



Australian Government

Gazette

No. C 01, Tuesday 6 January 2009

Published by the National Industrial Chemicals
Notification and Assessment Scheme - NICNAS

CHEMICAL

© Commonwealth of Australia 2007

ISBN 1035-9877

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth available from the Attorney-General's Department. Requests and inquiries concerning reproduction and rights should be addressed to:

Commonwealth Copyright Administration
Copyright Law Branch
Attorney-General's Department
Robert Garran Offices
National Circuit
Canberra ACT 2600

email: Commonwealth.Copyright@ag.gov.au <<mailto:Commonwealth.Copyright@ag.gov.au>>

web: <<http://www.ag.gov.au/cca>>



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.

CONTENTS

SPECIAL NOTICES

1	REMINDER NOTICE - INDUSTRIAL NANOMATERIALS - VOLUNTARY CALL FOR INFORMATION 2008	5
2	SECONDARY NOTIFICATION OF COMPLEX SOAP TH17	7
3	DATA COLLECTION BY NICNAS ON USES OF PERFLUOROOCTANE SULFONATE (PFOS) AND PERFLUOROALKYL SULFONATES (PFAS) AND RELATED SUBSTANCES AND PRODUCTS/MIXTURES CONTAINING THESE SUBSTANCES	9

NEW CHEMICALS

SUMMARY REPORTS

4	LTD/1381	POLYQUATERNIUM-72	10
5	LTD/1384	POLYMER IN ACUSOI 448	13
6	STD/1307	SILAN 449029 VP	15
7	PLC/770	POLYMER IN FINETONE T-6694	17
8	PLC/803	LEWATIT MONOPLUS TP 220	19
9	EX/116	DYNASYLAN 9116	22
10	EX/117	REWODERM LI 520 (PEG-200 HYDROGENATED GLYCERYL PALMATE)	25
11	EX/121	INFINEUM C9535	28
12	ACCESS TO FULL PUBLIC REPORT		31

PERMITS ISSUED

13	LOW VOLUME CHEMICAL PERMITS	32
14	COMMERCIAL EVALUATION CATEGORY PERMITS	33

15	EARLY INTRODUCTION PERMITS	34
AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES		
16	NOTICE OF CHEMICALS ELIGIBLE FOR LISTING ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES FIVE YEARS AFTER ISSUING OF ASSESSMENT CERTIFICATES	35
17	NOTICE OF CHEMICALS ELIGIBLE FOR IMMEDIATE LISTING ON THE AUSTRALIAN INVENTORY OF CHEMICAL SUBSTANCES AFTER ISSUING OF ASSESSMENT CERTIFICATES	37

1 REMINDER NOTICE - INDUSTRIAL NANOMATERIALS VOLUNTARY CALL FOR INFORMATION 2008

This Notice is to remind all persons who have manufactured or imported nanomaterials or products (mixtures) containing nanomaterials for commercial or research and development purposes in 2008 that a Voluntary Call for Information on Industrial Nanomaterials is currently open. The closing date for the Call is **Friday 23 January 2009**, which is just three weeks away.

The aims of the Call, which was published in the October 2008 Chemical Gazette, http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2008oct_whole.pdf, are to:

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

NICNAS undertook a Voluntary Call for Information in 2006 in relation to industrial nanomaterials that are in the marketplace and their intended applications (see http://www.nicnas.gov.au/Publications/Information_Sheets/General_Information_Sheets/NIS_Call_for_info_Nanomaterials.pdf). In 2008, NICNAS is extending this survey via the current Voluntary Call for Information to include industrial nanomaterials at the research and development stage and by ascertaining what categories of physico-chemical and toxicological data are held on each nanomaterials – though actual data are not to be submitted nor new data generated.

