed.</p> <p>The chemical has concerns relating to anabolic activity and also contains components which were identified as having potential for endocrine disrupting activity and estrogen receptor binding. Ajuga contains at least three classes of potentially bioactive compounds: clerodane diterpenes, phytoecdysteroids and iridoid glycosides. Clerodane diterpenes are known for their activity as insect alleochemicals (Camps F, 1993; Klein Gebbinck EA, 2002). Both the clerodane diterpenoids and the phytoecdysteroids with potential insect antifeedant and moulting hormone activities, respectively, may work interactively to potentiate the bioactivity of the Ajuga plants (Camps F, 1993).</p>
Coleus Barbatus Extract (AHN: Coleus forskohlii)	Coleus barbatus ext.	223748-52-5	<p>Based on the potential for adverse reproductive effects and in the absence of additional information to alleviate these concerns, the addition of Coleus barbatus extract to AICS is not proposed.</p> <p>The chemical has been reported to affect embryo implantation rates in rats and induce cardiovascular malformations in the chick embryo (Almeida, 2000; Nishikawa, 1989; Nishokawa 1995). A level for which no adverse effects are observed could not be established from the available data and hence a concentration which would establish an adequate margin of safety could not be defined.</p>

**References**

- Almeida FCG, Lemonica IP (2000). The toxic effects of *Coleus barbatus* B. on the different periods of pregnancy in rats. *J Ethnopharmacol*, 73: 53-60.
- Camps F (1993) Insect allelochemicals from *Ajuga* plants. *Phytochemistry*, 32 (6), 1361-1370.
- Klein Gebbinck EA, Jansen BJ, de Groot A (2002) Insect antifeedant activity of clerodane diterpenes and related model compounds. *Phytochemistry*, 61(7):737-70.
- Nishikawa T et al. (1989). A tetratogenic effect of forskolin on cardiovascular development in the chick embryo. *Reprod Toxicol.*, 3(2);139-42.
- Nishikawa T et al. (1995). The effect of forskolin on tetratogenicity of methylxanthines in the chick embryo heart. *Reprod Toxicol.*, 9(2):165-8.

## 11 NEW CHEMICALS FULL PUBLIC REPORTS

Reference Number	Applicant	Chemical or Trade Name	Hazardous Substance	Introduction Volume (per annum)	Use
<a href="#">STD/1418</a>	Salkat Australia Pty Ltd	Rewomid SPA	Yes	< 20 tonnes per annum	Component of personal care products
<a href="#">LTD/1508</a>	BP Australia Pty Ltd	Additive 309	ND	≤1 tonne per annum	Anti-corrosion and lubricant additive in grease formulations for use in mining, steel and printing industries
<a href="#">LTD/1561</a>	Hewlett Packard Australia Pty Ltd	PC-5	ND	≤ 2 tonnes per annum	Component of inks and coatings
	DIC Australia Pty Ltd				
<a href="#">LTD/1576</a>	Firmenich Limited	Jasmonitrile	Yes	<1 tonne per annum	Component of cosmetic and household cleaning products
<a href="#">LTD/1577</a>	Firmenich Limited	Aladinate	Yes	<1 tonne per annum	Component of cosmetic and household products
<a href="#">LTD/1582</a>	Givaudan Pty Ltd	Benzoic acid, 2-hydroxy-, (3Z)-1-methyl-3-hexen-1-yl ester	Yes	≤1 tonne per annum	Component of cosmetic and household cleaning products
<a href="#">LTD/1589</a>	Huntsman Advanced Materials (Australia) Pty Ltd	Polymer in Accelerator 2950	Yes	≤1 tonne per annum	A component of industrial coatings