The time taken to participate in this Call is estimated to be up to 4 hours to fill-in the questionnaire per nanomaterial, exclusive of the time you might need to locate and collect data. There are two options for providing information to this Call:

1. electronic lodgement of an emailed form to the NICNAS Reform Team at nag@nicnas.gov.au; or
2. faxed [to (02) 8577 8888] or posted lodgement of a written response on the emailed form (this form can also be posted to you if requested, and is also available in the October Chemical Gazette). If posting, send to:

REPLY PAID 58
NICNAS
Reform Team
GPO Box 58
Sydney NSW 2001

To participate in the Call, please lodge your response by **COB Friday 23 January 2009**.

If you would like any further information please contact:

- NICNAS
Dr Matthew Gredley
02 8577 8873
matthew.gredley@nicnas.gov.au

Or, please refer to the following websites:

- NICNAS –
<http://www.nicnas.gov.au/>
http://www.nicnas.gov.au/Current_Issues/Nanotechnology.asp

2 SECONDARY NOTIFICATION OF COMPLEX SOAP TH17

In accordance with section 65(2) of the *Industrial Chemicals (Notification and Assessment) Act*, 1989 (the Act), as amended, notice is given that the Director requires the secondary notification of the existing chemical **Complex Soap TH17**.

Additional Information Available for Complex Soap TH17

Complex Soap TH17 was assessed as a new industrial chemical (STD/1021) and a report published in August 2002. The assessment recommended that the chemical be classified as harmful by inhalation and if swallowed with the risk phrases R20/22. Since the publication of the NICNAS report, Scientific Consulting Company (SCC) from Germany representing KL Australia P/L, has made available to the Director, additional information in relation to water extractability of barium ions and in vitro permeability of Complex Soap TH17.

Reasons for Secondary Notification

The Director has decided that a secondary notification for Complex Soap TH17 is required because the additional data now provided has relevance to the hazardous nature of the chemical in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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 Complex Soap TH17 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 information relevant to an assessment of Complex Soap TH17 which was not originally covered in the August 2002 assessment report.

In addition importers must provide information on the following:

- annual quantities of the chemical imported (as 'pure' Complex Soap TH17 and/or in products/mixtures) in the calendar years 2006, 2007 and 2008 to date along with the concentrations of Complex Soap TH17 in the products/mixtures and the product names; and, the quantities proposed to be imported during the remainder of 2009.
- annual quantities of the chemical which have been formulated into products/mixtures by the applicant in the calendar years 2006, 2007 and 2008 to date, the concentration of Complex Soap TH17 in these products/mixtures and the product names; and, quantities proposed to be formulated during the remainder of 2009.

- known or potential Australian uses of Complex Soap TH17 and, if the conditions of use have varied from ready-to-use grease (containing 30% Complex Soap TH17) for long term and lifelong lubrication of rolling bearings in sealed components
- methods used or proposed to be used in handling, storing, formulation with and disposal of Complex Soap TH17;
- copies of Material Safety Data Sheets (MSDS) and labels for Complex Soap TH17 and its products;
- any unpublished studies relevant to human and environmental toxicity and risks associated with Complex Soap TH17 and any other published and unpublished information relevant to the assessment. If data are provided on analogue chemicals as being relevant to Complex Soap TH17, supportive data to justify the relevance of analogue data must also be provided;
- contact details of the persons to whom Complex Soap TH17 or products/mixtures containing Complex Soap TH17 have been supplied and/or those to whom it is intended to supply Complex Soap TH17 or products/mixtures containing Complex Soap TH17. This is important information which enables NICNAS to contact downstream users for information necessary for assessment. Customer lists are kept confidential.

The secondary notification application form can be found on the NICNAS website at:
http://www.nicnas.gov.au/Forms/Existing_Chemicals/Form1a_SN_PEC_Word.doc

An application that some or all of this information should be exempt from publication may be made under section 75 of the Act, using the approved form which can be found at:
http://www.nicnas.gov.au/Forms/Existing_Chemicals/Form3_Exemption_Information_Word.doc

A fee of \$683 applies for claims of confidentiality.

Applications must be received no later than **4 February 2009**.