<a href="#">LTD/1591</a>	BASF Australia Ltd	Polymer in Efka 4050 and Efka 4055	ND	≤ 10 tonnes per annum	A component of paints
<a href="#">LTD/1595</a>	Honda Australia Pty Ltd	Polymer C in SL211B	ND	≤ 2 tonnes per annum	Component of moisture-cured adhesives for automotive use
<a href="#">LTD/1596</a>	Honda Australia Pty Ltd	Polymer W in SL211B	ND	≤ 2 tonnes per annum	Component of moisture-cured adhesives for automotive use
<a href="#">LTD/1600</a>	Roland Digital Group Australia Pty Ltd	Acrylate Monomer in ECO-UV, EUV-BK	Yes	< 1 tonne per annum	A component of UV-curable inks at ≤ 30%
<a href="#">PLC/1015</a>	DSM Nutritional Products Australia Pty Limited	Tilamar Fix A1000	No	≤ 6 tonnes per annum	Component of hair care products
<a href="#">PLC/1042</a>	Dupont (Australia) Ltd	RC-74001	No	< 10 tonnes per annum	Component of automotive refinish paints
<a href="#">PLC/1047</a>	Amtrade International Pty Ltd	Polymer in VECTRA E 950IRX Series	No	≤ 50 tonnes per annum	Component in plastics
	Cintox Australia Pty Ltd				
<a href="#">PLC/1048</a>	Honda Australia Pty Ltd	Polymer SU-1	ND	≤ 300 kg per annum	A component of automotive adhesive
<a href="#">PLC/1049</a>	Honda Australia Pty Ltd	Polymer SU-2	ND	≤ 1200 kg per annum	A component of automotive adhesive
<a href="#">PLC/1052</a>	Lubrizol International Inc	Z-129	No	≤ 300 tonnes per annum	Component of overprint varnishes
<a href="#">PLC/1053</a>	Lubrizol International Inc	Z-130	No	≤ 20 tonnes per annum	Used as a component of surface coatings

<a href="#">PLC/1054</a>	Evonik Australia Pty Ltd	Trogamid CX7323	No	≤ 30 tonnes per annum	Component used in the manufacture of plastic articles
<a href="#">PLC/1060</a>	Bayer MaterialScience Pty Ltd	Polymer in Bayhydrol UH XP 2648/1	No	≤100 tonnes per annum	Component of coatings
<a href="#">SAPLC/131</a>	PPG Industries Australia Pty Ltd	Polymer in HP-28-8107	No	≤ 2100 tonnes per annum	Component of paints for industrial exterior roofing and walling coil coatings
<a href="#">SAPLC/132</a>	Specialty Polymers & Chemicals Pty Ltd	Polymer in Zeonor 1000 Series	No	≤50 tonnes per annum	Raw material used in the manufacture of moulded plastic articles
<a href="#">SAPLC/133</a>	Specialty Polymers & Chemicals Pty Ltd	Polymer in 1400 Series	No	≤50 tonnes per annum	Raw material used in the manufacture of moulded plastic articles
<a href="#">SN/24</a>	Estee Lauder Pty Ltd	Glycine, N-coco acyl derivs., potassium salts (Potassium Cocoyl Glycinate)	Yes	≤ 2 tonnes per annum	A surfactant in a wash-off cosmetic product
<a href="#">EX/173</a>	United Terminals Pty Ltd	Infineum 6399	No	< 65 tonnes per annum	An additive for diesel fuels

**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 from the NICNAS website**

## **12 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.

### 13 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
822	Bayer MaterialScience Pty Ltd	Bayhydrol A 2695	Component of coatings
823	Evonik Australia Pty Ltd	Polymer in Vestamid ZA4841	Component of plastic articles
826	Evonik Australia Pty Ltd	Polymer in Viscoplex 12/6886	Additive in driveline oils
827	DuPont (Australia) Ltd	RC-74002A	Component of automotive refinish paints
828	DuPont (Australia) Ltd	RC-74002B	Component of automotive refinish paints
829	Cytec Australia Holdings Pty Ltd	Polymer 1 in Resydrol AZ 6710 and AZ 6195w	Component of exterior wood coatings
830	Cytec Australia Holdings Pty Ltd	Polymer 2 in Resydrol AZ 6710 and AZ 6195w	Component of exterior wood coatings
831	A.S. Harrison & Co Pty Ltd	Polymer in OMA 600	Fuel additive
832	Reschem Technologies Pty Ltd	Polymer 1 in NeoCryl A-1127	Component of printing inks
833	Reschem Technologies Pty Ltd	Polymer 2 in NeoCryl A-1127	Component of printing inks



## 14 COMMERCIAL EVALUATION CATEGORY PERMIT

The permits listed in Table 2 were issued to import or manufacture the following chemicals for commercial evaluation under section 21G of the *Industrial Chemicals (Notification and Assessment) Act 1989*.