Additional persons with relevant information

In addition to the requirement to apply for secondary notification, any persons with information relevant to the assessment of Complex Soap TH17 that was not originally covered in the August 2002 assessment report are encouraged to submit the information for consideration. A copy of the assessment report (STD/1021) can be found on the NICNAS website at:

<http://www.nicnas.gov.au/publications/CAR/new/std/stdFULLR/std1000FR/std1021FR.pdf>

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*.

Applicants are requested to contact Dr Julija Filipovska by telephone (02) 8577 8895, fax: (02) 8577 8888 or e-mail: julija.filipovska@nicnas.gov.au for further information.

3 DATA COLLECTED BY NICNAS ON USES OF PERFLUOROOCCTANE SULFONATE (PFOS) AND PERFLUOROALKYL SULFONATE (PFAS) AND RELATED SUBSTANCES AND PRODUCTS/MIXTURES CONTAINING THESE SUBSTANCES

The Director of NICNAS sought information under section 48 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) on the manufacture, importation and use of perfluorooctane sulfonate (PFOS) and perfluoroalkyl sulfonate (PFAS) and their related substances, and products/mixtures containing these substances. A notice calling for information was published in the *Chemical Gazette* of 1 April 2008.

One hundred and forty eight responses were received to the call for information. It was reported that no manufacture of these chemicals occurs in Australia. Of the 148 responses twenty seven respondents indicated import and/or formulation activities with PFOS, PFAS and their related substances. Majority of the responses indicated that neither importation nor use of PFOS or PFAS had occurred since the last NICNAS call for information in 2006. In accordance with section 50A of the Act, summaries of the information collected are published in NICNAS Alert 8, which can be accessed on the NICNAS website:

http://www.nicnas.gov.au/Publications/NICNAS_Alerts.asp

4 PUBLICATION SUMMARY REPORT

Polyquaternium-72 Summary Report Reference No: LTD/1381

Croda Singapore Pty Ltd (Trading as Croda Australia) (ABN: 34 088 345 457) of Ground Floor, Suite A1, 44-46 Mandarin Street, Villawood, NSW 2163 has submitted a limited notification statement in support of their application for an assessment certificate for Polyquaternium-72. The notified polymer is intended to be used as a component of hair care products at concentrations of < 4.5%. Up to 3 tonnes of the notified polymer will be imported per annum for each of the first five years.

Hazard Classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human Health Risk Assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental Risk Assessment

On the basis of the likely biodegradability and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

Control Measures

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Good hygiene practices
- Employers should ensure that the following personal protective equipment is used by reformulation workers to minimise occupational exposure to the notified polymer:
 - Safety glasses
 - Gloves
 - Protective clothing

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000; or

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of hair care products at concentrations of < 4.5%, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 3 tonnes, or is likely to increase, significantly;
 - if the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

5 PUBLICATION SUMMARY REPORT

Polymer in Acusol 448 Summary Report Reference No: LTD/1384

Rohm and Haas Australia Pty Ltd (ABN 29 004 513 188) of 969 Burke Road Camberwell VIC 3124 and Ecolab Pty Ltd (ABN 59 000 449 990) of 6 Hudson Avenue Castle Hill NSW 2154 have submitted a limited notification statement in support of their application for an assessment certificate for Polymer in Acusol 448. The notified polymer is intended to be used as a component of domestic and industrial cleaners and detergents. Thirty tonnes of the notified polymer will be imported per annum for each of the first five years.

Hazard Classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human Health Risk Assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental Risk Assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

Control Measures

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical in the product Acusol 448:
 - Coveralls
 - Impermeable gloves
 - Safety goggles

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures

consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of domestic and industrial cleaners and detergents, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 30 tonnes per annum, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

6 PUBLICATION SUMMARY REPORT

Silan 449029 VP Summary Report Reference No: STD/1307

Wacker Chemie AG (ABN 11 607 113 062) of 1/35 Dunlop Road Mulgrave VIC 3170 has submitted a standard notification statement in support of their application for an assessment certificate for Silan 449029 VP. The notified chemical is intended to be used as an additive for silicone sealant formulations. Eight tonnes of the notified chemical will be imported per annum for each of the first five years.

Hazard Classification

Based on the available data the notified chemical is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human Health Risk Assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental Risk Assessment

On the basis of the hydrolytic instability of the notified chemical and available data on ecotoxicity of the hydrolysis products and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

Control Measures

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical itself, however, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - further information on the genotoxic potential of the chemical becomes available,
 - the concentration of the notified chemical is > 10% in the imported silicone sealant formulations.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from an additive for silicone sealant formulations, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 8 tonnes per annum, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

7 PUBLICATION SUMMARY REPORT

Polymer in Finetone T-6694 Summary Report Reference No: PLC/770

DIC Australia Pty Ltd (ABN 12 000 079 550) of 323 Chisholm Road, Auburn NSW 2144 has submitted a polymer of low concern (PLC) notification statement in support of their application for an assessment certificate for Polymer in Finetone T-6694. The notified polymer is intended to be used as component of photocopier toner at a concentration of approximately 20% w/w. Up to 10 tonnes of the notified polymer will be imported per annum for each of the first five years.

Hazard Characterisation

No toxicological data were submitted. The notified polymer meets the PLC criteria and can therefore be considered to be of low hazard.

Human Health Risk Assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental Risk Assessment

Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

Control Measures

Occupational Health and Safety

- Specific engineering controls, work practices or personal protective equipment should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from Component of photocopier toner at a concentration approximately 20% w/w, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - if the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

8 PUBLICATION SUMMARY REPORT

Lewatit MonoPlus TP 220 Summary Report Reference No: PLC/803

Lanxess Pty Ltd (ABN: 58 071 919 116) of Unit 1, 31 Hill Road Homebush Bay NSW 2127 has submitted a polymer of low concern (PLC) notification statement in support of their application for an assessment certificate for LEWATIT MonoPlus TP 220. The notified polymer is intended to be used as an ion-exchange resin in the mining industry. Up to 1000 tonnes of the notified polymer will be imported per annum for each of the first five years.

Hazard Classification

Based on the available data, the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human Health Risk Assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental Risk Assessment

Based on the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

Control Measures

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified polymer should be disposed of by landfill.

Storage

- Store in original container protected from direct sunlight in a dry, cool, well ventilated area, away from incompatible materials and food and drink.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from use as an ion-exchange resin in the mining industry, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased or is likely to increase, significantly;
 - if the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

9 PUBLICATION SUMMARY REPORT

Dynasytan 9116 Summary Report Reference No: EX/116

Plastral Pty Ltd. (ABN 68 000 144 132) of 11b Lachlan St Waterloo NSW 2017 has submitted a standard notification statement in support of their application for an assessment certificate for Dynasytan 9116. The notified chemical is intended to be used as an additive for polyethylene to make plastic articles. Up to 100 tonnes of the notified chemical will be imported per annum for each of the first five years.

Since the assessment certificate has been granted for the above notified chemical, Bourouge Australia Pty Ltd of Suite 1013, St Kilda Road Towers, 1 Queens Road, Melbourne VIC 3004 has submitted an application for extension of the assessment certificate (No. 2364, STD/1206), together with a written agreement of the holder of the original certificate, Plastral Pty Ltd., for importing up to 0.3 tonne of the notified chemical per annum for use as an additive in the manufacture of plastic articles.

ASSESSMENT OF PUBLIC, OCCUPATIONAL HEALTH AND SAFETY AND ENVIRONMENTAL EFFECTS

Hazard Assessment

The notified chemical is of low acute toxicity via oral exposure (LD50 > 5002 mg/kg/bw).

A number of signs of severe dermal irritation were seen in two skin irritation studies, one using the notified chemical and following OECD TG and one using an analogue chemical and not conducted with OECD TG. The signs of irritation persisted in all animals for more than 24 hours. Based on this evidence, the notified chemical is classified in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004) as:

R38 – irritating to skin

Eye irritation and skin sensitisation (Buehler Test) studies using the notified chemical and following OECD TG showed slight eye irritation and negative allergic reaction.