**Table 2**  
**Commercial Evaluation Category Permits**

PERMIT NUMBER	COMPANY NAME	COMPANY POSTCODE	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	QUANTITY	USE	PERIOD APPROVED
792	Dow Chemical Australia Ltd	3018	Ploymer in Betaprime 5500 & 5504G	Yes	4000	Component of automotive windscreen sealent	2/5/12 to 2/5/13
794	The Valspar (Australia) Corporation Pty Limited	2761	Polymer in Resin G 515 (A)	ND	1000	Component of coatings for the internal and external surfaces of cans	22/5/12 to 22/5/13

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

## 15 LOW VOLUME CATEGORY PERMITS

The permits listed in Table 3 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 3**  
**Low Volume Category Permits**

PERMIT NUMBER	COMPANY NAME	COMPANY POSTCODE	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	USE
962	Chemiplas Australia Pty Ltd	3002	REAX 907	Yes	900
963	Huntsman Advanced Materials (Australia) Pty Ltd	3023			

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

# 16 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 4**

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

CHEMICAL NAME	MOLECULAR FORMULA	CAS NUMBER
1,3-Benzenedicarboxylic acid, 5,5'-[(1,6-dihydro-6-oxo-1,3,5-triazine-2,4-diyl)bis[ {(5-amino-3-(1,1-dimethylethyl)-1H-pyrazole-1,4-diyl)azo(4-cyano-1H-pyrazole-5,1-diyl)} ]]]bis-, pentapotassium salt	$C_{41}H_{35}N_{19}O_9.5K$	873773-68-3
Fatty acids, C16-C18 and C18-unsaturated, epoxidised, methyl esters, polymers with trimethylolpropane	Unspecified	188831-96-1
1-Propanaminium, N,N,N-trimethyl-3-[(2-methyl-1-oxo-2-propenyl)amino]-, chloride, polymer with N-(1-methylethyl)-2-propenamide, 2-methyl-2-[(1-oxo-2-propenyl)amino]-1-propanesulphonic acid and 2-propenoic acid, sodium salt	$(C_{10}H_{21}N_2O.C_7H_{13}NO_4S.C_6H_{11}NO.C_3H_4O_2.Cl)_x.xNa$	880345-00-6
2-Naphthalenesulfonic acid, 5,5'-[carbonylbis(imino-4,1-phenylene-2,1-diazenediyl)]bis[8-[2-(4-sulfophenyl)diazenyl]-, lithium salt (1:4)	$C_{45}H_{28}N_{10}O_{13}S_4.4Li$	765314-87-2
1-Tetradecanaminium, N-(carboxymethyl)-N,N-dimethyl-, inner salt	$C_{18}H_{37}NO_2$	2601-33-4
2-Propenoic acid, 2-methyl-, methyl ester, polymer with butyl 2-propenoate, N-(1,1-dimethyl-3-oxobutyl)-2-propenamide, ethenylbenzene and 2-propenoic acid	$(C_9H_{15}NO_2.C_8H_8.C_7H_{12}O_2.C_5H_8O_2.C_3H_4O_2)_x$	121772-02-9
Carbonic dichloride, polymer with 2,3-dihydro-3,3-bis(4-hydroxyphenyl)-2-phenyl-1H-isoindol-1-one and 4,4'-(1-methylethylidene)bis[phenol], bis[4-(1-methyl-1-phenylethyl)phenyl] ester	$(C_{26}H_{19}NO_3.C_{15}H_{16}O_2.CCl_2O)_x.2C_{15}H_{16}O$	503834-43-3
6-Benzothiazolesulfonic acid, 2-[4-cyano-5-[2-[2-[(2,6-diethyl-4-methyl-3-sulfophenyl)amino]-6-[(2,6-diethyl-4-methyl-3-sulfophenyl)(6-sulfo-2-benzothiazolyl)amino]-4-methyl-3-pyridinyl]diazenyl]-3-(1,1-dimethylethyl)-1H-pyrazol-1-yl]-, lithium salt (1:4)	$C_{50}H_{52}N_{10}O_{12}S_6.4Li$	873110-32-8
Distillates (petroleum), catalytic reformer	Unspecified	908356-16-1