A 28-days repeated dose inhalation study was conducted using an analogue chemical resulted in chronic inflammatory changes to the lung, dose related changes in haematological indices and morphological changes to the bone marrow in treated rats. Changes in leucocyte counts were seen at the lowest dose tested (0.5 ppm) and no NOAEL can be determined for this study. It is not expected that the notified chemical will display effects more adverse than those observed with trimethoxysilane (analogue 1) in this repeat dose inhalation study. Further testing on the notified chemical would be required for a satisfactory assessment of effects from repeated exposure. Based on this study the notified chemical is likely to be irritating to respiratory system:

R37 Irritating to respiratory system

There was no evidence of genotoxicity based on bacterial reverse mutation test (using an analogue chemical) and *in vitro* mammalian chromosome aberration test (using the notified chemical).

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R37/38 – Irritating to respiratory system and skin

Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

Public Health

There is No Significant Concern to public health based on the reported use pattern.

Environmental Effects

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Risk Assessment Relating to Extension Application

The proposed use, introduction volume and fate of the notified chemical will not change significantly under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment.

RECOMMENDATIONS

Regulatory Controls

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following hazard classification for the notified chemical:
 - R37/38 Irritating to respiratory system and skin
- The following risk phrases for products/mixtures containing the notified chemical apply:
 - $\geq 20\%$ R37/38 Irritating to respiratory system and skin
- Products containing $\geq 20\%$ notified chemical should carry the following warnings on the label:
 - S24 Avoid contact with skin
 - S25 Avoid contact with eyes
 - S36 Wear suitable protective clothing
 - S37 Wear suitable gloves

Control Measures

Occupational Health and Safety

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of by authorised landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical collection for reuse of the spilled material to the extent practicable or disposal.

Secondary Notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

10 PUBLICATION SUMMARY REPORT

Rewoderm LI 520 (PEG-200 hydrogenated glyceryl palmate) Summary Report Reference No: EX/117

Galderma Australia Pty Ltd (ABN 12 003 976 930) of 13B Narabang Way, Belrose NSW 2085 and Salkat Australia Pty Ltd (ABN 30 318 540 786) of 262 Highett Road, Highett VIC 3190 have submitted a polymer of low concern (PLC) notification statement in support of their application for an assessment certificate for Rewoderm LI 520 (PEG-200 hydrogenated glyceryl palmate). The notified polymer is intended to be used as a component of shampoos and body washes at up to 8%. The notified polymer will either be imported as part of finished consumer products or imported and incorporated into formulations in Australia. Thirty three tonnes of the notified polymer will be imported per annum for each of the first five years.

Since the assessment certificate has been granted for the above notified polymer, L'Oreal Australia Pty Ltd of 256 Bay Rd Sandringham VIC 3191 has submitted an application for extension of the assessment certificate (Nos. 2731 & 2732, PLC/736), together with a written agreement of the holders of the original certificate (Galderma Australia Pty Ltd & Salkat Australia Pty Ltd) for importing up to three tonnes of the notified polymer per annum for use as an emulsifier and viscosity improver in cosmetic products.

Human Health Risk Assessment

Under the conditions of the occupational settings described and when used in the proposed manner, the notified polymer is not expected to pose an unreasonable risk to workers and the public.

Environmental Risk Assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

Risk Assessment Relating to Extension Application

The proposed use, introduction volume and fate of the notified polymer will not change significantly under the proposed extension, although the extension application covers leave-on as well as wash-off products. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment.

Recommendations

Control Measures

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of to landfill.

Storage

- The following precautions should be taken regarding storage of the notified polymer:
 - Protect from freezing

Emergency procedures

- Spills and/or accidental release of the notified polymer should be soaked into an absorbent material.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from ingredient in personal care products, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 33 tonnes, or is likely to increase, significantly;
 - if the chemical has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Extension Application

The applicant for extension application has provided MSDS of a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

11 PUBLICATION SUMMARY REPORT

Infineum C9535 Summary Report Reference No: EX/121

Infineum Australia Pty Ltd. (ABN 24 084 881 863) of 2/6 Riverside Quay, Southbank VIC 3006 has submitted a polymer of low concern notification statement in support of their application for an assessment certificate for Infineum C9535. The notified polymer is intended to be used as cold flow additive for use in diesel fuels. Up to 200 tonnes of the notified polymer will be imported per annum for each of the first five years.

Since the assessment certificate has been granted for the above notified chemical, Shell Company of Australia Ltd (ABN 46 004 610 459) of 8 Redfern Road, East Hawthorn VIC 3123 has submitted an application for extension of the original assessment certificate (No. 1905, PLC/492) together with a written agreement of the current holder of the original certificate, Infineum Australia Pty Ltd. The notified polymer will be imported as a component in diesel fuel. Up to 200 tonnes of the notified polymer will be imported per annum for each of the first five years. The use of the notified polymer will not change.

Since the previous extension assessment certificate has been granted for the above notified chemical, BP Australia Pty Ltd (ABN 53 004 085 616) of 360 Elizabeth St, Melbourne VIC 3130 has submitted an application for extension of the original assessment certificate (No. 1905, PLC/492) together with a written agreement of the current holder of the original certificate, Infineum Australia Pty Ltd. The notified polymer will be imported as a component in diesel fuel. Up to 10 tonnes of the notified polymer will be imported per annum for each of the first five years. The use of the notified polymer will not change.

Occupational Health and Safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

Public Health

There is Negligible Concern to public health based on its reported use pattern.

Environmental Effects

The polymer is not considered to pose a risk to the environment based on its reported use pattern.

Risk Assessment Relating to Extension Applications

Previous Extension Application:

Use and fate of the notified polymer will not change under the proposed extension. The circumstances in the extension application are not expected to significantly change the environmental and health impacts. Therefore there are no changes required in the risk assessment.

Current Extension Application

The proposed use, introduction volume and fate of the notified polymer will not change significantly under the proposed extension. The circumstances in the extension application are not expected to impact on the original human health and environment risk assessment.

RECOMMENDATIONS*Control Measures*

Occupational Health and Safety

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.
 - Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by incineration

Emergency procedures

Land spill

- If the notified polymer is spilled outside the workplace, the liquid should be prevented from entering sewers, watercourses or low areas. The liquid should be contained with sand or earth and recovered by pumping or by absorption into sand or earth before being disposed in an approved manner.

Water spill

- The spill should be removed from the surface of the water by skimming or with suitable absorbent. If appropriate, sinking and/or dispersants may be used in non-confined waters.

Regulatory Obligations**Secondary Notification**

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under subsection 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

- (2) Under subsection 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet

Original Application:

The notifier has provided MSDS as part of the notification statement. The accuracy of the information on the MSDS remains the responsibility of the applicant.

Current Extension Application

The applicant for extension application has provided MSDS of a product containing the notified polymer. The accuracy of the information on the MSDS remains the responsibility of the extension applicant.

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 334-336 Illawarra Road, Marrickville NSW 2204.

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 8870 or fax: (02) 8577 8888.

13 LOW VOLUME CATEGORY PERMITS

The permits listed in Table 1 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 1
Low Volume Category Permits

PERMIT NUMBER	COMPANY NAME	COMPANY POSTCODE	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	USE	DATE
822	Procter and Gamble Australia Pty Ltd	2113	Blue Hair Dye 2 (Tetrabromophenol Blue)	Yes	Hair Dye	02.12.08
823	Cosmetic Suppliers Pty Ltd	2113				

14 COMMERCIAL EVALUATION CATEGORY PERMIT

The permit below was published in the 2nd December 2008 Chemical Gazette under section 21G of the *Industrial Chemicals (Notification and Assessment) Act 1989*. This listing was published with an incorrect trade name. The following listing contains the correct trade name.