fractionator residue, low-boiling, C9-rich C8-10-alkylate, sulfonated, sodium salts		
Formaldehyde, polymer with 2-propanone, bisulfited, monoethers with 3,4,5- trihydroxybenzoic acid, sodium salts	Unspecified	1101873-72-6

# 17 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 5**

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

CHEMICAL NAME	MOLECULAR FORMULA	CAS NUMBER
2-Butenedioic acid (2E)-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[ethanol] and 1,1'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bis[2-propanol]	$(C_{21}H_{28}O_4.C_{19}H_{24}O_4.C_4H_4O_4)_x$	1215294-11-3
1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, polymer with N, N-dimethyl-2-propenamide, calcium salt	$(C_7H_{13}NO_4S.C_5H_9NO)_x.xCa$	103115-52-2
1,3-Propanediol, 2,2-bis(hydroxymethyl)-, polymer with oxirane, ester with .alpha.-[[[3-[(carboxyamino)methyl]-3,5,5-trimethylcyclohexyl]amino]carbonyl]-.omega.-[(2-methyl-1-oxo-2-propen-1-yl)oxy]poly[oxy(methyl-1,2-ethanediyl)]	$(C_5H_{12}O_4.C_2H_4O)_x.x(C_3H_6O)_nC_{16}H_{26}N_2O_5$	1372709-44-8
Heptanenitrile, 2-propyl-	$C_{10}H_{19}N$	208041-98-9
2,5-Furandione, polymer with 1,3-diisocyanatomethylbenzene and .alpha.-hydro-.omega.-hydroxypoly(oxy-1,2-ethanediyl), 2-butanol- and 2-hydroxyethyl acrylate-1H-imidazole reaction products- and 2-oxepanone homopolymer cetyl ester blocked	Unspecified	1262231-49-1

## 18 NOTICE OF AMENDMENTS TO THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES

Notice is given in accordance with section 20AA of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) that the Director intends to remove the chemical in the table below from the Australian Inventory of Chemical Substances (AICS). Based on advice from Industry, 2-decanol, benzoate (CAS RN 31637-00-0) was wrongly included in the AICS by the nominator.

**Table 6**  
**Chemical to be removed**

CHEMICAL NAME	MOLECULAR FORMULA	CAS NUMBER
2-Decanol, benzoate	C <sub>17</sub> H <sub>26</sub> O <sub>2</sub>	31637-00-0

Under section 20AA of the Act a person may give a written statement to the Director within 3 months of this notice giving reasons why the chemical should not be removed. Section 20AA of the Act states that,

- 5) If the Director accepts the reasons why the chemical should not be removed, the Director must:
  - a) leave the chemical, and any particulars in respect of the chemical, in the Inventory; and
  - b) publish a notice in the Chemical Gazette that the chemical is not going to be removed; and
  - c) give a copy of the notice to the person who gave the statement.
- 6) If the Director rejects the reasons why the chemical should not be removed, the Director must:
  - a) give the person who made the statement notice of the decision to reject the reasons; but
  - b) not remove the chemical, or any particulars in respect of the chemical, until 28 days after the date of the giving of the notice or, if the person applies to the Tribunal for review of the decision, until the review has been finalised.

Therefore any such written statement should be provided by **5 September 2012** and addressed to:

The Director  
NICNAS  
GPO Box 58  
Sydney, NSW, 2001

Or by fax to (02) 8877 8888 or e-mail: [aics.officer@nicnas.gov.au](mailto:aics.officer@nicnas.gov.au)