Table 2
Commercial Evaluation Category Permits

PERMIT NUMBER	COMPANY NAME	COMPANY POSTCODE	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	QUANTITY	USE	PERIOD APPROVED
736	HB FULLER COMPANY AUSTRALIA PTY LTD	3175	Rakoll PUS 9654B	YES	4000 kg	Component of hot melt adhesive resin	24.11.2008

15 EARLY INTRODUCTION PERMITS FOR NON-HAZARDOUS INDUSTRIAL CHEMICALS

The permits listed in Table 3 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 3

Early Introduction Permits

PERMIT NUMBER	COMPANY NAME	CHEMICAL OR TRADE NAME	USE
583	PPG Industries Australia Pty Ltd	KZX-123	A component of automotive spray paint for original equipment manufacture
584	Akzo Nobel Pty Ltd	L-Glutamic acid, N,N-bis(carboxymethyl)-, tetrasodium salt	Chelating agent
585	PPG Industries Australia Pty Ltd	Powder 661	A component of automotive spray paint
586	Plastral Pty Ltd	Polymer in Mater Bi CF & CS	Polymer for use in consumer articles

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
2-Butenedioic acid (2Z)-, sodium salt, polymer with 2-propenoic acid, sodium salt, peroxydisulfuric acid $[(HO)S(O)_2]_2O_2$ disodium salt-initiated	Unspecified	152261-37-5
2-Oxepanone, polymer with 1,4-butanediol, 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane and 2,2'-oxybis[ethanol], 2-hydroxyethyl acrylate-blocked	Unspecified	123209-68-7
Siloxanes and Silicones, di-Me, hydrogen-terminated, polymers with N,N'-1,6-hexanedylbis[10-undecenamide], 11-oxo-11-[[6-[(1-oxohexadecyl)amino]hexyl]amino]undecyl group-terminated	Unspecified	351498-70-9
N-(4-ethoxyphenyl)-3-hydroxy-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	$C_{25}H_{18}Cl_3N_3O_3$	5012-29-3
2-propenoic acid, polymer with alpha-sulfo-omega-(2-propenyloxy) poly (oxy-1,2-ethanediyl) ammonium salt, sodium salt	Unspecified	330666-78-9
2-Propenoic acid, 2-methyl-, butyl ester, polymer with butyl 2-propenoate, ethenylbenzene, 2-ethylhexyl 2-propenoate, ethyl 2-propenoate and 2-propenoic acid	$(C_{11}H_{20}O_2.C_8H_{14}O_2.C_8H_8.C_7H_{12}O_2.C_5H_8O_2.C_3H_4O_2)_x$	835885-23-9
Linseed oil, polymer with formaldehyde, maleic anhydride, nonylphenol, pentaerythritol and rosin	Unspecified	1072007-46-5
Linseed oil, polymer with formaldehyde, maleic anhydride, pentaerythritol, rosin and 4-(1,1,1,3-tetramethylbutyl)phenol	Unspecified	1072007-48-7
1,4-benzenedicarboxylic acid, polymer with 1,3-dihydro-1,3-dioxo-5-isobenzofurancarboxylic acid, hexanedioic acid, alpha, alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxypoly(oxy-1,2-ethanediyl)] and alpha, alpha'-[(1-methylethylidene)di-4,1-phenylene]bis[omega-hydroxypoly(oxy(methyl-1,2-ethanediyl))],	Unspecified	403655-74-3

adduct with 5-isocyanato-1-(isocyanatomethyl)-1,3,3-trimethylcyclohexane, reaction products with 5-amino-1,3,3-trimethylcyclohexanemethanamine		
2,5-Pyrrolidinedione, 1,1'-(iminodi-2,1-ethanediyl)bis[3-(octadecen-1-yl)-, branched	Unspecified	1062588-20-8

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
Poly(oxy-1,2-ethanediyl), alpha-[3-carboxy(2-dodeceny)-1-oxypropyl]-omega-methoxy-	$(C_2H_4O)_n C_{17}H_{30}O_4$	328005-50-1